

Dec 19/25

DRAFT 9/17/01

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TOPIC: Coordination of Complementary and Alternative Medicine Research

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insert B1 Members: George Bernier, Effie Chow, Veronica Gutierrez, Bill Fair, and Tieraona Low Dog

ISSUE 1: Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers.

Background: An emerging dialogue between CAM and conventional medicine (Kaptchuk, Eisenberg, AIM, 8/7/01) and a growing willingness to experiment with integration appears to be taking place slowly. Fostering and strengthening this emerging dialogue to increase the understanding of one another's concerns and contributions, can help strengthen mutual respect, cooperation, coordination, and collaboration in CAM research and related activities.

Communication, cooperation, and collaboration are essential to the success of CAM research and research training. The parties to the dialogue should include conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

Trained and licensed CAM professionals should be included on research, journal, and regulatory advisory and review committees, as appropriate. (The voice of complementary and alternative medicine needs to be heard on NIH advisory committees for consideration during Institute and Center (IC) budget decisions. [Lenfant, 10/00]).

(Building working relationships among professionals from both conventional and CAM disciplines is essential to progress in studying and understanding CAM practices and products [Vazquez, 5/01]).

(Where there is scientific evidence that efficacy is equal, the inclination of CAM practitioners and users is to prefer natural methods that support the body's healing systems and [may] generally present less risk. But where efficacy is not equal, openness to conventional treatments is a reflection of the same mindset that we [CAM professionals] expect from the conventional community in turn [Dumas].)

Background Examples:

U of Pennsylvania (Al Fishman);

Harvard U, (Daniel Federman),

U of Maryland (Brian Berman),

Beth Israel Medical Center, NY (Woody Merrill),

King County system (Seattle meeting),

Bastyr University coordinated activities to create funding opportunities for scientific evidence-based models and databases for CAM and integrated health care (Seattle meeting).

Challenges:

1. Building on the emerging dialogue between CAM and conventional medicine.
 - a. Lack of mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers impedes progress in building knowledge about CAM (White, Oct'00).
 - b. Cultural taboos can affect the evaluation of research applications that are outside the mainstream (Cassman, 10/00).
2. Developing research applications of sufficient quality to compete successfully for research support.
3. Increasing institutional review board (IRB) familiarity with CAM and communication with CAM professionals to affect the ability of IRB members to evaluate adequately the CAM protocols that come before them. (Lenfant 10/00).
4. Including CAM professionals on advisory and review committees and in discussions on CAM-related research policy issues.

Draft Recommendations:

- 1⁹ 1. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors. ✓
- 2⁰ 2. Include trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation. ✓

B 2 ISSUE 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process.

Background: A frequently mentioned theme during Commission meetings was the need for high quality basic and clinical biomedical research and health services research in CAM to protect the public's health and safety and contribute to health care. Any of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg 5/01). Research was identified as an essential element in providing accurate information to increase the public's knowledge about CAM; and for educating and training CAM and conventional health care professionals, regulating the quality and use of CAM practices and products, and improving access to safe and effective CAM practices and products and coverage for them.

The Commissioners discussed with speakers the types of research on CAM needed to produce sufficient evidence of safety and effectiveness to endorse public use and integration of CAM into an evolving health care system. Basic research on mechanisms of action, which some people believe should be carried out simultaneously with research on safety and efficacy, was stressed during testimony. Other people see studies on the safety and efficacy of CAM practices and products as the immediate research need, but agree that building the science base for basic studies is essential. Testimony equally highlighted the value of and need for multiple approaches to examining issues of safety, efficacy, and effectiveness, including outcomes research, observational research and evaluations of practice-based data, epidemiologic studies, surveillance studies, behavioral/quality-of-life studies, demonstration projects, cost-effectiveness studies, and studies on health care delivery and other health services aspects of CAM.

While much public testimony supported the need for evidence-based research in CAM to establish safety and efficacy of CAM practices and products, it also revealed considerable public interest in why people turn to CAM and the potential of CAM research to contribute to the emerging areas of scientific study beyond isolated treatments for conditions or diseases. Many people who testified expressed admiration for the emphasis CAM places on wellness separate from disease and on the promotion of health and the prevention of disease. Speakers expressed interest in the emphasis CAM practitioners give to life-style, quality of life, the recognition that mind, body, and spirituality play a combined role in health, disease, and healing, and CAM's emphasis on the patient-practitioner interaction.

Therefore, in addition to examining CAM practices and products which, if found to be safe and effective, may be identified as complementary or alternative to conventional care for a condition, disorder, or disease, CAM may possibly contribute to emerging areas of scientific study that could increase our understanding of complete biological systems and how they interact; the ability of the body to heal itself; energy medicine, biofields, and electromagnetic fields; and the effects of culture on health and treatment. Answers to some of these questions may be found in the study of systems such as Ayurvedic Medicine, Traditional Chinese Medicine, Tibetan Medicine, Native American Medicine, African Medicine, Naturopathy, and other cultural systems that involve a complexity of elements. Applying rigorous scientific methods to the exploration of these areas will require input from experts in engineering, physics, chemistry, psychology, and cell and molecular biology, thus merging whole system concepts with modern reductionist expertise. (It would be useful to hold a conference on proposing evidence-based models for expanding current concepts of physiology and pathophysiology [Hammerschlag 5/01]).

The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial was recognized during testimony as the gold standard for examining clinical questions. However, because of the complexity and uniqueness of many CAM questions, much attention was paid to the importance of adapting clinical trial methodology, in a flexible and step-wise fashion, to the unique characteristics of CAM questions, while complying with human subject protections and appropriate institutional review board guidelines. Questions

of standardization/non-standardization, individualization/generalization, blinding, randomization, the placebo effect, and compound mixtures, need to be resolved within the context of the study design. Methodology and design adaptation, the Commission notes, is also required in conventional clinical research. Science has always followed its quests for knowledge by developing new ways to answer difficult questions and the Commissioners believe that pluralism in research design allows scientists to develop innovative methods to examine complex CAM questions. (Whenever possible control groups should be used to evaluate CAM treatments in comparison to standard treatments and CAM treatments in combination with conventional treatments, and standardization is necessary because studying non-standardized CAM treatments with individualized patients is not sufficient [Rabin 5/01].)

It is the view of some CAM researchers that the requirements for CAM research are higher than for conventional research. On the other hand, some people representing the conventional research community expressed the belief that CAM research often is not held to as high a standard as conventional research. The Commission agrees that CAM research must meet the same rigorous standards of quality that is expected of conventional research, neither lower nor higher.

The Commission commends NCCAM for its excellent leadership and contributions to CAM research and research methodology, research training, infrastructure development, (etc.), and supports continuing and increasing the Center's crucial activities, including its information dissemination responsibilities. The Commission also recognizes the important work of the ODS/OD/NIH and the collaborations between NCCAM and ODS and with other NIH/ICs. The Commissioners encourage the NIH/ICs to continue supporting CAM research collaboratively or separately, and want to note especially the work of both NCI's OCCAM and the NLM. In addition, the Commission encourages collaboration between NCCAM and other Federal agencies with research and health responsibilities, such as AHRQ, CDC, HRSA, FDA, and others.

Federal agencies need to be more proactive in evaluating aspects of CAM relevant to their missions. One area of need is the development by NIH/IC's of specific programs or other research initiatives to evaluate CAM practice-based data submitted by practitioners who believe that they have promising data on non-approved treatments. In order for such programs to be successful, the practitioners need to be knowledgeable about the process and instruments involved in collecting objective, verifiable data, as well as about human protection guidelines. It is also necessary that they be allowed (protected from prosecution) to submit their data to NIH/IC's for evaluation and possible research support. The inclusion of CAM professional expertise should be part of the solicitation process.

The growing influence of the public on the health care system became evident during testimony, pointing to the need to increase public participation in the shaping and prioritizing the CAM research agenda, and in institutional review board reviews and institutional research teams, the dissemination of research results, and the shaping of regulatory and health services activities. The Commission heard often about the value of integrating conventional and CAM approaches. In a random household telephone survey, of 831 respondents who saw a medical doctor and used CAM therapies in the previous year, 79 percent perceived the combination to be superior to

either one alone. Of 411 respondents who saw both a medical doctor and a CAM provider, 70 percent saw the medical doctor before or concurrent with their to a CAM provider (AIM, Sept/01, Eisenberg et al).

Challenges:

1. Assuring that CAM research is held to the same high research standards as conventional medicine—no lower and no higher
2. Assuring public participation in the development of the research agenda.
3. Accomplishing rigorously designed CAM protocols and gaining IRB approval:
collect objective data,
adapt, as necessary, orthodox scientific methodology to CAM studies,
resolve standardized/non-standardized and individualized/generalized issues,
resolve blinding and/or randomizing difficulties, placebo effect issues, and challenges associated with studying compound products.
4. Achieving standardization of CAM products for research.
5. Establishing the level of evidence that is sufficient for safety and efficacy.
6. Identifying and prioritizing all the types of research needed.
7. Increasing all resources needed for CAM clinical, basic, and health services research.
8. Convincing funders to support potential CAM research contributions in emerging areas of science.

Draft Recommendations:

~~21~~ 1. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system. ✓

~~21 & 2~~ 2. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs, or other research initiatives to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

~~21 & 3~~ 3. Fund clinical research on promising and/or frequently used CAM products that would be

unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

21.4.4 Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support mechanisms for high-risk, high-impact studies to expand understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.

21.4.5 Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.

(22) 6. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.

22a 7. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

22b 8. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

23 9. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities. ✓

22c 10. Request recommendations from the National Science Foundation on how to study, in a credible manner, high-risk, emerging scientific ideas associated with CAM. ✓

ISSUE 3: Research Training and Infrastructure

Background: Commissioners and speakers discussed the crucial role of a strong research infrastructure in conducting quality CAM research and research training. This effort requires the need for a plan to build long-term research capacity and infrastructure to train experts in research and CAM concepts, conduct research on CAM products and practices and on the underlying mechanisms of CAM practices and concepts. This goal will require a government-wide effort involving the NIH, NSF, DOD, NASA, and other agencies.

Research sites, both public and private, with sufficient resources should be strategically located

and each site should have a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. These sites should include CAM-trained practitioners and researchers on the faculty and/or as consultants, and should partner with accredited CAM institutions in the conduct of research and research training. (example: NIH research centers program). The Commission believes that the infrastructure for CAM research sites should be developed at both existing public and private research institutions and accredited CAM institutions.

The same rigorous training should be available for both CAM and conventional researchers. Both CAM and conventional researchers need knowledge of the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process, unbiased data collection, protocol design, IRB and other regulatory requirements, and the grant application and submission process. Investigators in CAM research need to have experienced mentors and incentives may have to be developed to attract them. (CAM research training should teach multiple outcome measures, including social contextual assays and biopsychological measures of health, carried out by multidisciplinary teams to allow broader paradigms of health and healing [Blanks, 5/01]). (In addition, representatives from research centers supported Federally, privately, or by foundations should meet periodically not only to present progress reports but also to exchange experiences on how best to educate researchers in CAM practices and how to introduce CAM practitioners to the research culture (Hammerschlag 5/01)).

Challenges:

1. Assuring adequate funding and other resources and strategic planning for developing or strengthening CAM research infrastructure sites and training programs.
2. Developing incentives to attract conventional researchers to serve as mentors and study CAM questions.
3. Increasing collaborations between CAM and conventional institutions to enhance training opportunities and improve the quality of training.

Draft Recommendations:

21A 1. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources to the National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions. ✓

21B 2. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices, who have received the same rigorous research training in basic, clinical, and health services research. ✓

21C 3. Continue to support career development awards to enable investigators focusing on CAM to

develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

ISSUE 4: Public-Private-Nonprofit partnerships and investment in CAM research and related activities.

Background: The growing willingness of the public, private, and nonprofit sectors to form partnerships offers exciting possibilities in stimulating and supporting much needed CAM research. Also, mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program offer the private sector opportunities for research support. Collaborative public-private-nonprofit research support could contribute in important ways to the emerging areas of scientific study of interest to CAM and conventional medicine.

The provision of incentives for private sector involvement in CAM research and the resolution of intellectual property issues could spur private activity (see FYI/NOTE below). Provision of proprietary protection around process, extraction, production, and use of unique mixtures and combination of agents could help move in this area. {It would be desirable if dietary supplement manufacturers used what the NIEHS National Toxicology Program learns about toxicology/carcinogenicity in these complex materials to conduct studies on remaining untested popular supplements being consumed [Matsen 5/01]}. (Consideration should be given to development of a rigorous review process including industry and academic scientists [Rudden,10/00]). (Successful manufacturers of CAM products should be encouraged to conduct studies and explore collaborations with strong research institutions [Eisenberg 5/01].) (Public agencies should be encouraged to partner with foundations interested in enhancing their research, research training, and conference support [Templeton 10/00].) (Consideration might be given to inviting foundation representatives to sit on Federal advisory groups to discuss potential areas of support and partnership, such as grant funding opportunities. The nonprofit sector might consider creating a consortium through which pooled funds could be used to augment support for CAM conferences, pilot projects, etc., possibly including the announcement of funding opportunities and the convening of advisory/review groups of knowledgeable, reputable scientists in the areas to be presented, discussed or studied [Hayes.10/00]).

FYI/NOTE: It should be noted that because it is often not possible to patent CAM products, there has been little private research on these products by private companies. Submissions of petitions to gain approval for the right to make health claims also are not economical because pharmaceutical companies or manufacturers of CAM products that might go to the expense of gaining such approval would face competition from other manufacturers that could sell similar products as dietary supplements.

Under the provisions of DSHEA, dietary supplements can make structure function claims. Approved drugs can make health claims about preventing, curing, treating, or mitigating a disease. However, as stated above, because drug approval is a labor-intensive process requiring substantial research, time, and money, most dietary supplement manufacturers do not seek drug status for their products. The unintended effect is that in some instances when there is research on a dietary supplement that could support a claim, the dietary supplement is still limited to the structure function claim because dietary supplements are considered foods.

Certain dietary supplements can make health claims under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). For example, there is significant scientific agreement that calcium can prevent osteoporosis and a health claim for both calcium-containing foods and dietary supplements has been approved by the FDA.

Challenges:

1. Stimulating nonprofit organizations to become involved in research on CAM practices and products, e.g., providing seed money and investment in pilot studies, supporting conferences.
2. Creating incentives to increase private sector involvement in CAM research, possibly through tax incentives, resolving intellectual property and other issues to increase product research and product standardization.
3. Encouraging Federal funding for research on CAM products in collaboration with the private and nonprofit sectors.

Draft Recommendations:

- 215
1. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships. ✓
 - 218 2. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk. ✓
 - 214 3. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support. ✓
 - 216 4. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. ✓
 - 217 5. Conduct a systematic study on creating incentives to increase private sector involvement in CAM research, possibly through tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships. Stimulate private sector investment, either separately or collaboratively, on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products. ✓
 - 218 6. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. ✓
- 21K
- 9
- 21AA
- 47

- 21K 5. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment, in partnership with Federal agencies or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.
- 21K 6. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

ISSUE 5: Publishing literature on CAM research and systematic reviews of the literature

Background: Many speakers agreed that CAM research results need to be published in recognized, rigorously peer-reviewed research journals to provide accurate and reliable knowledge about CAM to researchers, practitioners, and ultimately the public. The quality of the research and the standards of review that the research must meet to gain journal publication affect how readers determine the reliability and usefulness of the information.

To ensure a fair and accurate review, speakers emphasized that CAM expertise should be represented on journal review boards when reviewing CAM research submissions, and CAM journals should include conventional scientific expertise on their review boards. CAM practitioners and researchers should be encouraged to read the highest quality conventional journals and conventional practitioners and researchers should be encouraged to read CAM journals of equal quality.

(Recent increases in research funding and the establishment of CAM research centers should increase the publication of high quality studies on CAM therapies submitted to research journals [Fontanarosa5/01]). (It is necessary to document the basis for claims. Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand [Fontanarosa, 5/01].)

Commissioners also discussed with speakers the availability and use of information gained from the published literature, including systematic literature reviews, evidence-based reports, and the role of NLM databases, such as PubMed and MedlinePlus. Representatives of AHRQ, the Cochrane Collection, and NLM described their CAM-related activities as well as their efforts to cooperate. They also talked about the value of strengthening the process for making reviews of the research literature available to practitioners, community health centers, and policy makers, and to offer clear and understandable summaries of reviews to the public through NLM's MedlinePlus and other information services.

(AHRQ and the Cochrane Collection are finding ways to collaborate with each other and with NLM [Kamerow, Berman, and Lindberg, 5/01].)

Challenges:

1. Increasing the submission and publication of CAM research articles that are successfully submitted to journals with the highest standards of review.

2. Assuring the inclusion of reviewers experienced in CAM on journal review boards when CAM submissions are reviewed and conventional scientists on CAM journal review boards.

3. Increasing systematic reviews of the research literature, their use, and their availability to practitioners and the public.

Draft Recommendations:

2/1/24 1. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

7/6/24 2. The Commission recommends that public and private resources be provided to support systematic reviews of research literature.

2/6/24 3. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria. ✓

2/6/24 4. Produce and maintain up-to-date summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force. ✓

2/6/24 5. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

White House Commission on Complementary and Alternative Medicine Policy
October 4-6, 2001
Neuroscience Building
6001 Executive Blvd.
Conference Rooms C & D
Bethesda, MD

← DRAFT PRELIMINARY AGENDA →

Thursday, October 4

8:00 – 8:15 Welcome and Introductions

Dr. James Gordon, Chair

Dr. Stephen Groft, Executive Director

I. 8:15 – 10:15 Session I. Definition of CAM

Facilitators: Mr. Tom Chappell

Dr. Wayne Jonas

Staff Lead: Mr. James Swyers

10:15 – 10:30 BREAK

II. 10:30 – 12:30 Session II. Information Development and Dissemination

Facilitators: Dr. David Bresler

Dr. Tieraona Low Dog

Staff Lead: Ms. Corinne Axelrod

12:30 – 1:30 LUNCH

III. 1:30 – 3:30 Session III. Coordination of CAM Research

Facilitators: Dr. Wayne Jonas

Dr. Dean Ornish

Staff Lead: Ms. Geraldine Pollen

3:30 – 3:45 BREAK

IV. 3:45 – 5:45 Session IV. Education and Training of Health Care Practitioners in CAM

Facilitators: Dr. George Bernier

Dr. Joseph Pizzorno

Staff Lead: Dr. Joseph Kaczmarczyk

5:45 Adjourn

new Issues for discussion

Friday, October 5

8:00 – 8:15 Welcome and Introductions - *Dr. James Gordon*

V. 8:15 – 10:15 Session V. Access to and Delivery of CAM

Facilitators: Ms. Linnea Larson

Dr. Joseph Fins

Staff Lead: Ms. Michele Chang

10:15 – 10:30 BREAK

VI. 10:30 – 12:30 Session VI. Coverage and Reimbursement

Facilitator: Mr. George DeVries

Staff Lead: Ms. Maureen Miller

12:30 – 1:30 LUNCH

VII. 1:30 -3:30 Session VII. CAM in Wellness, Self-Care, Health Promotion and Disease Prevention

Facilitator: Dr. Dean Ornish

Staff Lead: Ms. Corinne Axelrod

3:30 – 3:45 BREAK

4:00 – 5:00 Public Comments

5:00 Adjourn

Saturday, October 6 (Bethesda Marriott, 6711 Democracy Boulevard, Bethesda, MD)

8:00 – 8:15 Welcome and Introductions - *Dr. James Gordon*

8:15 – 10:15 Session VIII. Coordinating and Centralizing Federal CAM Efforts

Facilitator: Dr. Donald Warren

Staff Lead: Dr. Joseph Kaczmarczyk

10:15 – 10:30 BREAK

10:30 – 12:00 Review of draft recommendations

12:00 – 12:30 Process of Preparation of Final Report - *Dr. Stephen Groft*

12:30 Adjourn

Next Meeting December 6-7, 2001, Washington, DC Hubert H. Humphrey Building

Research

Gery Miller

Draft Recommendations (General Policy):

A. To protect the public's health and safety, continue strong support of rigorous epidemiologic and clinical research to establish the safety and efficacy of CAM practices and products, basic research to discover and explain the underlying mechanisms of action, and health services research to improve CAM use within the health care system. Any one of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg, 5/01, Grollman 5/01).

Research
Infrastructure

1. Enhance CAM research training opportunities and improve the quality of research and training through the support of infrastructure development at strategically placed sites at both accredited conventional and CAM institutions. Increase collaborations between CAM and conventional institutions through faculty exchange and consultation. Include CAM-trained practitioners and researchers as part of the training faculties (Pearson, 5/01). *and*

2. Strengthen funding for developing a critical mass of research sites, both public and private, with sufficient resources and infrastructure to conduct basic, clinical, and health services research in CAM, train researchers and clinical experts, and deliver integrated care services (Fishman 10/00, Federman 10/00; Berman 5/01, D. Eisenberg 5/01). In addition to randomized clinical trials, include such research modalities as clinical outcomes, observational and qualitative studies, demonstration projects, cost-effectiveness studies, etc..

diff

3. Ensure that the same rigorous research training to conduct basic, clinical, or health services research is available for both CAM and conventional researchers. Investigators in CAM research need to be trained in research methodology, understand the CAM modality they are studying, have an experienced mentor, and work in a collaborative environment. Develop incentives for conventional researchers to attract high quality mentors.

B. Partner with CAM in expanding the current research paradigm by funding CAM research partnerships with conventional researchers to focus on the examination of wellness separate from disease and the effects of life-style on health; the role of mind, body, and spirituality in health, *on or around* disease, and the body's ability to heal; the role of stress; the effect of the practitioner-patient interaction on the quality of care and on healing; the understanding of complete biological systems and interacting biological systems (last item/Cassman 10/00), and biofields, electromagnetic fields, and energy medicine.

1. CAM research training should teach multiple outcome measures, including social contextual assays and biopsychological measures of health carried out by multidisciplinary teams to allow broader paradigms of health and healing (Blanks, 5/01).

2. Develop incentives to attract conventional basic researchers to study these areas.

3. Stimulate public-private-nonprofit research support for CAM to expand the research paradigm.

C. Recognize the emerging consumer-oriented health care system (Kaptchuk, Eisenberg, ATM, 8/7/01) and develop a process to allow the public to be heard when setting the CAM research agenda, and invite CAM professionals to be included in CAM-related research policy efforts.

add on to Rec.

not a per { D. Ensure that the standards of research quality are the same for CAM as they are for conventional medical research—neither lower nor higher. All CAM research should be methodologically sound, meet high standards of design and execution, be consistent with the type of information being sought, and incorporate step-wise approaches to research sequence and design, as is done in conventional medical research. Clinical research should comply with human subject protections and appropriate institutional review board guidelines. *Principles?*

yes Develop programs to bring together a variety of disciplines to find innovative research approaches to solving difficult questions in focused CAM areas (example: NCI/SPORE program). *including research methodologists and*

2. Assemble a think-tank of methodologists and CAM professionals to discuss ideas about methodology and CAM (Gallahan, 10/00).

2 { E. Include trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation. (NIH, FDA, IRB's, FSMB, etc.). Also include CAM and conventional professionals, as appropriate, on faculty or as consultants in CAM research and training academic environments.

Expand language in report
1 1. Encourage CAM professional organizations to reach out to NIH and other Federal health agencies to communicate their interest in working with the agencies to enhance and improve CAM research activities (L'enfant 10/00).

a 2. Federal health agencies should increase communication with CAM professionals and set up initiatives or programs that help reduce prejudging CAM to allow adequate and fair evaluation of CAM submissions outside the mainstream (Cassman 10/00).

2 { F. Support multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians and researchers to interact and exchange ideas and discuss research approaches to studying CAM questions (Hausman, 10/00).

G. Encourage the growing willingness of the public-private-nonprofit sectors to collaborate in support of projects on the standardization of products, which are needed in research. Encourage the training of interdisciplinary research teams supported by public-private partnerships to enhance progress in research and research training (Blanks, 5/01). *document, research team*

1 1. Stimulate private sector support for CAM in such areas as product research and product standardization through such mechanisms as tax incentives, resolving intellectual property and other issues.

eg. of funding program

2. Use mechanisms such as the NIH Small Business Innovative Research program and the ~~technology transfer~~ cooperative research program to offer the private sector opportunities for research support. Encourage successful manufacturers of CAM products to conduct studies (Eisenberg 5/01), and explore collaborations with strong research institutions. *S BTTA*

3. Encourage NIH and other public agencies to partner with foundations interested in enhancing their CAM research-related activities in research, research training, and conference support, and invite foundation representatives to sit on advisory groups as appropriate. (Templeton 10/00).

4. Encourage the nonprofit sector to host CAM meetings to discuss partnership opportunities and bring together CAM and conventional researchers and professionals. Invite foundation representatives to publically-supported CAM research centers to learn and discuss opportunities for involvement (Templeton 10/00).

1. More funds support may do the job

5. Encourage the ^{creation} of a consortium of private funding sources to augment CAM basic, clinical, and health services research by Federal agencies. (Eisenberg, 5/01). Encourage foundations to consider creating a collaborative pool of funds, announce funding competitions, and set up advisory/review groups of knowledgeable, reputable scientists in the areas to be studied (Hayes 10/00). Add foundations to mailing lists that could inform them about research grant opportunities (Hayes 10/00) and encourage foundations to fund pilot projects.

*Recommend
Research
funding
should
be
published*

H. Decisions on regulating the use of and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses (Fontanarosa 5/01). Manuscripts on CAM research results should be submitted to journals that are recognized for the most rigorous peer review, whether they are conventional or CAM journals, on-line, or in print. (Relman, 5/01). Qualified members with CAM expertise should sit on conventional journal review boards when reviewing CAM submissions and experts in conventional research should sit on CAM journal review boards. *already done*

1. Increase the publication of high quality studies on CAM that are submitted to research journals (Fontanarosa 5/01).

2. Encourage CAM practitioners to read the highest quality conventional journals and conventional practitioners to read CAM journals of equal quality.

for the public

9. Develop non-technical (lay) summaries ^{for the public} of all systematic reviews of the literature, including those in the Cochrane library, and make them available to the public through PubMed, and increase the availability of these reviews through on-line subscriptions by policy-making offices, public libraries, and community health centers. (Berman)

Draft recommendations (Specific):

Increase support for the National Center for Complementary and Alternative Medicine (NCCAM), the Office of Dietary Supplements (ODS), and the Office of Cancer Complementary and Alternative Medicine (OCCAM); and encourage other NIH Institutes and Centers (IC's) to fund CAM research in collaboration with NCCAM or separately.

Encourage all NIH/IC's to establish best case series evaluation programs and communicate the availability of such programs to expand potential research opportunity to practitioners who believe they have promising data on nonstandard treatments.

Strengthened collaborations between NCCAM and other Federal agencies, such as AHRQ, CDC, HRSA, and support health services research and other research on CAM by all Federal agencies with research or health related missions. Continue to conduct AHRQ's Evidence-based Practice Center systematic reviews on CAM treatments, which can be used by private and public entities as a basis for the development of tools such as practice guidelines, performance measures, and review criteria.

Fund clinical research on promising products that would be unlikely to receive a patent and therefore not likely to attract private research dollars.

Establish reliable standards for CAM products so that products with consistent composition are available for research.

Use control groups to evaluate CAM treatments compared to standard conventional treatments and CAM in combination with conventional treatments. Good CAM research will not occur unless the approaches studied are standardized. The study of non-standardized approaches with individual patients is not sufficient (Rabin, 5/01).

Study basic mechanisms of action and toxicity to help anticipate adverse reactions and identify risks and benefits, and lead to new treatments (Grollman 5/01).

Hold a conference sponsored by NCCAM and/or the NAS to propose evidence-based models for expanding current concepts of physiology and pathophysiology (Hammerschlag.5/01).

(A) Conduct research on why people use CAM, what they mean when they say it works, and what they find satisfying about CAM in comparison to conventional medicine (Callahan, 10/00).

Fund NCCAM and other IC's at an adequate level to support a strong research infrastructure at strategically-placed sites that will improve and enhance CAM research and research training programs and support and encourage CAM research training by Federal health agencies with research training programs.

Fund career development awards to enable investigators focusing on CAM to develop into independent investigators (Phillips, 5/01).

Fund mid-career awards to provide support for the ~~time required to mentor~~ new CAM investigators (Phillips, 5/01).

Encourage representatives from NCCAM-funded centers to meet periodically, not only to present progress reports, but also to exchange experiences on how best to educate researchers in CAM practices, and how to introduce CAM practitioners to the research culture. (Hammerschlag, 5/01).

Already done

Train students at conventional and CAM institutions in critiquing CAM trials (Hammerschlag, 5/01).

MOVE TO INFORMATION:

Make information on results of CAM research that already exist more readily available.
Use the NCCAM clearinghouse to make new information available on a monthly basis.
(Berman, 5/01).

Veronic's recommendation: Open research RCA (RFA?) opportunities to beyond current favorites.

Call Christine Gertz, NCCAM re. Palmer consortium with other chiropractic schools, look on NCCAM web site and
check out NCCAM RFA on Frontier Medicine.

Groft, Stephen (WHCCAMP)

Effie

From: Pollen, Geraldine (WHCCAMP)
Sent: Thursday, August 30, 2001 4:21 PM
To: 'Dean Ornish'; 'Effie Chow'; 'George Bernier'; 'Tieraona Low Dog'; 'Veronica Gutierrez'; 'William Fair'; 'Wayne Jonas'
Cc: Groft, Stephen (WHCCAMP); Chang, Michele (WHCCAMP); Kaczmarczyk, Joseph (WHCCAMP); Miller, Maureen (WHCCAMP); Axelrod, Corinne (WHCCAMP); Axelrod, Corinne (WHCCAMP)
Subject: Work Group A Issue #6

Dear Workgroup A,

Yesterday I sent you the background document for the research conference call that is scheduled for tomorrow, Friday, August 31 from 2:00-4:00 EST.

I mentioned in the note transmitting the document that I would send to you today information on Issue #6 as it relates to research. Issue #6, you may recall, related to the possibility of prosecution that physicians fear when they practice nonstandard treatments and want to submit their treatment data for evaluation and possible research support.

Our work group, during the last conference call, discussed dropping this issue because it appeared to be a licensing issue. Steve Groft and I suggest that this issue, which came up a number of times during testimony, has two parts. Strictly as a practice issue unrelated to research, it will be handled by the work group looking at licensing. However, when it involves practitioners who want to conduct research or submit data for evaluation and feel they cannot, it becomes a research issue that involves the FDA, IRB's and NIH programs (such as the best case series program of the NCI). Earlier today, I spoke with someone at the Federation of State Medical Boards. FSMB and some state medical boards, e.g., Kentucky and Nevada, are becoming more aware of the need to recognize CAM use in a less punitive way while still protecting the public from harm. The FSMB is developing new guidelines that probably will address research on nonstandard treatments. The new guidelines are in the development stage at this time, but hopefully we may have the opportunity to review the draft after October 19. Having a better idea of the direction FSMB is headed will help us as we consider this issue. Eventually, much of the overlapping areas of the individual work groups will come together in the final report.

Speak to you tomorrow.

*Geraldine (Gerry) B. Pollen
Senior Analyst
White House Commission on
Complementary and Alternative
Medicine Policy
Phone: (301) 435-7592
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To: Dr. WAYNE JONAS

Groft, Stephen (WHCCAMP)

From: Pollen, Geraldine (WHCCAMP)
Sent: Wednesday, August 29, 2001 6:19 PM
To: 'Dean Ornish'; 'Effie Chow'; 'George Bernier'; 'Tieraona Low Dog'; 'Veronica Gutierrez'; 'Wayne Jonas'; 'William Fair'
Cc: Corinne Axelrod; Joseph Kaczmarczyk; Ken Fisher; Maureen Miller; Michele Chang; Stephen Groft
Subject: Work Group A: Background Document
Importance: High

Hello Work Group A:

Attached you will find a document (in Word and rich text format) that incorporates the discussion during our August 17 conference call, responses I received from work group members on ranking of issues and recommendations, and phone conversations. I strongly suggest that you read the text under Discussion as well as the challenges and draft recommendations, because it contains the background for what follows, briefly recapping the themes from the interim report and moving beyond it.

I have not completed work on research-related aspects of issue # 6. Hopefully, I will be able to send you something on this issue late tomorrow.

Looking forward to our conference call. Effie and Veronica, I'll fax the document to you as well.

Geraldine (Gerry B. Pollen)
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White House Commission on
Complementary and Alternative
Medicine Policy
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- Documentation
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8/29/01
GP

TOPIC: Coordination of Complementary and Alternative Medicine Research

Staff Lead: Gerry Pollen

Facilitators: Wayne Jonas and Dean Ornish

ISSUE (*Tieraona #4, Veronica #3, Wayne #3*): Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers.

Discussion: Building working relationships among professionals from both conventional and CAM disciplines is essential to progress in studying and understanding CAM practices and products (Vazquez, 5/01). Where there is scientific evidence that efficacy is equal, the inclination of CAM practitioners and users is to prefer natural methods that support the body's healing systems and [may] generally present less risk. But where efficacy is not equal, openness to conventional treatments is a reflection of the same mindset that we [CAM professionals] expect from the conventional community in turn (Dumas).

An emerging dialogue between CAM and conventional medicine (Kaptchuk, Eisenberg, AIM, 8/7/01) and a growing willingness to experiment with integration appears to be taking place slowly. Fostering and strengthening this emerging dialogue to increase understanding one another's concerns and contributions, can help strengthen cooperation, coordination, and collaboration in research and related activities.

Background Examples:

U of Pennsylvania (Al Fishman);

Harvard U, (Daniel Federman),

U of Maryland (Brian Berman),

Beth Israel Medical Center, NY (Woody Merrill),

King County system (Seattle meeting),

Bastyr University coordinated activities to create funding opportunities for scientific evidence-based models and databases for CAM and integrated health care (Seattle meeting).

Challenges:

Lack of mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers impedes progress in building knowledge about CAM (White, Oct'00). Cultural taboos can affect the evaluation of research applications that are outside the mainstream (Cassman, 10/00).

The voice of complementary and alternative medicine is not heard on NIH advisory councils and committees and does not influence Institute and Center (IC) budget decisions. (Lenfant, 10/00).

Lack of familiarity with CAM and communication with CAM professionals affects the ability of IRB members to evaluate adequately the CAM protocols that come before them. (Lenfant and Fins 10/00).

Need to build on the emerging dialogue between CAM and conventional medicine.

Draft Recommendations (not ranked):

1. Support multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians and researchers to interact and exchange ideas and discuss research approaches to studying CAM questions (Hausman, 10/00).
2. Include trained and licensed CAM professionals, who are involved in research or related activities, on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation. (NIH, FDA, IRB's, FSMB, etc.). Also include CAM and conventional professionals, as appropriate, on faculty or as consultants in CAM research and training academic environments.
3. Strengthen funding to develop a critical mass of academic health center sites with sufficient resources and infrastructure to conduct basic, clinical, and health services research in CAM, train researchers and clinical experts, and deliver integrated care services (Fishman 10/00, Federman 10/00; Berman 5/01, D. Eisenberg 5/01).

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INSERT: Veronica Gutierrez' ranked recommendations:

1. Encourage working relationships among professionals from multiple conventional and CAM disciplines to progress in studying and understanding CAM practices and products. (Vazquez, 5/01)
2. Inspire mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers. (Kaptchuk, Eisenberg, AIM, 8/7/01).
3. Increase mutual respect by stimulating communication & research collaboration. (White, 10/00)
4. Allow CAM voices to be heard on NIH advisory councils, and committees. (Ienfant, 10/00).
5. Eliminate cultural taboos that impede willingness to evaluate research application that are outside the mainstream. (Cassman, 10/00)
6. Support multidisciplinary conferences and workshop to discuss research approaches to studying CAM questions. (Hausman, 10/00)
7. Increase opportunities for CAM and conventional practitioners, clinicians, and researchers to interact and exchange ideas.
8. Include trained and licensed CAM professionals, who are involved in research or related activities, on research and regulatory advisory and review committees.
9. Adopt, as appropriate, any regulations that might impede such representation.
10. Strengthen funding to develop a critical mass of academic health centers with sufficient resources and infrastructure to conduct basic, clinical, and health services research, train researchers, and clinical experts.

(Eisenberg, 5/01)

11. Stimulate academic health centers to partner with accredited CAM institutions to examine ways in which they can include an integration of research of mutual interest. (Fishman and Federamn, 10/00), (Jonas 10/00)

Supporting Principles: #1, #2, #3, #4, #5, #7, #8, #9, #10

=====

ISSUE (Tieraona #1, Veronica #4, Wayne #1): Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process.

*Explicit statement
Same standard
1st Point*

Discussion: A frequently mentioned theme during Commission meetings was the need for high quality basic and clinical biomedical research and health services research in CAM to protect the public's health and safety. Research was identified as an important element in providing accurate information to increase the public's knowledge about CAM; and for educating and training CAM and conventional health care professionals, regulating the quality and use of CAM practices and products, and improving access to safe and effective CAM practices and products and coverage for them.

The Commission agrees that CAM research must meet the same rigorous standards of quality that is expected of conventional research, but notes that requirements for CAM research should be neither lower nor higher than for conventional research. The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial was identified during testimony as the gold standard for examining clinical questions. However, because of the complexity and uniqueness of many CAM questions, much attention was paid to the importance of adapting clinical trial methodology, in a flexible and step-wise fashion, to the unique characteristics of CAM questions, while complying with human subject protections and appropriate institutional review board guidelines. Such adaptation is also required in conventional clinical research. The Commissioners believe that the concept of pluralism in methodological design allows the use of multiple methods in finding new approaches to examine complex questions. Science has always followed its quests for knowledge by developing new ways to answer difficult questions.

The Commissioners discussed with speakers the types of research on CAM needed to produce sufficient evidence of safety and effectiveness to endorse public use and integration of CAM into an evolving health care system. Basic research on mechanisms of action, which some people believe should be carried out simultaneously with research on safety and efficacy, was stressed during testimony. Other people see studies on the safety and efficacy of CAM practices and products as the immediate research need, but agree that building the science base for basic studies is essential. Testimony equally highlighted the value of and need for other approaches to examining safety and effectiveness issues, including outcomes research, observational research, best case series evaluations, epidemiology, surveillance studies, qualitative research, demonstration projects, studies on cost-effectiveness, health care delivery, and other health

services aspects of CAM

While much public testimony supported the need for evidence-based research in CAM to establish safety and efficacy of CAM practices and products, it also revealed considerable public interest in why people turn to CAM and the potential contribution of CAM research to expanding the current research paradigm beyond isolated treatments for conditions or diseases. People who testified expressed admiration for the emphasis CAM places on wellness separate from disease prevention; the importance of life-style on health (throughout life); the recognition that mind, body, and spirituality play a combined role in health, disease, and healing; and the importance that CAM places on the patient-practitioner interaction as part of treatment.

Therefore, there may be two ^{overlapping} tracks for CAM research. The first track examines CAM practices and products which, if found to be safe and effective, may be identified as complementary or alternative to conventional care for a condition, disorder, or disease. The second track, which may be more difficult to grasp and investigate, offers the possibility of an expanded research paradigm by increasing our understanding of the whole person and the ability of the body to heal; energy medicine, biofields, and electromagnetic fields; complete biological systems and how they interact; and the effects of culture on health and treatment. Answers to some of these questions may be found in the study of systems such as Ayurvedic Medicine, Traditional Chinese Medicine, Native American Medicine, African Medicine, Naturopathy, which involve a complexity of elements.

Challenges:

Assuring that CAM research is held to the same standards as conventional research—no lower and no higher

Making sure the public is heard regarding the research agenda.

Designing CAM protocols and gaining IRB approval:

- collect objective data,
- adapt, as necessary, orthodox scientific methodology to CAM studies
- resolve the standardized/non-standardized, individualized vs. generalized issues
- resolve blinding and/or randomizing difficulties, and the placebo effect
- obtaining CAM products for research that are standardized.

Establishing the level of evidence that is sufficient for safety and efficacy.

Identifying and prioritizing the types of research needed.

Increasing funding for clinical and basic research on practices and products

Strengthening funding for Federal agencies conducting health services research.

described by the argument

"isolated track"
"system of healing"

Convincing all funders to support research to expand the research paradigm.

Draft Recommendations (not ranked):

1. To protect the public's health and safety, continue strong support rigorous research on the safety and efficacy and basic mechanisms of CAM practices and products and make more readily available information on results of CAM research that already exist.
2. Assure that all CAM research is methodologically sound, meets high standards of design and execution, is consistent with the type of information being sought, and incorporates step-wise approaches to research sequence and design, as is done in conventional medical research, and in clinical research complies with human subject protections and appropriate institutional review board guidelines.
3. Ensure that the standards of research quality are the same for CAM as they are for conventional medical research—neither lower nor higher.
4. Increase support for the National Center for Complementary and Alternative Medicine (NCCAM), the Office of Dietary Supplements (ODS), and the Office of Cancer Complementary and Alternative Medicine (OCCAM); and encourage other NIH Institutes and Centers (IC's) to fund CAM research in collaboration with NCCAM or separately.
5. Encourage all NIH/IC's to establish best case series evaluation programs and communicate the availability of such programs to expand potential research opportunity to practitioners who believe they have promising data on nonstandard treatments.
6. Strengthened collaborations between NCCAM and other Federal agencies, such as AHRQ, CDC, HRSA, and support health services research and other research on CAM by all Federal agencies with research or health related missions.
7. Recognize the emerging consumer-oriented health care system (Kaptchuk, Eisenberg, AIM, 8/7/01) and develop a process to allow the public to be heard when setting the CAM research agenda and invite CAM professionals to be included in research policy efforts.
8. Bring together a variety of disciplines to find innovative research approaches to difficult questions in focused CAM areas (example: NCI/SPORE program). Assemble a think tank of methodologists and CAM professionals to discuss ideas about methodology and CAM (Callahan, 10/00).
9. Establish safety and efficacy and general effectiveness of herbal medicines, followed by basic studies of mechanisms of action and toxicity to help anticipate adverse reactions, which will identify risks-benefits, and lead to new treatments (Grollman 5/01)
10. Fund epidemiologic and clinical research to establish safety and efficacy, basic research to

discover and explain the underlying mechanisms of action, and health services research to improve CAM use within the health care system. Any one of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg, 5/01).

11. Fund clinical research on promising products that would be unlikely to receive a patent and therefore not likely to attract private research dollars.

12. Establish reliable standards for CAM products so that products with consistent composition are available for research.

13. Use control groups to evaluate CAM treatments compared to standard conventional treatments and CAM in combination with conventional treatments. Good CAM research will not occur unless the approaches studied are standardized. The study of non-standardized approaches with individual patients is not sufficient (Rabin, 5/01).

14. Fund CAM research that will expand the current research paradigm by focused examination of wellness separate from disease and the effects of life-style on health, the role of mind, body, and spirituality in health, disease, and healing, and the effect of the practitioner-patient interaction on the quality of care and on healing.

15. Partner with CAM professionals in the next phase of research that examines the complete biological systems that were broken down in earlier research to study their components and the study of interacting biological systems. (Cassman 10/00)

16. Hold a conference sponsored by NCCAM and/or the NAS to propose evidence-based models for expanding current concepts of physiology and pathophysiology (Hammerschlag, 5/01).

17. Conduct research on why people use CAM, what they mean when they say it works, and what they find satisfying about CAM in comparison to conventional medicine (Callahan, 10/00).

INSERT: Veronica Gutierrez' ranked recommendations:

1. Apply the same level of standards to research criteria; neither higher nor lower than conventional research. Maintain a level playing field.
2. Pursue public interest in CAM by expanding research horizons through its emphasis on (1) life-style, health promotion and wellness separate from disease prevention; (2) the importance of patient-practitioner interaction to treatment; and (3) the role of both mind and body in health, disease, and healing, including understanding the body's healing ability, the role of the brain and belief, and the role of stress, and (4) biofields and electromagnetic fields.
3. Expand research models to include outcome-based, observational & qualitative research, demonstration projects, cost-effectiveness, safety, & efficacy studies.

4. Acknowledge & respond to consumer & public interest in research.
 5. NCCAM to collaborate with other Federal agencies, such as AHRQ, CDC, HRSA, & others.
 6. Utilize control groups. (Rabin, 5/01)
 7. Hold a conference to propose evidence-based models for expanding current concepts of physiology & pathophysiology. (Hammerschlag, 5/01)
 8. Research why people utilize CAM.
 9. Research what services the people are seeking.
- Supporting Principles:** #1 through #10 (except #5 & #6)
-

ISSUE (*Tieraona* #3, *Veronica*, #1, *Wayne* #2): Research Training and Infrastructure

Discussion: Commissioners and speakers discussed the need for a strong research infrastructure, which is crucial to the conduct of quality research and research training in CAM. This research infrastructure should be strategically located. Each site should have a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. These sites should include CAM professionals on the faculty and/or as consultants and should partner with accredited CAM institutions in the conduct of research and research training. (example: NIH research centers program).

The same rigorous training should be available for both CAM and conventional researchers. Both CAM and conventional researchers need knowledge of the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process, data collection, protocol design, IRB and other regulatory requirements, and the grant application and submission process.

Two ideas that were discussed were developing CAM centers or programs at existing academic research centers and establishing centers for CAM research and training at accredited CAM institutions.

Challenges:

Stimulating adequate funding and strategic planning for developing or strengthening research infrastructure sites and training programs.

Developing incentives for conventional researchers to attract high quality mentors.

Increasing collaborations between institutions to enhance training opportunities and improve the quality of training.

Draft recommendations (not ranked):

1. Ensure that the same rigorous research training to conduct basic, clinical, or health services research is available for both CAM and conventional researchers. Investigators in CAM research need to be trained in research methodology, understand the CAM modality they are studying, have a mentor, and work in a collaborative environment.
2. Fund NCCAM and other IC's at an adequate level to support a strong research infrastructure at strategically-placed sites that will improve and enhance CAM research and research training programs.
3. Support and encourage CAM research training by other Federal health agencies with research training programs.
4. Increase collaborations between accredited CAM and conventional institutions, through faculty exchange and consultation, to enhance training opportunities and improve the quality of training. Include CAM-trained practitioners and researchers as part of training faculties (Pearson, 5/01).
5. Support the development of research and research training infrastructures at CAM institutions.
6. Fund career development awards to enable investigators focusing on CAM to develop into independent investigators (Phillips, 5/01).
7. Develop incentives for conventional researchers to attract high quality mentors.
8. Fund mid-career awards to provide support for the time required to mentor new CAM investigators (Phillips, 5/01).
9. Encourage representatives from NCCAM-funded centers to meet periodically, not only to present progress reports, but also to exchange experiences on how best to educate researchers in CAM practices, and how to introduce CAM practitioners to the research culture. (Hammerschlag, 5/01).
10. Train students at conventional and CAM institutions in critiquing CAM trials (Hammerschlag, 5/01).
11. CAM research training should teach multiple outcome measures, including social contextual assays and biopsychological measures of health carried out by multidisciplinary teams to allow broader paradigms of health and healing (Blanks, 5/01).

INSERT: Veronica Gutierrez' ranked recommendations

1. More funding for NCCAM. (Blanks, 5/01)
2. Research training supported by other Federal health agencies. Training should teach multiple outcome measures, including social context assays & biopsychological measures of health carried out by multidisciplinary teams to allow broader paradigms of health & healing. (Blanks, 5/01)
3. Infrastructure built in more institutions to allow more diversity.
4. Bring in basic science researchers to determine mechanism of actions. 5. Adopt multiple models beyond RCTs across all Federal sectors.
6. Funding of career development awards. (Phillips 5/01)
7. Increased funding for mid-career awards to provide support for the time required to mentor new CAM investigators. (Phillips 5/01)
8. Include CAM trained practitioners & researchers as part of the training faculty.
9. Add CAM groups onto mailing lists & notify them about research grant opportunities.
10. Open research RCA opportunities beyond current "favorites".

Supporting Principles (As edited by Jim Swyers) #1, #2, #3, #4, #9, #10

ISSUE (*Tieraona* #2, *Veronica* #5, *Wayne* #4): Public-Private-Nonprofit partnerships and investment in CAM research and related activities.

Discussion: The growing willingness of the public, private, and nonprofit sectors to form partnerships offers exciting possibilities in stimulating and supporting much needed CAM research. Also, mechanisms such as the NIH Small Business Innovative Research program and the technology transfer cooperative research program offer the private sector opportunities for research support. The provision of incentives for private sector involvement in CAM research and resolving intellectual property issues could spur private activity. Provision of proprietary protection around process, extraction, production, and use of unique mixtures and combination of agents is needed. A rigorous review process including industry and academic scientists should be developed (Rudden,10/00).

It should be noted that because it is often not possible to patent CAM products, there has been little private research on these products by pharmaceutical companies. Submissions of petitions to gain approval for the right to make health claims also are not economical because pharmaceutical companies or manufacturers of CAM products that might go to the expense of gaining such approval would face competition from other manufacturers that could sell similar products as dietary supplements.

Under the provisions of DSHEA, dietary supplements can make structure function claims. Approved drugs can make health claims about preventing, curing, treating, or mitigating a disease. However, as stated above, because drug approval is a labor-intensive process requiring

substantial research, time, and money, most dietary supplement manufacturers do not seek drug status for their products. The unintended effect is that in some instances where there is research on a dietary supplement supporting that could support a claim, the dietary supplement is still limited to the structure function claim because dietary supplements are foods.

Certain dietary supplements can make health claims under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). For example, there is significant scientific agreement that calcium can prevent osteoporosis and a health claim for both calcium-containing foods and dietary supplements has been approved by the FDA.

Challenges:

Creation of incentives for nonprofit organizations to become involved in research on CAM practices and products, e.g., providing seed money and investment in pilot studies.

Creation of incentives for private sector involvement in CAM research possibly through tax incentives and resolving intellectual property and other issues to increase involvement in product research, product standardization.

Federal funding for research on CAM products in collaboration with the private and nonprofit sectors.

Draft recommendations (not ranked):

1. Establish better methods of coordination between private, public, and philanthropic sectors in support of CAM research (Templeton,10/00).
2. Create incentives for private company involvement in CAM research and related activities.
3. Involve companies in developing improved regulations and create incentives to encourage companies to invest in CAM research (Burkholder,10/00).
4. Encourage the nonprofit sector to host CAM meetings to discuss partnership opportunities and bring together CAM and conventional researchers and professionals. Invite foundation representatives to NIH/CAM research centers to learn and discuss opportunities for involvement (Templeton 10/00).
5. Encourage the creation of a consortium of private funding sources to augment CAM basic, clinical, and health services research by Federal agencies. (Eisenberg, 5/01).
6. Encourage NIH to partner with foundations interested in enhancing their CAM research-related activities to partner in research and research training support and conference support, and invite foundation representatives to sit on advisory councils and other advisory groups (Templeton 10/00).

7. Encourage public-private-nonprofit sector collaboration on safety and efficacy of products, and the standardization of products.
8. Encourage successful manufacturers of CAM products to conduct studies (Eisenberg 5/01), and explore collaborations with strong research institutions.
9. Add foundations to mailing lists that could inform them about research grant opportunities (Hayes 10/00) and encourage foundations to fund pilot projects.
10. Encourage foundations to consider creating a collaborative pool of funds, announce funding competitions, and set up advisory/review groups of knowledgeable, reputable scientists in the areas to be studied (Hayes 10/00).
11. Encourage the training of interdisciplinary research teams supported by public-private partnerships to enhance progress in research and training (Blanks,5/01).
12. Use mechanisms such as the NIH Small Business Innovative Research program and the technology transfer cooperative research program to offer the private sector opportunities for research support.

INSERT: Veronica Gutierrez' ranked recommendations:

1. Encourage the growing willingness of the public, private, & non-profit sectors to form partnerships supporting CAM research.
2. Encourage not-for-profit sector to host face-to-face meetings & visits to research sites & with research groups.
3. Encourage foundations to fund pilot projects, announce funding competitions & set up advisory/review groups from the areas to be studied.

Supporting Principles: #1 through #10

ISSUE (*Tieraona* #5, *Veronica* #5, *Wayne* # 5): Publishing literature on CAM research and systematic reviews of the literature

Discussion: Many speakers agreed that CAM research results need to be published in recognized peer-reviewed research journals to provide accurate and reliable knowledge about CAM to researchers, practitioners, and ultimately the public. The quality of the research and the standards of review the research must meet for journal publication affect how readers determine the reliability and usefulness of the information. Speakers also emphasized that CAM expertise on journal review boards should be represented when reviewing CAM research submissions necessary to accomplish a full, fair, and accurate review.

Recent increases in research funding and the establishment of CAM research centers should increase the publication of high quality studies on CAM therapies submitted to research journals (Fontanarosa5/01). Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa5/01).

It is necessary to document the basis for claims. Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa5/01).

Challenges:

The conduct of research on CAM that can be successfully submitted to journals with the highest standards of review.

The inclusion of reviewers experienced in CAM on journal review boards when CAM submissions are reviewed.

Increase systematic reviews of the literature and their use.

Draft recommendations (not ranked):

1. CAM research results should be submitted to journals with the highest publication standards.
2. Qualified members with CAM expertise should sit on journal review boards when reviewing CAM submissions.
3. Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses (Fontanarosa5/01).
4. CAM manuscripts should be submitted to journals, both conventional and CAM, on-line and in print, that are recognized for the most rigorous peer review (Relman,5/01).
5. CAM practitioners should read the highest quality conventional journals and conventional practitioners should read CAM journals of equal quality.
6. Increase the availability of reviews in the Cochrane library through access to on-line subscriptions by policy-making offices, public libraries, and community health centers. (Berman)
7. Develop ~~executive~~ ^{non technical} summaries of Cochrane systematic reviews, made jargon free, and available through hyperlink to the public (Berman)

through PubMed

8. Use the NCCAM clearinghouse to make new information available on a monthly basis. (Berman, 5/01).

9. Continue to conduct AHRQ's Evidence-based Practice Center systematic reviews on CAM treatments, which can be used by private and public entities as a basis for the development of tools such as practice guidelines, performance measures, and review criteria.

INSERT: Veronica Gutierrez' ranked recommendations:

1. Increase publication of high quality studies on CAM submitted to research journals. (Fontanarosa 5/01)
2. CAM manuscripts should be submitted to journals both conventional & CAM on-line and in print that are recognized for the most rigorous peer review. (Relman, 5/01)
3. Qualified members with CAM expertise should sit on journal review boards when reviewing CAM submissions.
4. Provide improved availability of reviews in the Cochrane library through access to on-line subscriptions by policy-making offices, public libraries, and community health centers. (Berman, 5/01)
5. The NCCAM clearinghouse make new information available on a monthly basis. (Berman, 5/01)
6. AHRQ's Evidence-based Practice Centers continue to conduct systematic reviews on CAM & use information as a basis for the development of practice guidelines, performance measures, and review criteria.

Supporting Principles: #2, #3, #4, #7, #8, #9

Groft, Stephen (WHCCAMP)

From: Pollen, Geraldine (WHCCAMP)
Sent: Monday, August 27, 2001 2:20 PM
To: 'jpswyers@starpower.net'; Corinne Axelrod; Joseph Kaczmarczyk; Ken Fisher; Maureen Miller; Michele Chang; Stephen Groft
Subject: FW: WHC: SUMMARY CORRECTION
Importance: High

Please see below for correction to Research Work Group conference call summary.

-----Original Message-----

From: Pollen, Geraldine (WHCCAMP)
Sent: Monday, August 27, 2001 12:07 PM
To: 'Wayne Jonas'; 'Dean Ornish'; 'George Bernier'; 'Tieraona Low Dog'; 'Veronica Gutierrez'; 'Effie Chow'; 'William Fair'
Subject: WHC: SUMMARY CORRECTION
Importance: High

Hi Everyone:

Please see below in the text of this message a corrected copy of the August 17 conference call summary. The changes are italicized in bold in the 7th paragraph.

My notes were correct but my typing was not. Bill Fair made the comments in paragraph 7, which George Bernier brought to my attention. Also, I asked Bill about the SPORE program, which I had jotted down in my notes, but could not find among NIH activity codes. I assumed I had misheard and included the SCOR program in the summary. I have since spoken with Bill and he explained that NCI has revived the SPORE concept to stimulate innovative thinking. I have corrected both inaccuracies.

Thank you.

Gerry

WHCCAMP

Summary of Research Work Group
Conference Call
Friday, August 17, 2001
3:00-4:30 P.M. EST

Work Group Members who participated in the conference call were: Wayne Jonas, Dean Ornish, George Bernier, Bill Fair, Veronica Gutierrez, and Tieraona Low Dog. Effie Chow was out of the country and unable to join the group. Wayne Jonas and Dean Ornish served as group facilitators. Gerry Pollen served as staff leader. Other staff members who took part in the discussion were Steve Groft, Ken Fisher, and Michele Chang.

Except for issue #6, the group accepted the broad issues that were outlined in the agenda and formed the framework for the "strawman" document, which was developed to stimulate discussion beyond the interim report. Issue #4, which deals with the role of public, private, and not-for profit organizations will be redrafted to include the word, partnerships.

Discussion concentrated mainly on concepts members believe should be clearly articulated in the research section. Dean Ornish emphasized the idea that CAM is more than St. John's Wort vs. Prozac. CAM contributes to how we live physically, mentally, and spiritually and includes but goes beyond safety and efficacy and beyond wellness. CAM incorporates the circle of life from beginning to end and includes illness and suffering as catalysts to new understandings and changed behavior and view of life. The challenge is in finding out how to measure such things to discover what CAM can contribute and why people are turning to CAM.

It was noted that the history of medicine includes many systems of belief, of which the western model is only one. Tieraona Low Dog encouraged research on whole systems.

Wayne Jonas talked about research being relevant by being responsive to what the public is seeking.

The group agreed that all research should be held to the same standards, not higher or lower; the playing field should be level.

Bill Fair encouraged public-private-not-for-profit investments to go beyond product research to support research on spirituality and health, and gave the example of research supported by Medtronic on intercessory prayer. George also talked about the value of bringing together a variety of disciplines to study difficult research questions, such as biofields and electromagnetic fields, which might bring together physicists, basic biomedical researchers, and CAM professionals. *He gave as an example the NCI's SPORE (Specialized Programs for Research Excellence) program, which brings together multiple disciplines to find innovative research approaches to difficult questions in focused areas.*

Wayne Jonas pointed out the crucial role of research infrastructure and the building of strategically located sites with a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. These sites would partner with accredited CAM institutions to conduct the highest quality research and research training. He also used as an illustration the NIH research centers programs. Veronica Gutierrez emphasized not only partnering with CAM institutions with or without a research base, but building an adequate number of sites to increase access. Two ideas that were discussed were bringing CAM into existing research centers and establishing centers for CAM research.

Members talked about the crucial role of basic research to CAM. Wayne Jonas and Bill Fair emphasized the value of basic research and supported the idea of CAM and conventional partnership in simultaneous basic and clinical research efforts, which they believe offers a greater chance of funding. Tieraona Low Dog said that while she agrees that basic research is very important and needs to be carried out, the science base is in its infancy and has a long way to go. She stressed the immediate need to examine the safety and effectiveness of what the public is currently using, information that the public and practitioners need to know.

The members exchanged ideas about developing strategies to incorporate the concept of pluralism into methodology. A multiple method approach to research design opens up new ways to understanding complex questions. George Bernier and Bill Fair talked about outcomes research to examine questions that may not yet be appropriate for a clinical trial. Science must continue what it has always done which is to follow each quest for knowledge by developing new ways to answer difficult questions. Everyone agreed that pluralism in methodology requires that the same standards be in effect for CAM as it is for all research. This level playing field in research also requires equity and fairness for CAM on all review committees and boards as relevant, including journal review boards.

Members also talked about the responsibility of the Federal government in supporting research endeavors across the agencies, depending on the type of research needed, and helping to establish a level playing field for CAM whether at NIH, FDA, or other Federal agencies, holding it to standards no higher or lower than mainstream medical research. The group recognized the importance of not "stepping on the toes of NCCAM or any other agency.

The members agreed to send to Gerry Pollen by the close of business Wednesday their ranking of the issues and a ranking of their suggested recommendations, as well as any examples or models they think would help illustrate a recommendation or background discussion. She will make changes to the strawman document that reflect the discussion on August 17 and the information received from the members on the issues and

recommendations.

Gerry will also send the members 1) an outline of the key issues/ideas contained in the research section from the interim report which was requested, and 2) a clarification of issue #6 explaining the relationship between that issue and research.

Doris Kingsbury will be setting up a second conference call for the week of August 27.

If you have any comments on the accuracy of this summary, please let me know.

Groft, Stephen (WHCCAMP)

From: Pollen, Geraldine (WHCCAMP)
Sent: Wednesday, August 15, 2001 2:35 PM
To: Groft, Stephen (WHCCAMP); Chang, Michele (WHCCAMP); Kaczmarczyk, Joseph (WHCCAMP); Miller, Maureen (WHCCAMP); Fisher, Ken (WHCCAMP); 'jpswyers@starpower.net'
Subject: FW: WHCCAMP: Conference Call Package
Importance: High

Sorry. I forgot to cc you all when I sent this earlier. George Bernier was sent a separate message with the information within the text.

-----Original Message-----

From: Pollen, Geraldine (WHCCAMP)
Sent: Wednesday, August 15, 2001 12:52 PM
To: 'Wayne Jonas'; 'Dean Ornish'; 'Veronica Gutierrez'; 'William Fair'; 'Tieraona Low Dog'; 'Effie Chow'
Subject: WHCCAMP: Conference Call Package
Importance: High

Dear Research Work Group:

Our conference call on the first steps in preparing for the October '01 meeting is scheduled for this **Friday, August 17 from 3:00 to 4:30 EST**. Kate set aside an extra half hour in case we run over and some members want to continue. You should have received from Michele the phone number and passcode for this conference call. If you have any questions, please get in touch with Michele or me.

I have attached for your use during this conference call 1) an agenda; 2) a "strawman" document ; and 3) a draft definition of health services research. The "strawman," which is based on the issues identified in the interim report and testimony and written documents, has been prepared to stimulate discussion and begin the process of moving beyond the interim report.

Each work group is being asked to begin the evolving process of deciding on the issues, the challenges and the recommendations. The research "strawman" contains 6 broad issues each with a brief discussion, some challenges, and either background information and draft recommendations, or background material containing information for possible draft recommendations.

The "strawman" is a very first step in the process. There is more material to examine and share with you and a great deal of work to be done as we move through the process. During this conference call it's important to use this document as a starting point to agree on the issues, how they are stated, and if any are inaccurate or missing. Then begin the process that will continue during the next months of identifying the most important challenges and formulating draft recommendations in preparation for the October meeting. Regulatory issues and overlapping and inter-related areas among report sections will be pulled together during the report development process.

In addition to the attached documents, you have your copy of the interim report, the October '00 and May, and July '01 briefing books, your notes, and the transcripts on the WHCCAMP website. Also, your access and delivery (December) briefing book contains summaries of the October '00 research meeting and the Seattle town hall meeting.

Speak to you on Friday.

Geraldine (Gerry) B. Pollen

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White House Commission on
Complementary and Alternative
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Research17August
Agenda.rtf



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Mapping a Research Strategy for Global Medicine

*CR
Review
Conduct*

Figure 1

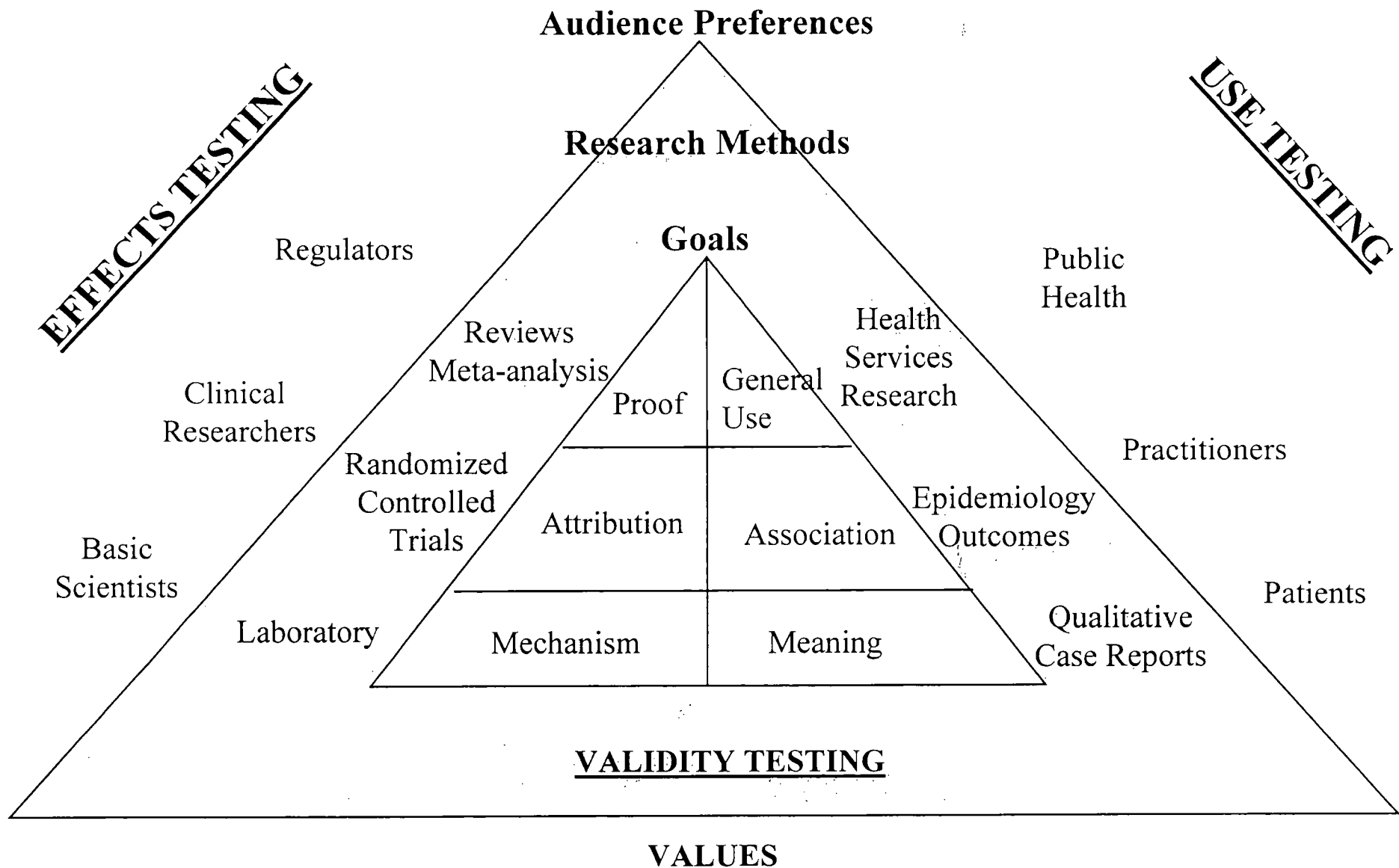
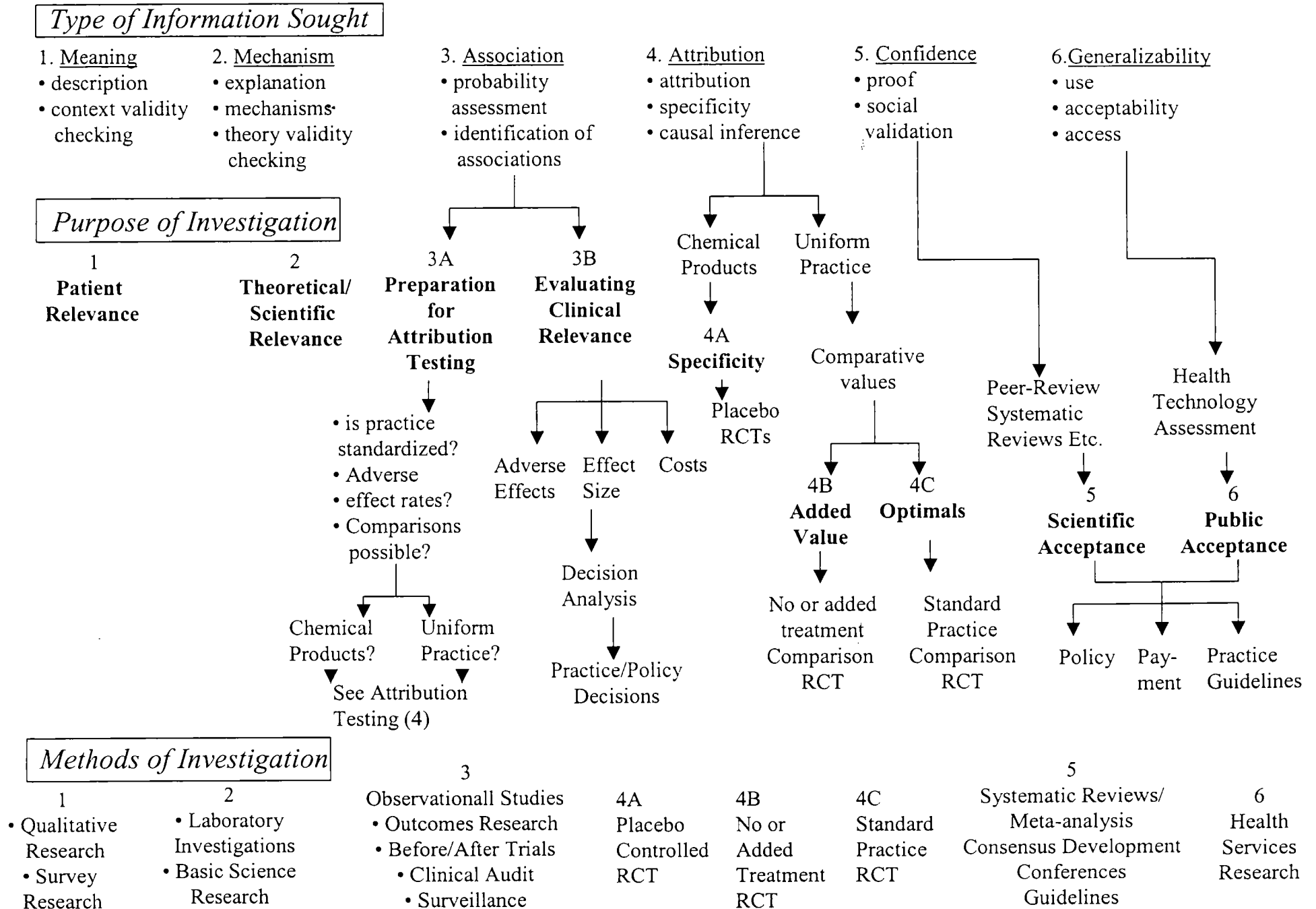


Figure 2

CAM Research Strategy Map



AGENDA FOR RESEARCH
WORK GROUP MEETING
AUGUST 17, 2001
3:00-4:30 P.M. EST

A. Discussion of broad research issues based on research section of interim report

B. “Strawman” framework to begin discussion on final report preparation: issues, challenges, recommendations

C. Major issues:

1. Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians, and researchers.
2. Conducting high quality CAM research and identifying the types of research needed
3. Research training and infrastructure
4. Public-Private-^{Partnership} ~~Not-for-profit involvement~~ and investment in CAM research and related activities
5. Publishing literature on CAM research and systematic review of the literature
6. State medical and other professional licensing boards and research opportunities for nonstandard treatments

TOPIC: Coordination of Complementary and Alternative Medicine Research

Staff Lead: Gerry Pollen

Facilitators: Wayne Jonas and Dean Ornish

***ISSUE 1. Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers.**

Discussion: Working relationships among professionals from multiple conventional and CAM disciplines are necessary prerequisites to progress in studying and understanding CAM practices and products (Vazquez, 5/01). Lack of mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers impedes progress in building knowledge about CAM. An emerging dialogue between CAM and conventional medicine (Kaptchuk, Eisenberg, AIM, 8/7/01) and a growing willingness to experiment with integration appears to be taking place slowly. Fostering and strengthening this emerging dialogue to increase understanding of one another's concerns and contributions, can help strengthen cooperation, coordination, and collaboration in research and related activities.

Challenges: Mutual respect is needed to stimulate communication and research collaboration (White, Oct'00). The voice of complementary and alternative medicine is not heard on NIH advisory councils and committees and does not influence Institute and Center (IC) budget decisions. (Lenfant, 10/00). Lack of communication with CAM professionals affects the ability of IRB members not familiar with CAM to evaluate adequately the CAM protocols that come before them. (Lenfant and Fins 10/00). Cultural taboos can impede willingness to evaluate research applications that are outside the mainstream (Cassman, 10/00). Accommodations in the FDA's regulatory framework for the study of botanical products are needed.

Background Examples: U of Pennsylvania (Al Fishman); Harvard U, (Daniel Federman), U of Maryland (Brian Berman), and Beth Israel Medical Center, NY (Woody Merrill), King County system (Seattle meeting), and coordinated activities to create funding opportunities for scientific evidence-based models and databases for CAM and integrated health care (Bastyr University, Seattle meeting). CAM proposals submitted to NIH should require involvement by CAM licensed professionals and be approved by a panel of CAM professionals (Hammerschlag, 5/01).

Draft Recommendations:

1. Support multidisciplinary conferences and workshops to discuss research approaches to studying CAM questions (Hausman, 10/00) and increase opportunities for CAM and conventional practitioners, clinicians and researchers to interact and exchange ideas.
2. Include trained and licensed CAM professionals, who are involved in research or related activities, on research and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate any regulations that might impede such representation.
3. Strengthen funding to develop a critical mass of academic health centers with sufficient resources and infrastructure to conduct basic, clinical, and health services research in CAM, train researchers and clinical experts, and deliver integrated care services (Eisenberg 5/01).

4. Stimulate academic health centers to partner with accredited CAM institutions and to examine ways in which they can include CAM in their organizations and allow integration in research, clinical care, and training activities. (Fishman and Federman, 10/00)).
5. Partner with CAM professionals in the phase of research examining complete biological systems that were broken down in earlier research to study their components, and in the study of interacting biological systems. (Cassman 10/00)
6. Create incentives to motivate basic scientists to partner with CAM practitioners in areas of mutual interest, such as the mechanisms of action involved in acupuncture (Jonas 10/00).
7. Encourage the formation of an integrated national or international society (Eisenberg, 5/01) or academy (Duffy, 5/01) for CAM research to share information and expertise on research and best practices, and inform public policy.

ISSUE 2: Conducting high quality CAM research and identifying the types of research needed.

Discussion: An often mentioned theme during both research meetings as well as heard at other meetings was that high quality basic and clinical biomedical research and health services research on CAM is needed to protect the public's health and safety. Research provides the basis for accurate information to increase the public's knowledge about CAM; for educating and training CAM and conventional health care professionals; for regulating the quality and use of CAM practices and products; and for improving access to safe and effective CAM practices and products and the coverage for them.

Most public testimony supported the importance of evidence-based research in CAM, and also revealed the public's interest in the potential contributions of CAM research to expand current research horizons through its emphasis on (1) life-style, health promotion and wellness separate from disease prevention; (2) the importance of patient-practitioner interaction to treatment; and (3) the role of both mind and body in health, disease, and healing, including understanding the body's healing ability, the role of the brain and belief, and the role of stress; and (4) biofields and electromagnetic fields.

There was much discussion on identifying the types of research needed to assure the safe use of CAM by the public and to integrate CAM into an evolving health care system. In addition to the need for basic research and randomized controlled clinical trials, much attention was paid to the adaptation of RCT methodology to CAM questions. Testimony equally addressed the value of outcomes research, observational research, qualitative research, demonstration projects, cost-effectiveness studies and other research to examine safety, efficacy, and other aspects of CAM practices and procedures.

Challenges: Research challenges range from (1) the need to collect objective data, adapt, as necessary, orthodox scientific methodology to CAM studies and resolve the standardized/non-standardized and individualized vs. generalized issues in designing CAM protocols, and gaining

IRB approval, to (2) responding to CAM's emphasis on wellness separate from disease and the connection between health and the whole person. Among additional challenges are blinding and/or randomizing difficulties, the placebo effect, studying the practitioner effect on outcomes, and whole system response.

The emerging consumer-oriented health care system and the public's interest in the research agenda were often identified as elements requiring recognition and response (Kaptchuk, Eisenberg, AIM, 8/7/01).

Background for developing draft recommendations:

1. Testimony supported increased support for NCCAM, the activities of ODS, and strong encouragement of other NIH/IC's to fund CAM research in collaboration with NCCAM or separately. [Note NCI example] Testimony also supported continued and strengthened collaborations between NCCAM and other Federal agencies, such as AHRQ and CDC, HRSA and others.
2. Among areas of basic research identified during testimony as needing attention and often mentioned were homeopathy, acupuncture, chelation therapy—Winn, 9/00, Margolis, 5/01.
3. Funding is needed for clinical research on promising products that would be unlikely to receive a patent and therefore not likely to attract private research dollars.
4. Reliable standards on CAM products are needed for research so that products with consistent composition are available.
5. The first need for quality studies is to establish safety, then efficacy, and finally general effectiveness of herbal medicines, followed by basic studies on mechanisms of action and toxicity to help anticipate adverse interactions, contribute to establishing risks-benefits, and lead to new treatments (Grollman, 5/15/01).
6. We need to know about the safety and efficacy on all biological remedies, and if shown to be safe and effective, they should be integrated into clinical practice, but the research must meet the rigorous standards established for biomedical research (Angell, 5/01).
7. Good research of CAM will not occur unless the approaches studied are standardized. The study of non-standardized approaches with individual patients is not sufficient (Rabin, 5/01). Control groups should be used to evaluate CAM treatments compared to standard conventional treatments and CAM in combination with conventional treatments (Rabin, 5/01).
8. CAM research should reflect the real-world practice of CAM (Hammerschlag, 5/01). NCCAM and/or the NAS should hold a conference to propose evidence-based models for expanding current concepts of physiology and pathophysiology (Hammerschlag, 5/01).
9. Funding is needed for epidemiologic and clinical research to establish safety and efficacy, basic research to discover and explain the underlying mechanisms of action, and health services

research to improve CAM use within the health care system. Any one of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg, 5/01).

10. Conducting research on why people use CAM, what they mean when they say it works, and what they find satisfying about CAM in comparison to conventional medicine would be valuable (Callahan, 10/00). A think tank of methodologists and CAM professionals should be assembled to discuss ideas about methodology and CAM (Callahan, 10/00).

11. Examples of research for which funding is needed: studies on toxicity pertaining to herbs and supplements; surveillance studies of adverse events of CAM therapies and/or their interaction with conventional therapies(CDC); epidemiology of CAM patterns of use among minority and underserved populations (CDC); studies on ethical practice and malpractice liability; studies on conventional/CAM practitioners co-management of patients; development of evidence-based, financially sustainable models of integrated clinical care delivery; evidence-based practice reports (AHRQ); CAM practice guidelines and CAM and conventional practitioner referral guidelines. [See Health Services Research Working Draft]

12. Assure that the public is heard when setting the CAM research agenda and invite CAM professionals to be included in research policy efforts.

ISSUE 3: Research Training and Infrastructure

OK

Discussion: In order to conduct quality research in CAM, financial support for research training and infrastructure support were identified as priorities. Building an integrated pool of researchers calls for the simultaneous strengthening or development of research infrastructures for CAM research at both accredited CAM and conventional institutions. The same rigorous training should be available and promoted for both CAM and conventional researchers in training. Both need knowledge of the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process, data collection, protocol design, IRB and other regulatory requirements, and the grant application and submission process.

Challenges: Adequate funding, reaching out, mentoring, helping those interested but inexperienced, collaboration between institutions to increase opportunities and improve quality of training, incentives for conventional researchers.

Background for developing draft recommendations:

1. More funding for NCCAM is vital to building the pool of researchers and concomitant infrastructures (Blanks, 5/01). Research training supported by other Federal health agencies is needed as well. The promotion of interdisciplinary teams through research training supported by public-private partnerships is an important approach to enhancing progress in research and training (Blanks,5/01).

2. The funding of career development awards will enable investigators focusing on CAM to develop into independent investigators (Phillips, 5/01). Increased funding for mid-career awards to provide support for the time required to mentor new CAM investigators (Phillips, 5/01).

3. Representatives from NCCAM-funded centers should meet periodically, not only to present progress reports, but also to exchange experiences on how best to educate researchers in CAM practices, and how to best introduce CAM practitioners to the research culture (Hammerschlag, 5/01). Students at allopathic and CAM institutions need training in critiquing CAM trials (Hammerschlag, 5/01).

4. Include CAM-trained practitioners and researchers as part of the training faculty (Pearson, 5/01)

5. Training should teach multiple outcome measures including social contextual assays and biopsychological measures of health carried out by multidisciplinary teams to allow broader paradigms of health and healing (Blanks, 5/01).

6. Investigators in CAM research need to be trained in research methodology, understand the CAM modality they are studying, have a mentor, and work in a collaborative environment.

ISSUE 4: Public-Private-Non-profit involvement and investment in CAM research and related activities.

Discussion: The growing willingness of the public, private, and non-profit sectors to form partnerships offers exciting possibilities in stimulating and supporting much needed CAM research.

It should be noted that because it is often not possible to patent CAM products, there has been little private research on these products by pharmaceutical companies. Submissions of petitions to gain approval for the right to make a health claims also are not economical because pharmaceutical companies or manufacturers of CAM products that might go to the expense of gaining such approval would face competition from other manufacturers that could sell similar products as dietary supplements.

Under the provisions of DSHEA, dietary supplements can make structure function claims. Approved drugs can make health claims about preventing, curing, treating, or mitigating a disease. However, as stated above, because drug approval is a labor-intensive process requiring substantial research, time, and money, most dietary supplement manufacturers do not seek drug status for their products. The unintended effect is that in some instances where there is research on a dietary supplement that could support such a claim, the dietary supplement is still limited to the structure function claim because dietary supplements are foods.

Certain dietary supplements can make health claims under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). For example, there is significant scientific agreement that calcium can prevent osteoporosis and a health claim for both calcium-containing

foods and dietary supplements has been approved by the FDA.

Challenges: Creation of incentives for private and not-for-profit involvement in CAM research, e.g., seed money and pilot investments, product standardization, product research, other CAM research, and other collaborative activities. Federal funding for research on CAM products in collaboration with the private sector.

Background for developing draft recommendations:

1. Better methods of coordination between private, public, and philanthropic sectors in support of CAM research need to be developed (Templeton,10/00). The not-for-profit sector could host face-to-face meetings and site visits by foundation representatives to NIH/CAM research centers to learn and discuss opportunities for involvement (Templeton 10/00). NIH should be more aggressive in seeking opportunities for foundation representatives to sit on advisory councils and other advisory groups (Templeton 10/00).
2. NCCAM might consider convening a meeting to discuss private, not-for-profit, and public agency coordination (Ades 10/00).
3. Collaboration of public and private sectors on safety and efficacy of products.
4. Successful manufacturers of CAM products should be encouraged to conduct studies (Eisenberg 5/01), and should explore collaborations with strong research institutions.
5. Foundations should be included on mailing lists and notified about research grant opportunities (Hayes 10/00). Foundations should be encouraged to fund pilot projects and might consider creating a collaborative to pool funds, announce funding competitions, and set up advisory/review groups of knowledgeable, reputable scientists in the area to be studied (Hayes 10/00).
6. Companies need to be involved in developing improved regulations and companies need incentives to invest in CAM research (Burkholder,10/00).
7. Support for basic, clinical, and health services research should be sought through a consortium of private funding sources to augment CAM research by Federal agencies (Eisenberg, 5/01).
8. Mechanisms such as the NIH Small Business Innovative Research program and the technology transfer cooperative research program offer the private sector opportunities for research support. The provision of incentives for private sector involvement in CAM research and resolving intellectual property issues could spur private activity. Provision of proprietary protection around process, extraction, production, and use of unique mixtures and combination of agents is also needed. A rigorous review process including industry and academic scientists should be developed (Rudden,10/00).

ISSUE 5: Publishing literature on CAM research and systematic reviews of the literature

Discussion: CAM research results published in recognized peer-reviewed research journals is necessary to provide accurate and reliable knowledge about CAM to researchers, practitioners, and ultimately the public. The quality of the research and the standards of review the research must meet for journal publication affect how readers determine the reliability and usefulness of the information. CAM expertise on journal review boards when reviewing CAM research submissions is necessary to a full and accurate review.

Challenges: It is important to conduct good research on CAM and successfully submit it to journals with the highest standards of review. Journals should include on their review boards reviewers experienced in CAM when reviewing CAM submissions.

Some Standards

Background for developing draft recommendations:

1. Recent increases in research funding and the establishment of CAM research centers should increase the publication of high quality studies on CAM therapies submitted to research journals (Fontanarosa5/01). Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa5/01).
2. Qualified members with CAM expertise should sit on journal review boards when reviewing CAM submissions.
3. The first focus for submission of publication should be on safety and interactions between CAM therapies and conventional therapies (Laine,5/01). Large clinically significant studies are looked at first (Fontanarosa5/01).
4. It is necessary to document the basis for claims. CAM manuscripts should be submitted to journals, both conventional and CAM, on-line and in print, that are recognized for the most rigorous peer review (Relman,5/01). CAM practitioners should read conventional journals and conventional practitioners should read CAM journals.
5. Availability of reviews in the Cochrane library should be increased through access to on-line subscriptions by policy-making offices, public libraries, and community health centers. Executive summaries of systematic reviews should be developed, made jargon free, and available through hyperlink to the public. The NCCAM clearinghouse could be used to make new information available on a monthly basis. (Berman,5/01).
6. AHRQ's Evidence-based Practice Centers should continue to conduct systematic reviews on CAM treatments, which can be used by private and public entities as a basis for the development of tools such as practice guidelines, performance measures, and review criteria.

ISSUE 6: State medical and other professional licensing boards and research opportunities for nonstandard treatments.

Discussion: At several meetings, those who testified described the impediments practitioners

face when they conduct practice-based research to collect data and when they want to pursue opportunities to study their nonstandard treatments or submit them for study by qualified research teams. It appears that the exclusive focus of State licensing boards, especially medical boards, to discipline and prosecute quackery, places these practitioners in a difficult situation. While recognizing and fully supporting the primary responsibility of state licensing boards to protect the public from poor and dangerous medical care, there seems to be a need for licensing boards to explore ways to communicate with practitioners who have done no harm and allow them to collect data on nonstandard treatments and submit early data that may be promising to qualified research programs for evaluation and possible research support.

Background: The “Special Committee on Questionable and Deceptive Health Care Practices,” convened in 1977 by the U.S. Federation of State Medical Boards (FSMB), provided guidance on evaluating conventional and nonconventional practices in light of good medical practice. The federation has been developing guidelines to assist in educating and regulating physicians who use CAM in their practices or co-manage patients with licensed CAM providers. According to the FSMB, practice-based or institutional-based research should be part of a systematic research program designed under accepted standards of scientific research and expected to produce valid data. (Winn, 8/00),

Challenges: Dr. James Winn, FSMB Vice President, echoed other speakers in supporting the need for research. He emphasized the physician’s responsibility to practice good medicine and indicated that if a claim of effectiveness is proven true, the practice should be used appropriately. What is missing, however, is the intersection between what the State may view as a fraudulent practice and the practitioner’s belief that the practice is promising, data need to be collected, and the treatment deserves to be evaluated for research support.

Draft Recommendations:

1. Encourage medical boards to meet with practitioners who have done no harm about their practice-based research on nonstandard treatments, including informed consent, patient safety, and data collection, before assessing the board’s next steps.
2. Encourage medical boards to develop a process that both protects the public and allows practitioners ~~who have done no harm~~ to apply to established research programs for evaluation of their data on nonstandard treatments and possible research support.

FSMB Board

Health Services Research (HSR) – Working Draft

Definitions

Institute of Medicine (IOM): HSR is a multidisciplinary field of inquiry, both basic and applied, that examines access to, and the use, costs, quality, delivery, organization, financing, and outcomes of health care services to produce new knowledge about the structure, processes, and effects of health services for individuals and populations.

Agency for Health Research and Quality (AHRQ, formerly AHCPR): HSR is a field of inquiry that examines the impact of the organization, financing and management of health care services on the delivery, cost, access to, and outcomes of such services.

Involved Disciplines – medicine, nursing and other health professions, statistics, epidemiology, sociology, law, economics, political science, management, operations research, psychology, social work

Stakeholders – policy makers, purchasers/payers, federal and state agencies, public and private organizations, managers, clinicians and health practitioners, lawyers, consumers

HSR and research-related activities (including demonstrations):

- access to health care (including special populations)
- delivery and management (including models of care such as managed care)
- utilization patterns
- workforce assessment (including numbers, type, competency, distribution)
- quality of health care (including quality assessment and improvement)
- outcomes evaluation (what works/comparisons of approaches and modalities)
- Clinical practice (best practice) guidelines
- cost-effectiveness of safe and effective modalities
- Payment and financing models
- Health information, statistics, and epidemiology
- Health technology assessment
- Health policy/economics

Other Definitions:

IOM's Definition of Health Technology Assessment: any evaluation of the cost, efficacy, cost-effectiveness, patterns of use, and the ethical, economic, and social consequences of the use of a medical technology.

AHRQ's Definition of Clinical Practice Guidelines: a set of directions or principles to assist the health care practitioner with patient care decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances.

Revised 9/6/01

Draft Recommendations:

1. Increase support for clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care systems in all Federal agencies with research or related health responsibilities.

2. Encourage NIH/IC's to establish best case series evaluation programs and communicate the availability of such programs to expand potential research opportunities to practitioners who believe they have promising data on nonstandard treatments.

approved - use language in BCS

3. Support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

4. Continue to support the Agency for Health Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

specific ideas *comprehensions*

5. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars.

6. Support research *to determine* on why people use CAM, how they determine effectiveness, and what they find satisfying about CAM in comparison to conventional medicine.

7. Provide resources, both public and private, to strengthen the CAM research infrastructure to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services.

8. Encourage CAM research training by Federal health agencies with research training programs; ensure that the same rigorous research training for basic, clinical, or health services research is available to conventional and CAM researchers; and encourage the training of interdisciplinary research teams supported by public-private partnerships to enhance progress in research and research training.

9. Encourage public, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of wellness separate from disease and the effects of lifestyle on health; the role of mind, body, and spirituality in health, disease, and the body's ability to heal; the effect of the practitioner-patient interaction on the quality of care and on healing; and the understanding of complete biological systems and interacting biological systems, including biofields and energy medicine.

10. Ensure that the public's voice is heard when setting the CAM research agenda.

10-13

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Quality of care
11. Ensure that the standards of research quality are the same for CAM as they are for conventional medical research—neither lower nor higher.

12. Develop programs to bring together a variety of disciplines to find innovative research approaches to solving difficult questions in focused CAM areas (example: NCI/SPORE program).

10-13 13. Include trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

14. ~~Continue public support for and encourage private and nonprofit support for~~ multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians and researchers to exchange ideas and discuss research approaches to studying CAM questions.

15. Develop incentives to stimulate ~~public-private-nonprofit~~ sector collaboration on research on the safety and efficacy of CAM products, and on projects to standardize the composition of CAM products.

16. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

17. Encourage the creation of novel funding mechanisms by the private and nonprofit sectors to augment Federal agency support for CAM research, research training, and for conferences and workshops.

alone 18. Encourage the submission of CAM manuscripts to journals that are recognized for the most rigorous peer review, and the inclusion of both CAM expertise and conventional research expertise on journal review boards when reviewing CAM manuscripts.

alone 19. Develop non-technical (lay) summaries of all systematic reviews of the literature and include them in publicly available information services, such as the National Library of Medicine's PubMed.

more to
#4 *Bullet Specific Recs.*

Wayne Jonas
- George Barnier
- Veronica
- Effie

Gerry Pollen
Steve J.

I Issue Background
II Challenge
III Recommendation
(Presentations)
By # 1- Issue
By Implementative 2-
Org
3- By Principle

TOPIC: Coordination of Complementary and Alternative Medicine Research

Staff Lead: Gerry Pollen

Facilitators: Wayne Jonas and Dean Ornish

Preamble - Hx

ISSUE: Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers.

Discussion: Building working relationships among professionals from both conventional and CAM disciplines is essential to progress in studying and understanding CAM practices and products (Vazquez, 5/01). Where there is scientific evidence that efficacy is equal, the inclination of CAM practitioners and users is to prefer natural methods that support the body's healing systems and [may] generally present less risk. But where efficacy is not equal, openness to conventional treatments is a reflection of the same mindset that we [CAM professionals] expect from the conventional community in turn (Demas).

An emerging dialogue between CAM and conventional medicine (Kaptchuk, Eisenberg, AIM, 8/7/01) and a growing willingness to experiment with integration appears to be taking place slowly. Fostering and strengthening this emerging dialogue to increase understanding one another's concerns and contributions, can help strengthen mutual respect, cooperation, coordination, and collaboration in research and related activities.

Communication, cooperation, and collaboration are essential to the success of CAM research and research training, between or among conventional and CAM researchers, clinicians, and practitioners; between CAM and conventional research centers, programs, and institutions; professional leadership organizations and Federal research and health agencies; and the public, private, and nonprofit sectors. Also, trained and licensed CAM professionals should be

included on research, journal, and regulatory advisory and review committees, as appropriate.

Background Examples:

U of Pennsylvania (Al Fishman);
Harvard U, (Daniel Federman),
U of Maryland (Brian Berman),
Beth Israel Medical Center, NY (Woody Merrill),
King County system (Seattle meeting),
Bastyr University coordinated activities to create funding opportunities for scientific evidence-based models and databases for CAM and integrated health care (Seattle meeting).

Challenges:

Lack of mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers impedes progress in building knowledge about CAM (White, Oct'00).

Cultural taboos can affect the evaluation of research applications that are outside the mainstream (Cassman, 10/00).

Build on the emerging dialogue between CAM and conventional medicine.

The voice of complementary and alternative medicine needs to be heard on NIH advisory committees to influence Institute and Center (IC) budget decisions. (Lenfant, 10/00).

Lack of familiarity with CAM and communication with CAM professionals affects the ability of IRB members to evaluate adequately the CAM protocols that come before them. (Lenfant 10/00).

Develop research applications of sufficient quality to compete successfully for research support.

Inclusion of CAM professionals in CAM-related research policy issues.



ISSUE: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process.

Discussion: A frequently mentioned theme during Commission meetings was the need for high quality basic and clinical biomedical research and health services research in CAM to protect the public's health and safety. Research was identified as an essential element in providing

accurate information to increase the public's knowledge about CAM; and for educating and training CAM and conventional health care professionals, regulating the quality and use of CAM practices and products, and improving access to safe and effective CAM practices and products and coverage for them.

The Commissioners discussed with speakers the types of research on CAM needed to produce sufficient evidence of safety and effectiveness to endorse public use and integration of CAM into an evolving health care system. Basic research on mechanisms of action, which some people believe should be carried out simultaneously with research on safety and efficacy, was stressed during testimony. Other people see studies on the safety and efficacy of CAM practices and products as the immediate research need, but agree that building the science base for basic studies is essential. Testimony equally highlighted the value of and need for multiple approaches to examining issues of safety, efficacy, and effectiveness, including outcomes research, observational research, best case series evaluations, epidemiologic studies, surveillance studies, behavioral/quality-of-life studies, demonstration projects, cost-effectiveness studies, and studies on health care delivery and other health services aspects of CAM. Any of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg 5/01).

The Commission recognizes the importance of research and agrees that CAM research must meet the same rigorous standards of quality that is expected of conventional research. The Commission notes, however, that to open doors to the study of CAM questions and achieve scientific quality in CAM research, the same level of scientific inquiry should be required,

neither higher nor lower than for conventional research.

While much public testimony supported the need for evidence-based research in CAM to establish safety and efficacy of CAM practices and products, it also revealed considerable public interest in why people turn to CAM and the potential of CAM research to contribute to the expansion of the current research paradigm beyond isolated treatments for conditions or diseases. Many people who testified expressed admiration for the emphasis CAM places on wellness as something separate from disease; and on the promotion on health and the prevention of disease. Speakers expressed interest in the emphasis CAM practitioners give to life-style, quality of life, and the recognition that mind, body, and spirituality play a combined role in health, disease, and healing; as well as CAM's emphasis on the patient-practitioner interaction.

Therefore, in addition to examining CAM practices and products which, if found to be safe and effective, may be identified as complementary or alternative to conventional care for a condition, disorder, or disease, CAM offers the possibility of contributing to emerging areas of scientific study that could increase our understanding of complete biological systems and how they interact; the ability of the body to heal itself; energy medicine, biofields, and electromagnetic fields; and the effects of culture on health and treatment. *Answers to some of these questions may be found in the study of systems such as Ayurvedic Medicine, Traditional Chinese Medicine, Native American Medicine, African Medicine, Naturopathy, which involve a complexity of elements (leave in or take out?).* [If NCCAM and/or the NAS have not already done so,] it might be useful to hold a conference on proposing evidence-based models for expanding current concepts of physiology and and pathophysiology (Hammerschlag 5/01).

The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial was identified during testimony as the gold standard for examining clinical questions. However, because of the complexity and uniqueness of many CAM questions, much attention was paid to the importance of adapting clinical trial methodology, in a flexible and step-wise fashion, to the unique characteristics of CAM questions, while complying with human subject protections and appropriate institutional review board guidelines. Questions of standardization/non-standardization, individualization/generalization, blinding, randomization, and the placebo effect need to be resolved within the context of the study design. Methodology and design adaptation, the Commission notes, is also required in conventional clinical research. Science has always followed its quests for knowledge by developing new ways to answer difficult questions and the Commissioners believe that pluralism in research design allows scientists to develop innovative methods to examine complex questions. The Commission suggests that whenever possible control groups be used to evaluate CAM treatments in comparison to standard conventional treatments and CAM treatments in combination with conventional treatments, and encourages standardization because studying non-standardized CAM treatments with individualized patients is not sufficient (Rabin 5/01).

The Commission commends NCCAM for its excellent leadership and contributions to CAM research, research training, infrastructure development, (etc.), and supports continuing and increasing the Center's crucial activities, including its information dissemination responsibilities. The Commission also recognizes the important work of the ODS/OD/NIH and the collaborations

between NCCAM and ODS and with other NIH/ICs. The Commissioners encourage the NIH/ICs to continue supporting CAM research collaboratively or separately, and want to note especially the work of NCI's OCCAM.. In addition, the Commission encourages collaboration between NCCAM and other Federal agencies with research and health responsibilities, such as AHRQ, CDC, HRSA, and others.

Challenges:

Assuring that CAM research is held to the same standards as conventional research—no lower and no higher

Making sure the public is heard regarding the research agenda.

Designing CAM protocols and gaining IRB approval:

- collect objective data,
- adapt, as necessary, orthodox scientific methodology to CAM studies
- resolve the standardized/non-standardized, individualized vs. generalized issues
- resolve blinding and/or randomizing difficulties, and the placebo effect
- obtaining CAM products for research that are standardized.

Establishing the level of evidence that is sufficient for safety and efficacy.

Identifying and prioritizing the types of research needed.

Increasing funding for clinical and basic research on practices and products

Strengthening funding for Federal agencies conducting health services research.

Convincing all funders to support research to expand the research paradigm.

ISSUE: Research Training and Infrastructure

Discussion: Commissioners and speakers discussed the need for a strong research infrastructure, which is crucial to the conduct of quality research and research training in CAM. Research sites, both public and private, with sufficient resources should be strategically located and each site should have a critical mass of personnel, equipment, basic and clinical research expertise, core

laboratory facilities, and clinical environments with patient access. These sites should include CAM-trained practitioners and researchers on the faculty and/or as consultants and should partner with accredited CAM institutions in the conduct of research and research training. (example: NIH research centers program). The Commission believes that the infrastructure for CAM research sites should be developed at both existing public and private research institutions and accredited CAM institutions.

The same rigorous training should be available for both CAM and conventional researchers. Both CAM and conventional researchers need knowledge of the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process, data collection, protocol design, IRB and other regulatory requirements, and the grant application and submission process. Investigators in CAM research need to have experienced mentors and incentives may have to be developed to attract them. CAM research training should teach multiple outcome measures, including social contextual assays and biopsychological measures of health, carried out by multidisciplinary teams to allow broader paradigms of health and healing (Blanks,5/01). In addition, representatives from research centers supported Federally, privately, or by foundations should meet periodically not only to present progress reports but also to exchange experiences on how best to educate researchers in CAM practices and how to introduce CAM practitioners to the research culture (Hammerschlag 5/01).

Challenges:

Stimulating adequate funding and strategic planning for developing or strengthening research

infrastructure sites and training programs.

Developing incentives for conventional researchers to attract high quality mentors.

Increasing collaborations between institutions to enhance training opportunities and improve the quality of training.

 ISSUE: Public-Private-Nonprofit partnerships and investment in CAM research and related activities.

Discussion: The growing willingness of the public, private, and nonprofit sectors to form partnerships offers exciting possibilities in stimulating and supporting much needed CAM research. Also, mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program offer the private sector opportunities for research support. Collaborative public-private-nonprofit research support could contribute in important ways to the emerging areas of scientific study of interest to CAM and conventional medicine.

The provision of incentives for private sector involvement in CAM research and resolving intellectual property issues could spur private activity (see the NOTE below). Provision of proprietary protection around process, extraction, production, and use of unique mixtures and combination of agents could help move in this area. It would be desirable if dietary supplement manufacturers used what the NIEHS National Toxicology Program learns about toxicology/carcinogenicity in these complex materials to conduct studies on remaining untested popular supplements being consumed (Matsen 5/01). Consideration should be given to development of a rigorous review process including industry and academic scientists

(Rudden,10/00). Successful manufacturers of CAM products should be encouraged to conduct studies and explore collaborations with strong research institutions (Eisenberg 5/01). Public agencies should be encouraged to partner with foundations interested in enhancing their research, research training, and conference support (Templeton 10/00).. Consideration could be given to inviting foundation representatives to sit on Federal advisory groups to discuss potential areas of support and partnership, such as grant funding opportunities. The nonprofit sector might consider creating a consortium through which pooled funds could be used to augment support for CAM conferences, pilot projects, etc., possibly including the announcement of funding opportunities and the convening of advisory/review groups of knowledgeable, reputable scientists in the areas to be presented, discussed or studied (Hayes.10/00).

NOTE: It should be noted that because it is often not possible to patent CAM products, there has been little private research on these products by pharmaceutical companies. Submissions of petitions to gain approval for the right to make health claims also are not economical because pharmaceutical companies or manufacturers of CAM products that might go to the expense of gaining such approval would face competition from other manufacturers that could sell similar products as dietary supplements.

Under the provisions of DSHEA, dietary supplements can make structure function claims. Approved drugs can make health claims about preventing, curing, treating, or mitigating a disease. However, as stated above, because drug approval is a labor-intensive process requiring substantial research, time, and money, most dietary supplement manufacturers do not seek drug status for their products. The unintended effect is that in some instances where there is research

on a dietary supplement supporting that could support a claim, the dietary supplement is still limited to the structure function claim because dietary supplements are foods.

Certain dietary supplements can make health claims under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). For example, there is significant scientific agreement that calcium can prevent osteoporosis and a health claim for both calcium-containing foods and dietary supplements has been approved by the FDA.

Challenges:

Creation of incentives for nonprofit organizations to become involved in research on CAM practices and products, e.g., providing seed money and investment in pilot studies.

Creation of incentives for private sector involvement in CAM research possibly through tax incentives and resolving intellectual property and other issues to increase involvement in product research, product standardization.

Federal funding for research on CAM products in collaboration with the private and nonprofit sectors.

⑤

ISSUE: Publishing literature on CAM research and systematic reviews of the literature

Discussion: Many speakers agreed that CAM research results need to be published in recognized peer-reviewed research journals to provide accurate and reliable knowledge about CAM to researchers, practitioners, and ultimately the public. The quality of the research and the standards of review that the research must meet to gain journal publication affect how readers determine the reliability and usefulness of the information. To ensure a fair and accurate review, speakers emphasized that CAM expertise should be represented on journal review boards when reviewing CAM research submissions.

Recent increases in research funding and the establishment of CAM research centers should increase the publication of high quality studies on CAM therapies submitted to research journals (Fontanarosa5/01). Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa5/01). CAM practitioners and researchers should be encouraged to read the highest quality conventional journals and conventional practitioners and researchers should be encouraged to read CAM journals of equal quality.

It is necessary to document the basis for claims. Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa5/01).

Challenges:

The conduct of research on CAM that can be successfully submitted to journals with the highest standards of review.

The inclusion of reviewers experienced in CAM on journal review boards when CAM submissions are reviewed.

Increase systematic reviews of the literature and their use.

Recommendations
should
suggests
DRAFT 9/14/01

TOPIC: Coordination of Complementary and Alternative Medicine Research

Staff Lead: Gerry Pollen

Facilitators: Wayne Jonas and Dean Ornish

The Commission Recommended

ISSUE 1: Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers.

Background: An emerging dialogue between CAM and conventional medicine (Kaptchuk, Eisenberg, AIM, 8/7/01) and a growing willingness to experiment with integration appears to be taking place slowly. Fostering and strengthening this emerging dialogue to increase the understanding of one another's concerns and contributions, can help strengthen mutual respect, cooperation, coordination, and collaboration in research and related activities.

Communication, cooperation, and collaboration are essential to the success of CAM research and research training. The parties to the dialogue should include conventional and CAM researchers, clinicians, and practitioners; CAM and conventional research centers, programs, and institutions; CAM and conventional professional leadership organizations; and Federal and state research and health agencies; and the public, private, and nonprofit sectors.

Trained and licensed CAM professionals should be included on research, regulatory, and research journal advisory and review committees, as appropriate. (The voice of complementary and alternative medicine needs to be heard on NIH advisory committees for consideration during Institute and Center (IC) budget decisions. [Lenfant, 10/00]).

(Building working relationships among professionals from both conventional and CAM disciplines is essential to progress in studying and understanding CAM practices and products [Vazquez, 5/01]).

(Where there is scientific evidence that efficacy is equal, the inclination of CAM practitioners and users is to prefer natural methods that support the body's healing systems and [may] generally present less risk. But where efficacy is not equal, openness to conventional treatments is a reflection of the same mindset that we [CAM professionals] expect from the conventional community in turn [Dumas].)

Background Examples:

U of Pennsylvania (Al Fishman);

Harvard U, (Daniel Federman),

U of Maryland (Brian Berman),

Beth Israel Medical Center, NY (Woody Merrill),

King County system (Seattle meeting),

Bastyr University coordinated activities to create funding opportunities for scientific evidence-based models and databases for CAM and integrated health care (Seattle meeting).

Challenges:

1. Building on the emerging dialogue between CAM and conventional medicine.
 - a..Lack of mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers impedes progress in building knowledge about CAM (White, Oct'00).
 - b. Cultural taboos can affect the evaluation of research applications that are outside the mainstream (Cassman,10/00).
2. Developing research applications of sufficient quality to compete successfully for research support.
3. Increasing institutional review board (IRB) familiarity with CAM and communication with CAM professionals to affect the ability of IRB members to evaluate adequately the CAM protocols that come before them. (Lenfant 10/00).
4. Including CAM professionals on advisory and review committees and in discussions on CAM-related research policy issues.

ISSUE 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process.

Background: A frequently mentioned theme during Commission meetings was the need for high quality basic and clinical biomedical research and health services research in CAM to protect the public's health and safety and contribute to health care. Any of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg 5/01). Research was identified as an essential element in providing accurate information to increase the public's knowledge about CAM; and for educating and training CAM and conventional health care professionals, regulating the quality and use of CAM practices and products, and improving access to safe and effective CAM practices and products and coverage for them.

The Commissioners discussed with speakers the types of research on CAM needed to produce sufficient evidence of safety and effectiveness to endorse public use and integration of CAM into an evolving health care system. Basic research on mechanisms of action, which some people believe should be carried out simultaneously with research on safety and efficacy, was stressed during testimony. Other people see studies on the safety and efficacy of CAM practices and products as the immediate research need, but agree that building the science base for basic studies is essential. Testimony equally highlighted the value of and need for multiple approaches to examining issues of safety, efficacy, and effectiveness, including outcomes research, observational research and evaluations of practice-based data, epidemiologic studies, surveillance studies, behavioral/quality-of-life studies, demonstration projects, cost-effectiveness studies, and studies on health care delivery and other health services aspects of CAM.

While much public testimony supported the need for evidence-based research in CAM to establish safety and efficacy of CAM practices and products, it also revealed considerable public interest in why people turn to CAM and the potential of CAM research to contribute to the emerging areas of scientific study beyond isolated treatments for conditions or diseases. Many people who testified expressed admiration for the emphasis CAM places on wellness separate from disease and on the promotion on health and the prevention of disease. Speakers expressed interest in the emphasis CAM practitioners give to life-style, quality of life, the recognition that mind, body, and spirituality play a combined role in health, disease, and healing, and CAM's emphasis on the patient-practitioner interaction.

Therefore, in addition to examining CAM practices and products which, if found to be safe and effective, may be identified as complementary or alternative to conventional care for a condition, disorder, or disease, CAM may possibly contribute to emerging areas of scientific study that could increase our understanding of complete biological systems and how they interact; the ability of the body to heal itself; energy medicine, biofields, and electromagnetic fields; and the effects of culture on health and treatment. *Answers to some of these questions may be found in the study of systems such as Ayurvedic Medicine, Traditional Chinese Medicine, Tibetan Medicine, Native American Medicine, African Medicine, Naturopathy, and other cultural systems that involve a complexity of elements (leave-in-or-take-out?).* ([If NCCAM and/or the NAS have not already done so,] ^{will} it might be useful to hold a conference on proposing evidence-based models for expanding current concepts of physiology and and pathophysiology [Hammerschlag 5/01]).

The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial was recognized during testimony as the gold standard for examining clinical questions. However, because of the complexity and uniqueness of many CAM questions, much attention was paid to the importance of adapting clinical trial methodology, in a flexible and step-wise fashion, to the unique characteristics of CAM questions, while complying with human subject protections and appropriate institutional review board guidelines. Questions of standardization/non-standardization, individualization/generalization, blinding, randomization, the placebo effect, and compound mixtures, need to be resolved within the context of the study design. Methodology and design adaptation, the Commission notes, is also required in conventional clinical research. Science has always followed its quests for knowledge by developing new ways to answer difficult questions and the Commissioners believe that pluralism in research design allows scientists to develop innovative methods to examine complex questions. (Whenever possible control groups should be used to evaluate CAM treatments in comparison to standard treatments and CAM treatments in combination with conventional treatments, and encourages standardization because studying non-standardized CAM treatments with individualized patients is not sufficient [Rabin 5/01].)

It is the view of some CAM researchers that the requirements for CAM research are higher than for conventional research. On the other hand, some people representing the conventional research community expressed the belief that CAM research often is not held to as high a

standard as conventional research. The Commission agrees that CAM research must meet the same rigorous standards of quality that is expected of conventional research, neither lower nor higher.

The Commission commends NCCAM for its excellent leadership and contributions to CAM research and research methodology, research training, infrastructure development, (etc.), and supports continuing and increasing the Center's crucial activities, including its information dissemination responsibilities. The Commission also recognizes the important work of the ODS/OD/NIH and the collaborations between NCCAM and ODS and with other NIH/ICs. The Commissioners encourage the NIH/ICs to continue supporting CAM research collaboratively or separately, and want to note especially the work of NCI's OCCAM.¹¹ In addition, the Commission encourages collaboration between NCCAM and other Federal agencies with research and health responsibilities, such as AHRQ, CDC, HRSA, FDA, and others.

Federal agencies need to be more *all aspects of* proactive, through the grant application process or by developing programs to evaluate CAM ~~practices and products~~. One area of need is the development by NIH/IC's of specific research initiatives, either ~~through the grant application process or specially designed programs~~, to evaluate CAM practice-based data from practitioners who believe that they have promising data on non-approved treatments. In order for such programs to be successful, CAM practitioners need to be knowledgeable about the collection of objective, verifiable data and human protection guidelines. They need to be allowed ~~(protected from prosecution)~~ *without fear of* to submit their data to ~~highly reputable~~ research institutions for evaluation and possible research support. The inclusion of CAM professional expertise ~~in general~~ *grant or contract solicitation* and/or RFA language should be part of the process.

The growing influence of the public on the health care system became evident during testimony, pointing to the need to include public participation in shaping the research agenda, as well as in regulatory and health services activities. The Commission heard often about the value of integrating conventional and CAM approaches. In a random household telephone survey, of 831 respondents who saw a medical doctor and used CAM therapies in the previous year, 79 percent perceived the combination to be superior to either one alone. Of 411 respondents who saw both a medical doctor and a CAM provider, 70 percent saw the medical doctor before or concurrent with their to a CAM provider (AIM, Sept/01, Eisenberg et al).

Challenges:

1. Assuring that CAM research is held to the same high research standards as conventional medicine--no lower and no higher
2. Assuring public participation in the development of the research agenda.
3. Accomplishing rigorously designed CAM protocols and gaining IRB approval:
collect objective data,
adapt, as necessary, orthodox scientific methodology to CAM studies,

resolve standardized/non-standardized and individualized/generalized issues, resolve blinding and/or randomizing difficulties, placebo effect issues, and challenges associated with studying compound products.

4. Achieving standardization of CAM products for research.
5. Establishing the level of evidence that is sufficient for safety and efficacy.
6. Identifying and prioritizing all the types of research needed.
7. Increasing all resources need for CAM clinical, basic, and health services research
8. Convincing funders to support potential CAM research contributions in emerging areas of science.

ISSUE 3: Research Training and Infrastructure

Background: Commissioners and speakers discussed the crucial role that a strong research infrastructure has in conducting quality research and research training in CAM. Research sites, both public and private, with sufficient resources should be strategically located and each site should have a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. These sites should include CAM-trained practitioners and researchers on the faculty and/or as consultants and should partner with accredited CAM institutions in the conduct of research and research training. (example: NIH research centers program). The Commission believes that the infrastructure for CAM research sites should be developed at both existing public and private research institutions and accredited CAM institutions.

The same rigorous training should be available for both CAM and conventional researchers. Both CAM and conventional researchers need knowledge of the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process, unbiased data collection, protocol design, IRB and other regulatory requirements, and the grant application and submission process. Investigators in CAM research need to have experienced mentors and incentives may have to be developed to attract them. (CAM research training should teach multiple outcome measures, including social contextual assays and biopsychological measures of health, carried out by multidisciplinary teams to allow broader paradigms of health and healing [Blanks,5/01]). (In addition, representatives from research centers supported Federally, privately, or by foundations should meet periodically not only to present progress reports but also to exchange experiences on how best to educate researchers in CAM practices and how to introduce CAM practitioners to the research culture (Hammerschlag 5/01)).

Challenges:

1. Assuring adequate funding and other resources and strategic planning for developing or strengthening CAM research infrastructure sites and training programs.
2. Developing incentives for conventional researchers to attract high quality mentors and study CAM questions.
3. Increasing collaborations between CAM and conventional institutions to enhance training opportunities and improve the quality of training.

ISSUE 4: Public-Private-Nonprofit partnerships and investment in CAM research and related activities.

Background: The growing willingness of the public, private, and nonprofit sectors to form partnerships offers exciting possibilities in stimulating and supporting much needed CAM research. Also, mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program offer the private sector opportunities for research support. Collaborative public-private-nonprofit research support could contribute in important ways to the emerging areas of scientific study of interest to CAM and conventional medicine.

The provision of incentives for private sector involvement in CAM research and the resolution of intellectual property issues could spur private activity (see FYI/NOTE below). Provision of proprietary protection around process, extraction, production, and use of unique mixtures and combination of agents could help move in this area. {It would be desirable if dietary supplement manufacturers used what the NIEHS National Toxicology Program learns about toxicology/carcinogenicity in these complex materials to conduct studies on remaining untested popular supplements being consumed [Matsen 5/01]}. (Consideration should be given to development of a rigorous review process including industry and academic scientists [Rudden,10/00]). (Successful manufacturers of CAM products should be encouraged to conduct studies and explore collaborations with strong research institutions [Eisenberg 5/01].) (Public agencies should be encouraged to partner with foundations interested in enhancing their research, research training, and conference support [Templeton 10/00].) (Consideration might be given to inviting foundation representatives to sit on Federal advisory groups to discuss potential areas of support and partnership, such as grant funding opportunities. The nonprofit sector might consider creating a consortium through which pooled funds could be used to augment support for CAM conferences, pilot projects, etc., possibly including the announcement of funding opportunities and the convening of advisory/review groups of knowledgeable, reputable scientists in the areas to be presented, discussed or studied [Hayes.10/00]).

FYI/NOTE: It should be noted that because it is often not possible to patent CAM products, there has been little private research on these products by pharmaceutical companies. Submissions of petitions to gain approval for the right to make health claims also are not economical because pharmaceutical companies or manufacturers of CAM products that might go to the expense of gaining such approval

would face competition from other manufacturers that could sell similar products as dietary supplements.

Under the provisions of DSHEA, dietary supplements can make structure function claims. Approved drugs can make health claims about preventing, curing, treating, or mitigating a disease. However, as stated above, because drug approval is a labor-intensive process requiring substantial research, time, and money, most dietary supplement manufacturers do not seek drug status for their products. The unintended effect is that in some instances where there is research on a dietary supplement supporting that could support a claim, the dietary supplement is still limited to the structure function claim because dietary supplements are foods.

Certain dietary supplements can make health claims under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). For example, there is significant scientific agreement that calcium can prevent osteoporosis and a health claim for both calcium-containing foods and dietary supplements has been approved by the FDA.

Challenges:

1. Stimulating nonprofit organizations to become involved in research on CAM practices and products, e.g., providing seed money and investment in pilot studies.
2. Creating incentives to increase private sector involvement in CAM research, possibly through tax incentives, resolving intellectual property and other issues, and developing public-private partnerships.
3. Encouraging Federal funding for research on CAM products in collaboration with the private and nonprofit sectors.

ISSUE 5: Publishing literature on CAM research and systematic reviews of the literature

Background: Many speakers agreed that CAM research results need to be published in recognized rigorously peer-reviewed research journals to provide accurate and reliable knowledge about CAM to researchers, practitioners, and ultimately the public. The quality of the research and the standards of review that the research must meet to gain journal publication affect how readers determine the reliability and usefulness of the information.

To ensure a fair and accurate review, speakers emphasized that CAM expertise should be represented on journal review boards when reviewing CAM research submissions, and CAM journals should include conventional scientific expertise on their review boards. CAM practitioners and researchers should be encouraged to read the highest quality conventional journals and conventional practitioners and researchers should be encouraged to read CAM journals of equal quality.

(Recent increases in research funding and the establishment of CAM research centers should increase the publication of high quality studies on CAM therapies submitted to research journals [Fontanarosa5/01]). (It is necessary to document the basis for claims. Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and

effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa5/01].)

Challenges:

1. Increasing the submission and publication of CAM research articles that are successfully submitted to journals with the highest standards of review.
2. Assuring the inclusion of reviewers experienced in CAM on journal review boards when CAM submissions are reviewed and conventional scientists on CAM journal review boards.
3. Increase systematic reviews of the research literature, their use, and their availability to practitioners and the public.

Draft Recommendations:

1. ~~Continue to strengthen the emerging dialogue and developing cooperation between CAM and conventional medicine.~~ ^{practitioners} ~~regulation, education, and research should~~

2. Increase support, in all Federal agencies with research or related health responsibilities, for clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

a. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services.

b. Encourage CAM research training by all Federal health agencies with research training programs, and ensure that the same rigorous research training in basic, clinical, or health services research is available to conventional and CAM researchers.

c. Support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

d. Encourage NIH/Institutes and Centers (IC's), as appropriate, to develop programs, or apply current research mechanisms, to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide guidance and training to CAM practitioners in collecting well developed, objective data and compliance with human subject protections.

e. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

f. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

g. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine.

h. Support research to determine why people use CAM, how they determine

effectiveness, and what they find satisfying about CAM in comparison to conventional medicine.

i. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

3. Ensure that the standards of research quality for CAM are the same as they are for conventional medical research—neither lower nor higher.

a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

4. To ensure public participation when setting the CAM research agenda, include representatives of the public on advisory committees and/or through other means.

5. Include trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

6. Encourage the submission of CAM research results to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

7. Provide public and private resources to support systematic reviews of research literature.

a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

b. Develop non-technical, understandable summaries of all systematic reviews of the literature and include them in publicly available information services.

TOPIC: Coordination of Complementary and Alternative Medicine Research

Staff Lead: Gerry Pollen

Facilitators: Wayne Jonas and Dean Ornish

Members: George Bernier, Effie Chow, Veronica Gutierrez, Bill Fair, and Tieraona Low Dog

ISSUE 1: Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers.

Background: An emerging dialogue between CAM and conventional medicine (Kaptchuk, Eisenberg, AIM, 8/7/01) and a growing willingness to experiment with integration appears to be taking place slowly. Fostering and strengthening this emerging dialogue to increase the understanding of one another's concerns and contributions, can help strengthen mutual respect, cooperation, coordination, and collaboration in CAM research and related activities.

Communication, cooperation, and collaboration are essential to the success of CAM research and research training. The parties to the dialogue should include conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

Trained and licensed CAM professionals should be included on research, journal, and regulatory advisory and review committees, as appropriate. (The voice of complementary and alternative medicine needs to be heard on NIH advisory committees for consideration during Institute and Center (IC) budget decisions. [Lenfant, 10/00]).

(Building working relationships among professionals from both conventional and CAM disciplines is essential to progress in studying and understanding CAM practices and products [Vazquez, 5/01]).

(Where there is scientific evidence that efficacy is equal, the inclination of CAM practitioners and users is to prefer natural methods that support the body's healing systems and [may] generally present less risk. But where efficacy is not equal, openness to conventional treatments is a reflection of the same mindset that we [CAM professionals] expect from the conventional community in turn [Dumas].)

Background Examples:

U of Pennsylvania (Al Fishman);

Harvard U, (Daniel Federman),

U of Maryland (Brian Berman),

Beth Israel Medical Center, NY (Woody Merrill),

King County system (Seattle meeting),

Bastyr University coordinated activities to create funding opportunities for scientific evidence-based models and databases for CAM and integrated health care (Seattle meeting).

Challenges:

1. Building on the emerging dialogue between CAM and conventional medicine.
 - a. Lack of mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers impedes progress in building knowledge about CAM (White, Oct'00).
 - b. Cultural taboos can affect the evaluation of research applications that are outside the mainstream (Cassman,10/00).
2. Developing research applications of sufficient quality to compete successfully for research support.
3. Increasing institutional review board (IRB) familiarity with CAM and communication with CAM professionals to affect the ability of IRB members to evaluate adequately the CAM protocols that come before them. (Lenfant 10/00).
4. Including CAM professionals on advisory and review committees and in discussions on CAM-related research policy issues.

Draft Recommendations:

1. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.
2. Include trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

ISSUE 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process.

Background: A frequently mentioned theme during Commission meetings was the need for high quality basic and clinical biomedical research and health services research in CAM to protect the public's health and safety and contribute to health care. Any of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg 5/01). Research was identified as an essential element in providing accurate information to increase the public's knowledge about CAM; and for educating and training CAM and conventional health care professionals, regulating the quality and use of CAM practices and products, and improving access to safe and effective CAM

practices and products and coverage for them.

The Commissioners discussed with speakers the types of research on CAM needed to produce sufficient evidence of safety and effectiveness to endorse public use and integration of CAM into an evolving health care system. Basic research on mechanisms of action, which some people believe should be carried out simultaneously with research on safety and efficacy, was stressed during testimony. Other people see studies on the safety and efficacy of CAM practices and products as the immediate research need, but agree that building the science base for basic studies is essential. Testimony equally highlighted the value of and need for multiple approaches to examining issues of safety, efficacy, and effectiveness, including outcomes research, observational research and evaluations of practice-based data, epidemiologic studies, surveillance studies, behavioral/quality-of-life studies, demonstration projects, cost-effectiveness studies, and studies on health care delivery and other health services aspects of CAM.

While much public testimony supported the need for evidence-based research in CAM to establish safety and efficacy of CAM practices and products, it also revealed considerable public interest in why people turn to CAM and the potential of CAM research to contribute to the emerging areas of scientific study beyond isolated treatments for conditions or diseases. Many people who testified expressed admiration for the emphasis CAM places on wellness separate from disease and on the promotion of health and the prevention of disease. Speakers expressed interest in the emphasis CAM practitioners give to life-style, quality of life, the recognition that mind, body, and spirituality play a combined role in health, disease, and healing, and CAM's emphasis on the patient-practitioner interaction.

Therefore, in addition to examining CAM practices and products which, if found to be safe and effective, may be identified as complementary or alternative to conventional care for a condition, disorder, or disease, CAM may possibly contribute to emerging areas of scientific study that could increase our understanding of complete biological systems and how they interact; the ability of the body to heal itself; energy medicine, biofields, and electromagnetic fields; and the effects of culture on health and treatment. Answers to some of these questions may be found in the study of systems such as Ayurvedic Medicine, Traditional Chinese Medicine, Tibetan Medicine, Native American Medicine, African Medicine, Naturopathy, and other cultural systems that involve a complexity of elements. (It would be useful to hold a conference on proposing evidence-based models for expanding current concepts of physiology and pathophysiology [Hammerschlag 5/01]).

The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial was recognized during testimony as the gold standard for examining clinical questions. However, because of the complexity and uniqueness of many CAM questions, much attention was paid to the importance of adapting clinical trial methodology, in a flexible and step-wise fashion, to the unique characteristics of CAM questions, while complying with human subject protections and appropriate institutional review board guidelines. Questions of standardization/non-standardization, individualization/generalization, blinding,

randomization, the placebo effect, and compound mixtures, need to be resolved within the context of the study design. Methodology and design adaptation, the Commission notes, is also required in conventional clinical research. Science has always followed its quests for knowledge by developing new ways to answer difficult questions and the Commissioners believe that pluralism in research design allows scientists to develop innovative methods to examine complex CAM questions. (Whenever possible control groups should be used to evaluate CAM treatments in comparison to standard treatments and CAM treatments in combination with conventional treatments, and standardization is necessary because studying non-standardized CAM treatments with individualized patients is not sufficient [Rabin 5/01].)

It is the view of some CAM researchers that the requirements for CAM research are higher than for conventional research. On the other hand, some people representing the conventional research community expressed the belief that CAM research often is not held to as high a standard as conventional research. The Commission agrees that CAM research must meet the same rigorous standards of quality that is expected of conventional research, neither lower nor higher.

The Commission commends NCCAM for its excellent leadership and contributions to CAM research and research methodology, research training, infrastructure development, (etc.), and supports continuing and increasing the Center's crucial activities, including its information dissemination responsibilities. The Commission also recognizes the important work of the ODS/OD/NIH and the collaborations between NCCAM and ODS and with other NIH/ICs. The Commissioners encourage the NIH/ICs to continue supporting CAM research collaboratively or separately, and want to note especially the work of both NCI's OCCAM and the NLM. In addition, the Commission encourages collaboration between NCCAM and other Federal agencies with research and health responsibilities, such as AHRQ, CDC, HRSA, FDA, and others.

Federal agencies need to be more proactive in evaluating aspects of CAM relevant to their missions. One area of need is the development by NIH/IC's of specific programs or other research initiatives to evaluate CAM practice-based data submitted by practitioners who believe that they have promising data on non-approved treatments. In order for such programs to be successful, the practitioners need to be knowledgeable about the process and instruments involved in collecting objective, verifiable data, as well as about human protection guidelines. It is also necessary that they be allowed (protected from prosecution) to submit their data to NIH/IC's for evaluation and possible research support. The inclusion of CAM professional expertise should be part of the solicitation process.

The growing influence of the public on the health care system became evident during testimony, pointing to the need to include public participation in shaping the CAM research agenda, as well as shaping regulatory and health services activities. The Commission heard often about the value of integrating conventional and CAM approaches. In a random household telephone survey, of 831 respondents who saw a medical doctor and used CAM therapies in the previous year, 79 percent perceived the combination to be superior to either one alone. Of 411 respondents who saw both a medical doctor and a CAM provider, 70 percent saw the medical doctor before or

concurrent with their to a CAM provider (AIM, Sept/01, Eisenberg et al).

Challenges:

1. Assuring that CAM research is held to the same high research standards as conventional medicine—no lower and no higher
2. Assuring public participation in the development of the research agenda.
3. Accomplishing rigorously designed CAM protocols and gaining IRB approval:
collect objective data,
adapt, as necessary, orthodox scientific methodology to CAM studies,
resolve standardized/non-standardized and individualized/generalized issues,
resolve blinding and/or randomizing difficulties, placebo effect issues, and challenges
associated with studying compound products.
4. Achieving standardization of CAM products for research.
5. Establishing the level of evidence that is sufficient for safety and efficacy.
6. Identifying and prioritizing all the types of research needed.
7. Increasing all resources needed for CAM clinical, basic, and health services research.
8. Convincing funders to support potential CAM research contributions in emerging areas of science.

Draft Recommendations:

1. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.
2. Encourage NIH/IC's, as appropriate, to develop programs, or other research initiatives to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.
3. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and

on projects to standardize the composition of CAM products, either separately or collaboratively.

4. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine.

5. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine.

6. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.

7. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

8. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

9. To ensure public participation when setting the CAM research agenda, include representatives of the public on advisory committees and/or through other means.

ISSUE 3: Research Training and Infrastructure

Background: Commissioners and speakers discussed the crucial role that a strong research infrastructure has in conducting quality CAM research and research training and the need to continue to strengthen this infrastructure. Research sites, both public and private, with sufficient resources should be strategically located and each site should have a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. These sites should include CAM-trained practitioners and researchers on the faculty and/or as consultants, and should partner with accredited CAM institutions in the conduct of research and research training. (example: NIH research centers program). The Commission believes that the infrastructure for CAM research sites should be developed at both existing public and private research institutions and accredited CAM institutions.

The same rigorous training should be available for both CAM and conventional researchers. Both CAM and conventional researchers need knowledge of the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process, unbiased data collection, protocol design, IRB and other regulatory requirements, and the grant application and submission

process. Investigators in CAM research need to have experienced mentors and incentives may have to be developed to attract them. (CAM research training should teach multiple outcome measures, including social contextual assays and biopsychological measures of health, carried out by multidisciplinary teams to allow broader paradigms of health and healing [Blanks,5/01]). (In addition, representatives from research centers supported Federally, privately, or by foundations should meet periodically not only to present progress reports but also to exchange experiences on how best to educate researchers in CAM practices and how to introduce CAM practitioners to the research culture (Hammerschlag 5/01)).

Challenges:

1. Assuring adequate funding and other resources and strategic planning for developing or strengthening CAM research infrastructure sites and training programs.
2. Developing incentives to attract conventional researchers to serve as mentors and study CAM questions.
3. Increasing collaborations between CAM and conventional institutions to enhance training opportunities and improve the quality of training.

Draft Recommendations:

1. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services.
2. Encourage CAM research training by all Federal health agencies with research training programs, and ensure that the same rigorous research training in basic, clinical, or health services research is available to conventional and CAM researchers.
3. Support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

ISSUE 4: Public-Private-Nonprofit partnerships and investment in CAM research and related activities.

Background: The growing willingness of the public, private, and nonprofit sectors to form partnerships offers exciting possibilities in stimulating and supporting much needed CAM research. Also, mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program offer the private sector opportunities for research support. Collaborative public-private-nonprofit research support could contribute in important ways to the emerging areas of scientific study of interest to CAM and conventional medicine.

The provision of incentives for private sector involvement in CAM research and the resolution of intellectual property issues could spur private activity (see FYI/NOTE below). Provision of proprietary protection around process, extraction, production, and use of unique mixtures and combination of agents could help move in this area. {It would be desirable if dietary supplement manufacturers used what the NIEHS National Toxicology Program learns about toxicology/carcinogenicity in these complex materials to conduct studies on remaining untested popular supplements being consumed [Matsen 5/01]}. (Consideration should be given to development of a rigorous review process including industry and academic scientists [Rudden,10/00]). (Successful manufacturers of CAM products should be encouraged to conduct studies and explore collaborations with strong research institutions [Eisenberg 5/01].) (Public agencies should be encouraged to partner with foundations interested in enhancing their research, research training, and conference support [Templeton 10/00].) (Consideration might be given to inviting foundation representatives to sit on Federal advisory groups to discuss potential areas of support and partnership, such as grant funding opportunities. The nonprofit sector might consider creating a consortium through which pooled funds could be used to augment support for CAM conferences, pilot projects, etc., possibly including the announcement of funding opportunities and the convening of advisory/review groups of knowledgeable, reputable scientists in the areas to be presented, discussed or studied [Hayes.10/00]).

FYI/NOTE: It should be noted that because it is often not possible to patent CAM products, there has been little private research on these products by private companies. Submissions of petitions to gain approval for the right to make health claims also are not economical because pharmaceutical companies or manufacturers of CAM products that might go to the expense of gaining such approval would face competition from other manufacturers that could sell similar products as dietary supplements.

Under the provisions of DSHEA, dietary supplements can make structure function claims. Approved drugs can make health claims about preventing, curing, treating, or mitigating a disease. However, as stated above, because drug approval is a labor-intensive process requiring substantial research, time, and money, most dietary supplement manufacturers do not seek drug status for their products. The unintended effect is that in some instances when there is research on a dietary supplement that could support a claim, the dietary supplement is still limited to the structure function claim because dietary supplements are considered foods.

Certain dietary supplements can make health claims under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). For example, there is significant scientific agreement that calcium can prevent osteoporosis and a health claim for both calcium-containing foods and dietary supplements has been approved by the FDA.

Challenges:

1. Stimulating nonprofit organizations to become involved in research on CAM practices and products, e.g., providing seed money and investment in pilot studies, supporting conferences.
2. Creating incentives to increase private sector involvement in CAM research, possibly through tax incentives, resolving intellectual property and other issues, and developing public-private partnerships.

3. Encouraging Federal funding for research on CAM products in collaboration with the private and nonprofit sectors.

Draft Recommendations:

1. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

2. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine.

3. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

4. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services.

5. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment, in partnership with Federal agencies or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

ISSUE 5: Publishing literature on CAM research and systematic reviews of the literature

Background: Many speakers agreed that CAM research results need to be published in recognized, rigorously peer-reviewed research journals to provide accurate and reliable knowledge about CAM to researchers, practitioners, and ultimately the public. The quality of the research and the standards of review that the research must meet to gain journal publication affect how readers determine the reliability and usefulness of the information.

To ensure a fair and accurate review, speakers emphasized that CAM expertise should be represented on journal review boards when reviewing CAM research submissions, and CAM journals should include conventional scientific expertise on their review boards. CAM practitioners and researchers should be encouraged to read the highest quality conventional journals and conventional practitioners and researchers should be encouraged to read CAM journals of equal quality.

(Recent increases in research funding and the establishment of CAM research centers should increase the publication of high quality studies on CAM therapies submitted to research journals [Fontanarosa5/01]). (It is necessary to document the basis for claims. Decisions on regulating

use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa, 5/01].)

Commissioners also discussed with speakers the availability and use of information gained from the published literature, including systematic literature reviews, evidence-based reports, and the role of NLM databases, such as PubMed and MedlinePlus. Representatives of AHRQ, the Cochrane Collection, and NLM described their CAM-related activities as well as their efforts to cooperate. They also talked about the value of strengthening the process for making reviews of the research literature available to practitioners, community health centers, and policy makers, and to offer clear and understandable summaries of reviews to the public through NLM's MedlinePlus and other information services.

(AHRQ and the Cochrane Collection are finding ways to collaborate with each other and with NLM [Kamerow, Berman, and Lindberg, 5/01].)

Challenges:

1. Increasing the submission and publication of CAM research articles that are successfully submitted to journals with the highest standards of review.
2. Assuring the inclusion of reviewers experienced in CAM on journal review boards when CAM submissions are reviewed and conventional scientists on CAM journal review boards.
3. Increasing systematic reviews of the research literature, their use, and their availability to practitioners and the public.

Draft Recommendations:

1. Encourage the submission of CAM research results to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.
2. Provide public and private resources to support systematic reviews of research literature.
3. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.
4. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

Draft Recommendations:

1. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

2. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

a. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services.

b. Encourage CAM research training by all Federal health agencies with research training programs, and ensure that the same rigorous research training in basic, clinical, or health services research is available to conventional and CAM researchers.

c. Support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

d. Encourage NIH/IC's, as appropriate, to develop programs, or other research initiatives to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

e. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

f. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

g. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the

role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine.

h. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine.

i. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

3. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.

a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

4. To ensure public participation when setting the CAM research agenda, include representatives of the public on advisory committees and/or through other means.

5. Include trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

6. Encourage the submission of CAM research results to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

7. Provide public and private resources to support systematic reviews of research literature.

a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

b. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

Coordinating and Centralizing Federal CAM Efforts

Staff Lead: Joe Kaczmarczyk

Members: Donald Warren (Facilitator), Veronica Gutierrez, Wayne Jonas, and Effie Chow

Issue: How Can Federal CAM Efforts Be Coordinated and Centralized?

Background: There is a need to coordinate and centralize Federal CAM efforts. While the NIH's National Center for Complementary and Alternative Medicine (NCCAM) is recognized for its leadership in CAM research, NCCAM should not be expected to coordinate and centralize all Federal CAM efforts in addition to performing its vital research roles. Rather, other options for coordinating and centralizing Federal CAM efforts need to be considered. These options include assigning this responsibility to an existing Federal entity or establishing a new Federal entity to focus exclusively on coordinating and centralizing Federal CAM efforts.

Since there is precedent for establishing new mission-specific Federal offices which were the result of task force recommendations such as the Office of Minority Health (OMH) and Office on Women's Health (OWH), consideration should be given to this approach, along with answering a number of questions. What should this office be called? Where should it be located in the Federal organizational structure? When, how, and by whom should it be established? What should its functions include? How should it be funded? What should its relationship to NCCAM be?

Naming this new Office should be delayed until its location is more certain. The Office should be positioned at the Departmental or higher level to facilitate its coordination and centralization roles. Locations within the Department of Health and Human Services (DHHS) could include either the Office of the Secretary's Office of Public Health and Science (OPHS) where OMH and OWH are located or within one of the thirteen program offices that comprise the OPHS. Among the OPHS program offices in which the proposed Federal CAM Office could be located, the Office of the Surgeon General which has a small budget and very small number of FTEs and the Office of Disease Prevention Health Promotion which could like provide linkage with *Health People 2010* and beyond appear to be the most likely but less than ideal possibilities. Alternatively, it could be located in the White House either by creating a new office in the Executive Office of the President following the examples of the Office of National AIDS Policy or Office of Faith-Based and Community Initiatives or by placing it within an existing office such as the Office of Domestic Policy. A White House location certainly would provide an opportunity to influence policy but not permanence, since it would be vulnerable to the vagaries of Washington.

Who establishes this proposed Office will determine when, how, and where it will be located. For example, the President, at his discretion, could establish the Office in the White House Office rather quickly and easily. Similarly, the Secretary could establish the Office relatively quickly by doing so without authorizing legislation and position it

within the Department. Congress could create the Office legislatively and place it wherever it chooses through a much more protracted process but one which would provide permanence, a legislative mandate which is *de rigueur* for influence and effectiveness in the Federal culture, and appropriations. Because of the potential for significant latency between the conclusion of the White House Commission on Complementary and Alternative Medicine Policy and the completion of the legislative process to create and implement the proposed Office, an alternative scenario, in which the momentum of the Commission is maintained and implementation of the Commission's recommendations is initiated to the extent possible, ought to be considered. An alternative scenario could involve a temporary or "foster" home for the proposed Office in either the White House or the Department where it could reside until legislation is enacted.

Although the functions of the proposed Office will be determined in large measure by whom and how the Office is created, those functions ought to include the following five broad categories:

1. Coordination and centralization of Federal CAM activities
2. Federal CAM policy liaison with conventional health care and CAM professionals, organizations, educational institutions, and commercial ventures
3. Planning and convening conferences, workshops, and necessary advisory groups
4. Centralized Federal media point of contact
5. Facilitation of implementation of WHCCAMP recommendations.

Coordination and centralization of Federal CAM activities require the proposed Office to be placed at highest possible level in the Federal Government. If the Office were located in DHHS, it could influence essentially only HHS Agencies and would have to limit its purview to non-research activities in order to complement rather than compete with NCCAM. It would be challenging indeed to coordinate CAM activities across Departments. This could be attempted by establishing a Trans-Departmental CAM Coordinating Committee that possibly could include Departments of Defense, Veterans Affairs, Education, Agriculture, Justice, State, and others. However, how would the DHHS Office establish its leadership role and staff and fund this Trans-Departmental CAM Coordinating Committee? Clearly, it would be easier and more effective to coordinate CAM activities across Departments if the proposed Office were located in the White House. In addition, it would be easier--but a daunting task nonetheless--to ascertain the extent of Federal CAM activities which is unknown despite previous Congressional inquiries.

Federal CAM policy liaison with conventional health care and CAM professionals, organizations, educational institutions, and commercial ventures could entail, for example, activities such as facilitating:

- Development and implementation of basic or core curricula (undergraduate, postgraduate, and CME/CE) for conventional and CAM practitioners proposed by WHCCAMP Education and Training Work Group;
- Identification of scholarship and loan program opportunities;
- Development of postgraduate training (e.g., residencies and fellowships);

- Development of public education on CAM in health care (including high school and below through involvement of the Department of Education);
- Interaction and relationships between conventional health care and CAM (including CAM commercial ventures).

Perhaps one of the most important liaison activities of the proposed Office would be to establish an Advisory Council similar to that of NCCAM to bring the various stakeholders together to develop an agenda that reflects public input.

Planning and convening conferences, workshops, and necessary advisory groups could create unique opportunities to:

- Explore contentious CAM issues, for example, involving licensure, access and delivery, education and training, information development and dissemination, and reimbursement;
- Bring conventional health care and CAM together to develop dialogue and collaborative activities.

Being the centralized Federal media point of contact for CAM would not involve any information clearinghouse function, since NCCAM has a legislative mandate to perform this function. Rather, the proposed Office could develop and implement a triage model for media calls or e-mail inquiries. So when an inquiry occurred, the proposed Office could direct the person to the appropriate person at the Departmental or Agency level through a network or previously identified information officers or other points of contact with known expertise and relevant purview. The proposed Office also could create a website which could include information about the Office and its functions along with CAM events calendar postings, links to other Federal websites, and hyper-link e-mail to the proposed Office.

Facilitation of implementation of WHCCAMP recommendations is arguably the most important role of the proposed Office, because without authority--or at least, a focus on the WHCCAMP recommendations--staff, and budget dedicated to overseeing, coordinating, and otherwise facilitating the implementation of the WHCCAMP recommendations, the likelihood of successful implementation of those recommendations is diminished significantly. This function could include interaction with and education of members of the Administration, Congress and their staffs, and affected Departments and Agencies on the issues.

This list of functions of the proposed Office is dynamic and will evolve with the addition of activities identified and suggested by the other WHCCAMP Work Groups. Although developed by the WHCCAMP Coordinating and Centralizing Federal CAM Efforts Work Group, the above list of functions resembles and is validated by the following paraphrased activities delineated by the "National Presence—Policy, Coalitions, Voice breakout group" at the Second Annual Integrative Medicine Industry Leadership Summit held on May 3-5, 2001 in Scottsdale, AZ which called for the establishment of a "Federal Office of Complementary and Alternative Medicine and Integrative Health Care":

- The national Office will have authority to oversee, coordinate, and direct all Federal CAM and Integrative Health Care activities;
- The Office shall establish “Blue Ribbon” panels to advise the Office and Congress on CAM and Integrative Health Care policy and legislative recommendations;
- In approaching research, this Office shall work to complement the role of the NIH’s NCCAM;
- An Advisory Council shall be established for this Office with representative organizations including national CAM, integrative medicine, public health and world medicine associations, academic consortia, and councils;
- The mandates of this Office will include, but not be limited to, implementation of the recommendations made by the White House Commission on Complementary and Alternative Medicine Policy.

The funding of the proposed Office will be determined by whom and how the Office is created. While NCCAM will continue to require adequate funding to address the research slice of the CAM “pie,” the proposed office will be responsible for taking care of the rest of the CAM “pie.” This may necessitate increased funding of Agencies plus sufficient budget and staff for the proposed Office to coordinate Federal CAM activities and collaborate with the appropriate stakeholders.

Challenges: The uncertainty of how the proposed Office is viewed by the Administration, Secretary, and Congress is a critical challenge. Federal reluctance should be anticipated in light of shrinking surplus estimates and budgets and efforts to “right-size Government.” Resistance to establishing the proposed Office should be expected from conventional health care professions, organizations, and institutions. On the other hand, CAM advocates, practitioners, organizations, and institutions may have unrealistic expectations of the proposed Office.

Draft Recommendation:

1. The President, Secretary of the Department of Health and Human Services, or Congress should create an Office at the highest possible and most appropriate level with sufficient staff and budget to perform functions that include, but are not limited to, coordination of Federal CAM activities; Federal CAM policy liaison with conventional health care and CAM professionals, organizations, institutions, and commercial ventures; planning and convening conferences, workshops, and necessary advisory groups, centralized Federal media point of contact; and facilitation of implementation of the WHCCAMP recommendations.

TOPIC: Coordination of Complementary and Alternative Medicine Research

Staff Lead: Gerry Pollen

Facilitators: Wayne Jonas and Dean Ornish

Members: George Bernier, Effie Chow, Veronica Gutierrez, Bill Fair, and Tieraona Low Dog

ISSUE 1: Increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians and researchers.

Background: An emerging dialogue between CAM and conventional medicine (Kaptchuk, Eisenberg, AIM, 8/7/01) and a growing willingness to experiment with integration appears to be taking place slowly. Fostering and strengthening this emerging dialogue to increase the understanding of one another's concerns and contributions, can help strengthen mutual respect, cooperation, coordination, and collaboration in CAM research and related activities.

Communication, cooperation, and collaboration are essential to the success of CAM research and research training. The parties to the dialogue should include conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

Trained and licensed CAM professionals should be included on research, journal, and regulatory advisory and review committees, as appropriate. (The voice of complementary and alternative medicine needs to be heard on NIH advisory committees for consideration during Institute and Center (IC) budget decisions. [Lenfant, 10/00]).

(Building working relationships among professionals from both conventional and CAM disciplines is essential to progress in studying and understanding CAM practices and products [Vazquez, 5/01]).

(Where there is scientific evidence that efficacy is equal, the inclination of CAM practitioners and users is to prefer natural methods that support the body's healing systems and [may] generally present less risk. But where efficacy is not equal, openness to conventional treatments is a reflection of the same mindset that we [CAM professionals] expect from the conventional community in turn [Dumas].)

Background Examples:

U of Pennsylvania (Al Fishman);

Harvard U, (Daniel Federman),

U of Maryland (Brian Berman),

Beth Israel Medical Center, NY (Woody Merrill),

King County system (Seattle meeting),

Bastyr University coordinated activities to create funding opportunities for scientific evidence-based models and databases for CAM and integrated health care (Seattle meeting).

Challenges:

1. Building on the emerging dialogue between CAM and conventional medicine.
 - a. Lack of mutual respect and willingness to enter into a dialogue on the part of conventional and CAM practitioners, clinicians, and researchers impedes progress in building knowledge about CAM (White, Oct'00).
 - b. Cultural taboos can affect the evaluation of research applications that are outside the mainstream (Cassman, 10/00).
2. Developing research applications of sufficient quality to compete successfully for research support.
3. Increasing institutional review board (IRB) familiarity with CAM and communication with CAM professionals to affect the ability of IRB members to evaluate adequately the CAM protocols that come before them. (Lenfant 10/00).
4. Including CAM professionals on advisory and review committees and in discussions on CAM-related research policy issues.

Draft Recommendations:

19. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.
20. Include trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

ISSUE 2: Conducting high quality CAM research, prioritizing types of research needed, and assuring public input into the process.

Background: A frequently mentioned theme during Commission meetings was the need for high quality basic and clinical biomedical research and health services research in CAM to protect the public's health and safety and contribute to health care. Any of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system (Eisenberg 5/01). Research was identified as an essential element in providing accurate information to increase the public's knowledge about CAM; and for educating and training CAM

and conventional health care professionals, regulating the quality and use of CAM practices and products, and improving access to safe and effective CAM practices and products and coverage for them.

The Commissioners discussed with speakers the types of research on CAM needed to produce sufficient evidence of safety and effectiveness to endorse public use and integration of CAM into an evolving health care system. Basic research on mechanisms of action, which some people believe should be carried out simultaneously with research on safety and efficacy, was stressed during testimony. Other people see studies on the safety and efficacy of CAM practices and products as the immediate research need, but agree that building the science base for basic studies is essential. Testimony equally highlighted the value of and need for multiple approaches to examining issues of safety, efficacy, and effectiveness, including outcomes research, observational research and evaluations of practice-based data, epidemiologic studies, surveillance studies, behavioral/quality-of-life studies, demonstration projects, cost-effectiveness studies, and studies on health care delivery and other health services aspects of CAM.

While much public testimony supported the need for evidence-based research in CAM to establish safety and efficacy of CAM practices and products, it also revealed considerable public interest in why people turn to CAM and the potential of CAM research to contribute to the emerging areas of scientific study beyond isolated treatments for conditions or diseases. Many people who testified expressed admiration for the emphasis CAM places on wellness separate from disease and on the promotion of health and the prevention of disease. Speakers expressed interest in the emphasis CAM practitioners give to life-style, quality of life, the recognition that mind, body, and spirituality play a combined role in health, disease, and healing, and CAM's emphasis on the patient-practitioner interaction.

Therefore, in addition to examining CAM practices and products which, if found to be safe and effective, may be identified as complementary or alternative to conventional care for a condition, disorder, or disease, CAM may possibly contribute to emerging areas of scientific study that could increase our understanding of complete biological systems and how they interact; the ability of the body to heal itself; energy medicine, biofields, and electromagnetic fields; and the effects of culture on health and treatment. Answers to some of these questions may be found in the study of systems such as Ayurvedic Medicine, Traditional Chinese Medicine, Tibetan Medicine, Native American Medicine, African Medicine, Naturopathy, and other cultural systems that involve a complexity of elements. Applying rigorous scientific methods to the exploration of these areas will require input from experts in engineering, physics, chemistry, psychology, and cell and molecular biology, thus merging whole system concepts with modern reductionist expertise. (It would be useful to hold a conference on proposing evidence-based models for expanding current concepts of physiology and pathophysiology [Hammerschlag 5/01]).

The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. The randomized

controlled clinical trial was recognized during testimony as the gold standard for examining clinical questions. However, because of the complexity and uniqueness of many CAM questions, much attention was paid to the importance of adapting clinical trial methodology, in a flexible and step-wise fashion, to the unique characteristics of CAM questions, while complying with human subject protections and appropriate institutional review board guidelines. Questions of standardization/non-standardization, individualization/generalization, blinding, randomization, the placebo effect, and compound mixtures, need to be resolved within the context of the study design. Methodology and design adaptation, the Commission notes, is also required in conventional clinical research. Science has always followed its quests for knowledge by developing new ways to answer difficult questions and the Commissioners believe that pluralism in research design allows scientists to develop innovative methods to examine complex CAM questions. (Whenever possible control groups should be used to evaluate CAM treatments in comparison to standard treatments and CAM treatments in combination with conventional treatments, and standardization is necessary because studying non-standardized CAM treatments with individualized patients is not sufficient [Rabin 5/01].)

It is the view of some CAM researchers that the requirements for CAM research are higher than for conventional research. On the other hand, some people representing the conventional research community expressed the belief that CAM research often is not held to as high a standard as conventional research. The Commission agrees that CAM research must meet the same rigorous standards of quality that is expected of conventional research, neither lower nor higher.

The Commission commends NCCAM for its excellent leadership and contributions to CAM research and research methodology, research training, infrastructure development, (etc.), and supports continuing and increasing the Center's crucial activities, including its information dissemination responsibilities. The Commission also recognizes the important work of the ODS/OD/NIH and the collaborations between NCCAM and ODS and with other NIH/ICs. The Commissioners encourage the NIH/ICs to continue supporting CAM research collaboratively or separately, and want to note especially the work of both NCI's OCCAM and the NLM. In addition, the Commission encourages collaboration between NCCAM and other Federal agencies with research and health responsibilities, such as AHRQ, CDC, HRSA, FDA, and others.

Federal agencies need to be more proactive in evaluating aspects of CAM relevant to their missions. One area of need is the development by NIH/IC's of specific programs or other research initiatives to evaluate CAM practice-based data submitted by practitioners who believe that they have promising data on non-approved treatments. In order for such programs to be successful, the practitioners need to be knowledgeable about the process and instruments involved in collecting objective, verifiable data, as well as about human protection guidelines. It is also necessary that they be allowed (protected from prosecution) to submit their data to NIH/IC's for evaluation and possible research support. The inclusion of CAM professional expertise should be part of the solicitation process.

The growing influence of the public on the health care system became evident during testimony, pointing to the need to increase public participation in the shaping and prioritizing the CAM research agenda, and in institutional review board reviews and institutional research teams, the dissemination of research results, and the shaping of regulatory and health services activities. The Commission heard often about the value of integrating conventional and CAM approaches. In a random household telephone survey, of 831 respondents who saw a medical doctor and used CAM therapies in the previous year, 79 percent perceived the combination to be superior to either one alone. Of 411 respondents who saw both a medical doctor and a CAM provider, 70 percent saw the medical doctor before or concurrent with their to a CAM provider (AIM, Sept/01, Eisenberg et al).

Challenges:

1. Assuring that CAM research is held to the same high research standards as conventional medicine—no lower and no higher
2. Assuring public participation in the development of the research agenda.
3. Accomplishing rigorously designed CAM protocols and gaining IRB approval:
 - collect objective data,
 - adapt, as necessary, orthodox scientific methodology to CAM studies,
 - resolve standardized/non-standardized and individualized/generalized issues,
 - resolve blinding and/or randomizing difficulties, placebo effect issues, and challenges associated with studying compound products.
4. Achieving standardization of CAM products for research.
5. Establishing the level of evidence that is sufficient for safety and efficacy.
6. Identifying and prioritizing all the types of research needed.
7. Increasing all resources needed for CAM clinical, basic, and health services research.
8. Convincing funders to support potential CAM research contributions in emerging areas of science.

Draft Recommendations:

21. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

- 21.d. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs, or other research initiatives to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.
- 21e. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.
- 21i. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support mechanisms for high-risk, high-impact studies to expand understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.
- 21j. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.
22. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.
- 22.a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).
- 22.b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.
- 22.c. Request recommendations from the National Science Foundation on how to study, in a credible manner, high-risk, emerging scientific ideas associated with CAM.
23. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities.

ISSUE 3: Research Training and Infrastructure

Background: Commissioners and speakers discussed the crucial role of a strong research infrastructure in conducting quality CAM research and research training. This effort requires the need for a plan to build long-term research capacity and infrastructure to train experts in research and CAM concepts, conduct research on CAM products and practices and on the underlying mechanisms of CAM practices and concepts. This goal will require a government-wide effort involving the NIH, NSF, DOD, NASA, and other agencies.

Research sites, both public and private, with sufficient resources should be strategically located and each site should have a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. These sites should include CAM-trained practitioners and researchers on the faculty and/or as consultants, and should partner with accredited CAM institutions in the conduct of research and research training. (example: NIH research centers program). The Commission believes that the infrastructure for CAM research sites should be developed at both existing public and private research institutions and accredited CAM institutions.

The same rigorous training should be available for both CAM and conventional researchers. Both CAM and conventional researchers need knowledge of the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process, unbiased data collection, protocol design, IRB and other regulatory requirements, and the grant application and submission process. Investigators in CAM research need to have experienced mentors and incentives may have to be developed to attract them. (CAM research training should teach multiple outcome measures, including social contextual assays and biopsychological measures of health, carried out by multidisciplinary teams to allow broader paradigms of health and healing [Blanks,5/01]). (In addition, representatives from research centers supported Federally, privately, or by foundations should meet periodically not only to present progress reports but also to exchange experiences on how best to educate researchers in CAM practices and how to introduce CAM practitioners to the research culture (Hammerschlag 5/01)).

Challenges:

1. Assuring adequate funding and other resources and strategic planning for developing or strengthening CAM research infrastructure sites and training programs.
2. Developing incentives to attract conventional researchers to serve as mentors and study CAM questions.
3. Increasing collaborations between CAM and conventional institutions to enhance training

opportunities and improve the quality of training.

Draft Recommendations:

21.a. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources to the National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions.

21.b. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices, who have received the same rigorous research training in basic, clinical, and health services research.

21.c. Continue to support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

ISSUE 4: Public-Private-Nonprofit partnerships and investment in CAM research and related activities.

Background: The growing willingness of the public, private, and nonprofit sectors to form partnerships offers exciting possibilities in stimulating and supporting much needed CAM research. Also, mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program offer the private sector opportunities for research support. Collaborative public-private-nonprofit research support could contribute in important ways to the emerging areas of scientific study of interest to CAM and conventional medicine.

The provision of incentives for private sector involvement in CAM research and the resolution of intellectual property issues could spur private activity (see FYI/NOTE below). Provision of proprietary protection around process, extraction, production, and use of unique mixtures and combination of agents could help move in this area. {It would be desirable if dietary supplement manufacturers used what the NIEHS National Toxicology Program learns about toxicology/carcinogenicity in these complex materials to conduct studies on remaining untested popular supplements being consumed [Matsen 5/01]}. (Consideration should be given to development of a rigorous review process including industry and academic scientists [Rudden,10/00]). (Successful manufacturers of CAM products should be encouraged to conduct studies and explore collaborations with strong research institutions [Eisenberg 5/01].) (Public agencies should be encouraged to partner with foundations interested in enhancing their research, research training, and conference support [Templeton 10/00].) (Consideration might be given to inviting foundation representatives to sit on Federal advisory groups to discuss potential areas of support and partnership, such as grant funding opportunities. The nonprofit sector might

consider creating a consortium through which pooled funds could be used to augment support for CAM conferences, pilot projects, etc., possibly including the announcement of funding opportunities and the convening of advisory/review groups of knowledgeable, reputable scientists in the areas to be presented, discussed or studied [Hayes.10/00]).

FYI/NOTE: It should be noted that because it is often not possible to patent CAM products, there has been little private research on these products by private companies. Submissions of petitions to gain approval for the right to make health claims also are not economical because pharmaceutical companies or manufacturers of CAM products that might go to the expense of gaining such approval would face competition from other manufacturers that could sell similar products as dietary supplements.

Under the provisions of DSHEA, dietary supplements can make structure function claims. Approved drugs can make health claims about preventing, curing, treating, or mitigating a disease. However, as stated above, because drug approval is a labor-intensive process requiring substantial research, time, and money, most dietary supplement manufacturers do not seek drug status for their products. The unintended effect is that in some instances when there is research on a dietary supplement that could support a claim, the dietary supplement is still limited to the structure function claim because dietary supplements are considered foods.

Certain dietary supplements can make health claims under the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA). For example, there is significant scientific agreement that calcium can prevent osteoporosis and a health claim for both calcium-containing foods and dietary supplements has been approved by the FDA.

Challenges:

1. Stimulating nonprofit organizations to become involved in research on CAM practices and products, e.g., providing seed money and investment in pilot studies, supporting conferences.
2. Creating incentives to increase private sector involvement in CAM research, possibly through tax incentives, resolving intellectual property and other issues to increase product research and product standardization.
3. Encouraging Federal funding for research on CAM products in collaboration with the private and nonprofit sectors.

Draft Recommendations:

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21.f. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships.

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21.g. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk.

21.h. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

21.k. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

21.L. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

ISSUE 5: Publishing literature on CAM research and systematic reviews of the literature

Background: Many speakers agreed that CAM research results need to be published in recognized, rigorously peer-reviewed research journals to provide accurate and reliable knowledge about CAM to researchers, practitioners, and ultimately the public. The quality of the research and the standards of review that the research must meet to gain journal publication affect how readers determine the reliability and usefulness of the information.

To ensure a fair and accurate review, speakers emphasized that CAM expertise should be represented on journal review boards when reviewing CAM research submissions, and CAM journals should include conventional scientific expertise on their review boards. CAM practitioners and researchers should be encouraged to read the highest quality conventional journals and conventional practitioners and researchers should be encouraged to read CAM journals of equal quality.

(Recent increases in research funding and the establishment of CAM research centers should increase the publication of high quality studies on CAM therapies submitted to research journals [Fontanarosa5/01]). (It is necessary to document the basis for claims. Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effective analyses instead of depending on traditional use, anecdotal reports, consumer interest, and market demand (Fontanarosa, 5/01].)

Commissioners also discussed with speakers the availability and use of information gained from the published literature, including systematic literature reviews, evidence-based reports, and the role of NLM databases, such as PubMed and MedlinePlus. Representatives of AHRQ, the Cochrane Collection, and NLM described their CAM-related activities as well as their efforts to cooperate. They also talked about the value of strengthening the process for making reviews of the research literature available to practitioners, community health centers, and policy makers, and to offer clear and understandable summaries of reviews to the public through NLM's MedlinePlus and other information services.

(AHRQ and the Cochrane Collection are finding ways to collaborate with each other and with

NLM [Kamerow, Berman, and Lindberg, 5/01].)

Challenges:

1. Increasing the submission and publication of CAM research articles that are successfully submitted to journals with the highest standards of review.
2. Assuring the inclusion of reviewers experienced in CAM on journal review boards when CAM submissions are reviewed and conventional scientists on CAM journal review boards.
3. Increasing systematic reviews of the research literature, their use, and their availability to practitioners and the public.

Draft Recommendations:

24. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

25. The Commission recommends that public and private resources be provided to support systematic reviews of research literature.

25.a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

25.b. Produce and maintain up-to-date summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force.

25.c. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

Draft Recommendations:

19. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

20. The Commission recommends including trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

21. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

21^e 21.a. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources for National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions.

21^f 21.b. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices who have received the same rigorous research training in basic, clinical, or health services research.

21^g 21.c. Continue to support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

21^h 21.d. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

21ⁱ 21.e. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research

dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

21.f. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships.

21.g. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk.

21.h. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

21.i. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support mechanisms for high-risk, high-impact studies to expand our understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.

21.j. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.

21.k. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

21.L. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

22. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.

22.a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example:

NCI/SPORE program).

22.b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

22.c. Request recommendations from the National Science Foundation on how to study, in a credible manner, the high-risk, emerging scientific ideas associated with CAM research.

23. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities. (D)

24. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts. /

25. The Commission recommends that public and private resources be provided to support systematic reviews of CAM research literature.

25.a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

25.b. Produce and maintain up-to-date summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force.

25.c. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

SEE ATTACHMENTS:

1. Projected Support for CAM by NIH Institutes and Centers
2. Federal Agencies with Research and Health-Related Activities

Appendix 4

FEDERAL AGENCIES WITH HEALTH RESEARCH AND/OR RELATED ACTIVITIES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health (NIH)
Agency for Healthcare Research and Quality (AHRQ)
Food and Drug Administration (FDA)
Health Resources and Services Administration (HRSA)
Substance Abuse and Mental Health Services Administration (SAMHSA)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare and Medicaid Services (CMS)
(formerly the Health Care Financing Administration)
Indian Health Service (IHS)

DEPARTMENT OF AGRICULTURE

DEPARTMENT OF DEFENSE

DEPARTMENT OF EDUCATION

DEPARTMENT OF LABOR

DEPARTMENT OF VETERANS AFFAIRS

INDEPENDENT AGENCIES

Consumer Product Safety Commission
Environmental Protection Agency
Federal Trade Commission
National Aeronautics and Space Administration
National Science Foundation

CAM SPENDING BY IC

(\$ in millions)

ICs	FY 1999 Actual	FY 2000 Actual	FY 2001 Estimate	FY 2002 Estimate
NCI	36.6	43.0	47.3	52.0
NHLBI	2.8	4.1	4.5	5.0
NIDCR	0.3	0.6	0.7	0.8
NIDDK	1.4	1.6	1.8	2.0
NINDS	5.3	4.6	5.1	5.6
NIAID	7.5	7.9	8.9	10.2
NIGMS	0.0	0.0	0.0	0.0
NICHD	1.2	1.6	1.8	2.0
NEI	0.7	1.0	1.2	1.3
NIEHS	1.4	3.0	3.4	3.8
NIA	3.1	6.0	6.9	7.7
NIAMS	0.2	0.3	0.4	0.4
NIDCD	0.4	0.4	0.5	0.6
NIMH	5.1	5.8	6.6	7.4
NIDA	0.4	0.3	0.4	0.4
NIAAA	0.0	1.1	1.2	1.3
NINR	1.7	3.3	3.6	3.9
NCRR	6.8	7.4	8.2	9.0
NCCAM*	40.5	77.8	89.1	100.1
FIC	0.6	0.6	0.6	0.7
OD	0.0	0.1	0.1	7.3
NIH**	116.0	170.5	192.3	221.5

Draft Recommendations:

19-25

19. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

20. The Commission recommends including trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

21. 3. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

a. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources for National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions.

b. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices who have received the same rigorous research training in basic, clinical, or health services research.

c. Continue to support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

d. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

e. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

Report
pg 9
21 f. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships. (A) pg 9

21 g. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk.

21 h. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

21 i. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support mechanisms for high-risk, high-impact studies to expand our understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.

21 j. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.

pg 9
21 k. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

21 l. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

22 a. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.

22 a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

22 b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying

CAM questions.

- 22 c. Request recommendations from the National Science Foundation on how to study, in a credible manner, the high-risk, emerging scientific ideas associated with CAM research. ✓
- 23 4. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities. ✓
- 7/10 5. The Commission recommends including trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation. *del* *del*
- 24 6. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts. ✓
- 26 7. The Commission recommends that public and private resources be provided to support systematic reviews of CAM research literature. ✓
- 26 a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria. ✓
- 26 b. Produce and maintain up-to-date summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force. ✓
- 26 c. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services. ✓

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