Report from the
Ex Director
Status Report
9 topics

— Tentative Consensus

Issues of Concern

~~Move Back to ORD~~
timekeepers
Camille WHCCAMP

E-Mail reality
32,500 about
72,851 from last
July 1 – Sept 30 proposed

Do we have to Pay Back?
timekeeper switch

6 June 2001 DRAFT Recommendations on Education, Training, Credentialing, and Licensure

Licensed Conventional Health Care Professionals:

- Develop a generic national curriculum for health professionals on CAM therapies and the skills necessary to assess CAM use by patients and their families with an emphasis on therapeutic relationship and interpersonal skill development.
- Develop a train-the-trainer initiative to provide health professions faculty with the skills to teach future health care professionals about CAM therapies.
- Create an easily accessible, evidence-based data resource on CAM therapies designed for health professions educators [and clinicians].

Conventional Health Care Professionals:

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- Expose students to CAM early and have CAM practitioners/professionals introduce the philosophy and underlying concepts of CAM.
- Provide joint training opportunities for conventional and CAM students.
- Include CAM on national board examinations

Graduate Education:

- While CAM education should be foundational at the undergraduate level, CAM education at the graduate level should provide opportunities for developing more sophisticated CAM skills in an interdisciplinary environment.
- Provide joint (i.e., both conventional and CAM) graduate education training opportunities.

Continuing Education (CE):

- Develop CE for conventional health care professionals to provide a basic understanding of CAM and its ability to complement conventional treatment.
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Graduate Education:

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- Require minimum levels of post-graduate education (such as residencies) for all non-allopathic and non-osteopathic physicians, leading to state certification or licensure.
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Continuing Education (CE):

- Develop and provide appropriate CE for CAM practitioners.

Credentialing and Licensure (and more):

- Articulate the following five principles to help guide states in developing regulations: (1) many providers want licensure to gain legitimacy and avoid criminal liability under medical license laws; (2) licensure is largely a matter of state law--states rely on the professional organizations to set standards and structures; (3) licensure has a potential dark side, in terms of diminishing the heart and soul of CAM practice; (4) several licensed CAM professions may share legal authority to practice a given modality; and (5) adopt one of several different models for licensing CAM providers based on the state's interest: (a) mandatory licensure, (b) title licensure, (c) registration, (d) exemption, (the Minnesota model), or (e) some variation or combination of the first four.
- Promote state licensure or certification of CAM practitioners to regulate and provide a common standard of practice.
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- Develop national standards for CAM health care that are comprehensive, evidence-based, updated regularly, and accessible to everyone.
- Fund confidential, non-discoverable CAM quality improvement and peer review to enhance the quality of care.
- Develop incentives and an easy-to-use method(s) of reporting adverse reactions, interactions, and /or events associated with CAM products and practices and communicating this information to conventional and CAM providers as well as consumers.
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- Require adequate record keeping of all providers of CAM products and practices so that outcomes can be complied and evaluated.
- Encourage full disclosure by all practitioners of their qualifications to provide CAM products and practices.

6 June 2001 DRAFT Recommendations on Access and Delivery

Recommendations Related to Conventional Medicine and Physician Resistance to CAM:

- Direct educational resources to training all conventional health professions in clinical and cost effectiveness of CAM approaches (especially nutrition), relationship-centered care, and how to interrelate with CAM practitioners.
- Train CAM practitioners how to interrelate with conventional health care professions.

Recommendations Related to Reimbursement, Coverage and Cost Issues:
Please note that because of an evidenced-based approach to reimbursement, research recommendations were categorized under the rubric of reimbursement, coverage, and costs issues.

- Create access to CAM therapies that are considered to be safe. However, embrace reimbursement only for those therapies that have strong evidence supporting their effectiveness.
- Determine the most common guidelines for setting limits for access and apply them to CAM.
- Insert language for CAM in Federal entitlement acts, such as Medicare, Medicaid, Indian Health Service, and CHAMPUS.
- Place a major focus on wellness and recommend policies for reimbursing CAM providers for health promotion.
- Promote the incorporation of new codes into Federally funded CAM research so that cost-effective CAM treatments can be identified as a solution to escalating health care expenses, especially where these procedures could have an impact on Medicare/Medicaid recipients.
- Promote research with side-by-side comparison of conventional health care and CAM to determine which gets better results and at lower costs.

Recommendations Related to Balance of Consumer Choice and Public Safety:

- Allow use of any medical treatment that has been in use in another country without evidence of harm.
- Encourage the FDA to require nutritional supplement and herbal remedy manufacturers to label their products with warning against possible adverse effects or toxicity, and recommendations for proper usage.
- Institute a system, such as that proposed by the World Health Organization, to establish guidelines for the assessment of herbal products to ensure proper identity and quality of both raw materials and finished products.
- Involve well-trained herbalists in the scientific study of safety and efficacy of herbs.

Recommendation Related to Needs of Special Populations:

- Develop demonstration projects that will allow hospice programs to provide care without a reimbursement, criteria, or prognostic cap.

Recommendations Related to Cultural and Linguistic Challenges (Including Traditional Healing):

- Require the FDA to recognize a "traditional medicines" category that would take into account the historical and traditional uses of herbs and permit manufacturers to put this information on the label.
- Develop "peer" education programs to disseminate credible information on CAM to minority and ethnic communities.

Recommendations Related to Integration of CAM vs. CAM Separatism:

- Break down barriers to collaboration of conventional health care with CAM practitioners.
- Develop a 20-year plan to integrate conventional medicine into patient-centered, whole-person health care.
- Do not fully integrate CAM therapies into mainstream medicine.

Recommendations Related to Models of Service Delivery

- Provide access for all populations to nutritional programs such as the Dean Ornish program.
- Use nurses as a resource to integrate CAM into conventional medicine and serve as a bridge to help educate doctors.
- Develop a system of integrative medicine in which a cadre of CAM and conventional health care practitioners, each with his/her own scope of practice and tools, coordinate care, cross-refer, and co-manage patients.
- Fund and coordinate systematic reviews of specific CAM methods organized by clinical conditions.
- Increase research by CAM practitioners and experienced clinical researchers on clinical implementation of specific CAM treatments for specific conditions.

Recommendations Related to CAM Service Delivery to Uninsured and Underinsured:

- Link school loan forgiveness programs for CAM practitioners to service to underserved populations.
- Facilitate inclusion of underserved populations in CAM clinical research and require provision of standard conventional care instead of placebo.
- Include a service component to uninsured, underinsured, and underserved populations in Federally-supported CAM training and research grants.
- Include CAM in all Federal programs to reduce health disparities.
- Fund Community and Migrant Health Centers to use their unique abilities to deliver CAM and educate uninsured and underinsure populations about CAM in culturally competent ways.

Peter

Peter 202-224-7303

3254

Renewal Jim - Stay on Mandate

Office

His needs

Interim Report / Clear (A)

Larry Wilson

* John Baylor

805-4471

Osteopathic

① Calendar ~~Hours~~

Suite 880 → Electricity

RSVP

6.00/2 ②

~~She~~ ~~Door~~ ~~Door~~

~~Keyplus Monitor~~

~~Get new Monitor~~

~~Ren~~

~~Jim Key~~

③ Desk

- File Cabinet
- Door Hooks
- 8 Hooks
- Table
- 4-5 Drawers

- Joe Levitt
- Food Safety - Hatchins Speech

GAO Report / DSHEA

8/11/01

9:00 - Phone Conference

Closed Session

~~FACA~~ Check for exemptions

* White House Commission

301-767-1750

① Status of Recommendation

8th - 12th Meeting on

14th - Peter Reinecke

② Wayne Jonas Retirement Party

Alan Dunoff - DSHEA

- Legal Counsel - to Commission
-
- Reviewer - Consultant - Reviewer

on medicine.com (Jay Bruce)

~~1 mo~~

Dark Field - Microscopy / [CLIA] → Repeat
- Live cell Analysis
- DHHS - Opinion
-

Stacks - Joanne Jessenheimer - NSG
- Sharing referrals -
- Mgt Services Operation

Clem Bezold - Phenotypes / Genotypes

Maureen Miller - / Military

324.54

Testimony of Alan Dumoff, J.D., M.S.W. **#62**

Before the White House Commission on
Complementary and Alternative Medicine Policy

301-984-8020
alandlmc@aol.com

I have been involved in the legal issues concerning CAM delivery for 13 years, and concerned about barriers to integrative efforts as far back as the early 1980's when, working as a psychotherapist, I became frustrated with the barriers to working collegially with nutritionists, chiropractors, and other CAM practitioners. I went to law school expressly to work on these issues. I do not speak on behalf of any one client today, but rather from the aggregate experience of representing physicians, acupuncturists, nutritionists, homeopaths, and a host of other practitioners as well as national credentialing bodies, associations and other organizations.

My topic has me scheduled out of turn; in my few minutes, I would like to highlight five items regarding reimbursement policy.

X) *Medical Necessity and Standards of Care.* The most insidious difficulty under reimbursement policy are decisions whereby Medicare or private insurers decide what constitutes appropriate, medically necessary care, ruling out payment for positive, innovative approaches because they are nonstandard. The rejection out of hand of nutritional approaches to care, despite extensive supporting literature, is but one example. While I'm sure this is clear, what I hope is also known to the Commission is the use by third-party payors of these standards to bludgeon holistic physicians about these practices. A physicians I represented was excluded from Medicare because the Health Care Financing Administration (HCFA) believed that nonstandard medicine is *per se* substandard medicine. In another case, a BlueCross BlueShield insurer complained to a state medical board because a physician was practicing nutritional medicine and innovative therapies, even though BlueCross was not being billed for noncovered therapies.

Recommendation: I believe that the Commission has an obligation to directly address the value and meaning of standards of medicine in the context of holistic and integrative care.

non-standard considered sub-standard

X) *E/M Coding.* Evaluation and management (E/M) coding for office visits, especially under revised and more stringent guidelines about complexity of decisionmaking and degree of morbidity, are designed with biomedical methods in mind. Holistic approaches that take a more searching view of etiology take longer but do not easily justify higher levels of coding. This encourages rapid and incomplete assessments. One physician I represent in Maryland was charged by the Board of Physician Quality Assurance with willfully overbilling. After attending a coding course at the behest of the Board, and noting that professional billers don't agree on the application of coding guidelines, this physician raised some reasonable and pointed questions about how holistic physicians can honestly work within a billing system that the physicians it was designed for are having difficulty.

Recommendation: The Commission has an opportunity to sensitize the AMA/HCFA Committee that drafts documentation and coding guidelines about the time intensive nature of holistic approaches to practice.

X) *Medicare's Same Day Rule.* Medicare routinely rejects multiple services that are done on the same day for the same purpose. This makes integrative delivery difficult. A patient seeing a physician for back pain cannot get reimbursed if she sees a chiropractor in the group the same day.

> *Recommendation*: The Commission could request that the Health Care Financing Administration review Medicare rules such as the same day rule for possible modifications that would better accommodate team, integrative practice. It is worth noting that, in working with a Florida client regarding Medicare issues, the local carrier issued the rather cryptic *non sequitur* that "team practice is dead." Support for team practice as an important principle in the new medicine by the Commission, with encouragement for regulations that support such practice, could be of great benefit.

4) *"Incident to" Billing.* As I mentioned in an article entitled "An Open Letter to the White House Commission on Complementary and Alternative Medicine: Suggestions for National Course Corrections" published in Mary Ann Liebert's *Alternative & Complementary Therapies*, one change HCFA is contemplating would effect the ability of CAM practitioners to bill under the name of a physician in a group practice.

> *Recommendation*: In the interest of brevity, I'll simply highlight the importance of that issue here and refer the Commission to that article and its recommendation.

5) *Getting Good Information.* Properly billing Medicare and private insurers is phenomenally complex. Every client site I visit has grave misconceptions about how to code office visits, use modifiers to bill for denial, waivers for non-covered CAM services, assign benefits . . . the list is quite lengthy. Many CAM services are delivered in small clinics with a few physicians and CAM practitioners, who do not have the resources or expertise to understand how to bill legally and successfully.

> *Recommendation*: Some form of clearinghouse or other means of providing concise and understandably information about legal and successful billing practices should be made available. The Commission could ask HCFA to provide materials on-line aimed at the usual issues that arise in integrative practices.

Lastly, I would like to urge the Commission to take greater advantage of legal expertise in this field. While it is refreshing to find a Washington institution that is not teeming with lawyers, there are a handful of attorneys in the United States who specialize in the legal concerns regarding CAM, a body of experience I believe could serve the Commission well.

Thank you for you attention, and more importantly, your efforts.

11140 Rockville Pike

Edson Lane

Right Turn in

Turtle 5:30

301-984-8020

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February 22-23 WHCCAMP Meeting
CAM and Education, Training, Licensing, and Credentialing
Discussion Group I

Discussion Group I considered education and training in CAM for conventionally-trained physicians. The following Commissioners served as members of Discussion Group I: Joseph J. Fins, Chair, George M. Bernier, Jr., Effie Poy Yew Chow, Joseph E. Pizzorno, Jr.,and Veronica Gutierrez. Staff support was provided by Geraldine Pollen, a member of the Commission staff. The outline below summarizes the Group's discussion at the WHCCAMP meeting on February 22-23, 2001, in Washington D.C.

A. General Concepts

1. Provision of resources to medical institutions to implement the following articulated principles.
2. Encourage institutions/organizations, no mandates.
3. Appreciate the evolutionary aspect of this process.

B. Articulated Principles

1. In order to ensure patient safety, conventional practitioners need a minimum core knowledge base in CAM to recognize its potential impact and influence on patient well-being and conventional medical practice.
2. Foster communication skills, which is a generalizable competency.
3. Accept the patient unconditionally (even if the physician does not agree with the patient's treatment choices). The rationale for this approach is:
    - 3a. enhances doctor/patient communication
    - 3b. fosters trust and disclosure
    - 3c. allows improved identification of conventional drug/CAM agent interactions.
    - 3d. allows optimization of care/therapy
4. Promote interdisciplinary communication with CAM practitioners to maximize patient safety and optimize clinical outcomes, while respecting patient choice.

C. Basic Elements of Medical Education and Training in CAM

1. Public health dimensions of CAM
2. CAM as an element of culture, practice, and expression
3. Safety and efficacy
    - 3a. regulated practice areas (toward communication/collaboration)
    - 3b. unregulated practice areas (surveillance)
4. Educational categories of CAM, e.g., history, philosophy, typical practice, scientific base
5. Emerging CAM scientific base/research methodologies
6. Communication between conventional and CAM practitioners

D. Undergraduate CAM-related Medical Education

1. Provide resources (private, not-for-profit, public) for:
    1a. faculty development
    1b. curricula development, e.g., AAMC project; NBME process
    1c. additional text books
2. Include CAM in:
    2a. NLM site
    2b. medical journals
3. Foster collaboration with established CAM professional organizations and accredited CAM institutions for curriculum development and local faculty support.
4. Incorporate CAM in established doctor/patient relationship (DPR) classes; professionalism and ethical issues; CAM and research; medical history/physical exam (HX/PE) classes.
5. Include CAM in existing curricula, e.g., public health, pharmacology, cross-cultural curricula, medical ethics.
6. Pursue the scientific basis of CAM
    6a. basic science
    6b. research methodology
7. Add Problem-based Learning (PBL) classes
8. Foster interdisciplinary team including CAM professionals/collaborative skills set
9. Encourage advanced/supplementary electives for students (collaboration, methodology, research).

E. Graduate CAM-related Medical Education

1. Work with the Residency Review Committee (RRC) of the Accreditation Council of Graduate Medical Education (ACGME) to develop specialty-specific, minimum competencies, explore the feasibility of electives for residents in accredited CAM residency programs or teaching clinics.
2. Requisite humanistic/professionalism for board eligibility
3. Develop HX/PE skills to include CAM
4. Training for interaction with CAM providers
5. Encourage research training experience/fellowships; NCCAM, NCI, etc.
6. Health Resources and Services Administration (HRSA) health services fellowships; systems/organizations of care, e.g., CAM in managed care organizations and operational-integrative issues.
7. Public health/CDC surveillance for adverse events, e.g., EMS/L-tryptophan.

F. Continuing Medical Education Related to CAM

1. Traditional CME model building upon undergraduate and graduate training does not apply yet.
2. Accredited CAM education that qualifies for CME credit, e.g., Accreditation Council for Continuing Medical Education (ACCME) establish process to assess threshold for credit/criteria.
3. Independent study in systems of care or isolated treatment modalities, e.g., traditional Chinese medicine vs. acupuncture.

Workgroup #2

Workgroup Members: David Bresler, Charlotte Kerr, Julia Scott, Donald Warren
Staff: Corinne Axelrod

I. Undergraduate Level

Students in undergraduate programs may or may not be interested in pursuing studies in health, but an understanding of different concepts of health and healing will be of value to them throughout their lives. All students should have an introductory course that exposes them to different concepts of healing from around the world, and the philosophy and principles of CAM. The introductory course should also provide an opportunity for them to experience some CAM modalities. This will provide a valuable perspective for those who pursue a career in conventional medicine, and may spark an interest among others in pursuing a career in CAM. Regardless of their future careers, this understanding is likely to have a positive impact on the health and well-being of all the students. Curriculums should not be limited to evidenced-based approaches, and should include a risk-benefit explanation for each modality.

II. Graduate Level

Graduate schools should also provide an introductory course on CAM, in case students were not exposed to it at the undergraduate level. In addition, they should provide more advanced coursework, including specific skills training as appropriate to their area of study, and assure an adequate knowledge base for practitioners to make referrals.

III. Incentives to Include CAM in the Curriculum (Undergraduate and Graduate)

For Students:
1) Include questions on exams (institutional and national)
2) Possible reductions of future health insurance premiums for people who complete the basic course in CAM

For Schools:
1) Possible reductions in school insurance premiums
2) Decreased cost of student health services
3) Opportunities to form community partnerships (corporate sponsors, private donations, foundations)
4)Possible site for NIH research grants

IV. Continuing Education

Organizations offering CEUs should include CAM courses and they should be applicable to the reliscensing and recertification of practitioners in the same way that non-CAM courses are applied. Practitioners of other disciplines should be encouraged to participate and agreements between organizations should facilitate CEU credit wherever possible

V. Other

1) National credentialing exams should include CAM questions that reflect a broader view of healing

2) Primary practitioner liability coverage should include referrals to CAM practitioners.

Discussion Group 3

Attendees: Tieraona Low Dog, Chair, George DeVries, Wayne Jonas, Dean Ornish, Xiaoming Tian

Discussion Group 3 met during the afternoon of February 22nd and the morning of February 23rd to discuss possible recommendations, issues and concerns regarding the education, training, continuing education, and licensure (and/or certification) of conventionally trained "western" practitioners who integrate CAM into their practice. The group began its working sessions with a discussion of the differences in philosophy among medical traditions, the fundamental differences in the approach to health care, and the ensuing difficulties in addressing educational needs. The importance of learning salutogenesis -- self-care and healthy living skills -- was discussed, especially for health professionals themselves.

Members agreed that, regardless of individual interest in or acceptance of CAM, medical students and practicing physicians – as well as other health professionals – needed to have a basic knowledge about alternative therapies because most patients will be using one or more such therapies. Practitioners should be asking patients about their use of nontraditional therapies, and considering the possible interaction with the practitioner's conventional approach. Members discussed generally what should be the focus of "basic" education in alternative therapies and the difficulty of finding and allocating time during the four years of medical school.

The group also distinguished basic knowledge from more in-depth study and training for those health professionals interested in integrative practice. Continuing education needs were discussed, in addition to licensure and accountability. Thus, the scope or parameters of the recommendations span:

- Practitioners who need to "be aware" of CAM to those who practice CAM
- Levels of education from undergraduate, to graduate, to fellowships
- The need for separate CAM programs vs. the need for integrating information into all programs (consider first level care givers and specialists)
- Every practitioner's need for an ability to evaluate modalities.

The groups' suggestions for draft recommendations are:

1. Health care practitioners, during undergraduate education and at the postgraduate level, should be given opportunities to learn experiential methods and practices for self-healing. These should include –

    - Good nutrition
    - Regular exercise

- Stress management (such as meditation)
- Positive communication and supportive relationship skills
- Compassion and social service.

2. Early in the undergraduate and at the postgraduate level, health practitioner education programs should include –

- an introduction to the philosophy , practices, and principles (at least the NIH categories) of the most prevalent complementary and alternative health care modalities,
- self care, and
- how to critically evaluate the safety and efficacy of therapies, including CAM therapies.

3. During the clinical training years, educational programs should provide opportunities for health practitioners to be exposed to, or learn in depth, self care and one or more CAM practices (such as acupuncture or meditation).

4. The undergraduate and postgraduate education of health practitioners in CAM should be evaluated using current methods of testing and evaluation.

5. CAM should be incorporated into established undergraduate and graduate courses where there is relevant evidence-based science. For example,

    a. Through study of pharmacology, practitioners should become knowledgeable about proven supplements such as glucosamine.
    b. Students and practitioners should be made aware of cultural differences in health care and self care, and develop a cultural competency for their geographic area of practice.

6. Special funds should be provided by federal and private sources to support the development and implementation of curriculum on self care, evidence-based CAM, and clinical evaluation into undergraduate and postgraduate health practitioner education programs, and for faculty development and training in these area.

7. Nationally recognized educational accrediting organizations should develop and incorporate standards, and review criteria, for evidence-based core competencies in CAM. (These standards will help ensure that practitioners will be able to manage and coordinate the care of patients utilizing CAM.)

    Five core competencies are --
    knowledge of CAM practices
    skills in assessing CAM use in culturally sensitive ways

skills in critical appraisal of safety and efficacy of CAM proactices
ability to communicate and guide patients in CAM use
ability to refer, follow, and collaborate with CAM practitioners in developing integrated patient care, as appropriate

8. There should be opportunities at the postgraduate level or through continuing education for physicians and health practitioners to learn about CAM principles and evidence-based practices, and to learn a CAM practice in- depth.

9. Work with federal and state oversight bodies (FDA, FSMB etc.) for the development of guidelines for the delivery of CAM by licensed professionals, e.g., physicians, nurses, midwives, lay midwives, dentists, pharmacists.

10. State medical boards should include members and or consultants who are trained and experienced about CAM practices.

11. Physicians who use CAM practices should be held to the same standards of medical practice as practitioners of allopathic medicine.

12. Practitioners who practice CAM modalities are encouraged to receive appropriate training and to maintain knowledge and skills through evidenced-based continuing education. Allopathic medicine should be held to the same standard.

Summary of WHCCAMP Discussion Group #4
Breakout Session One February 22, 2001

Present: Linnea Larson (Chair), Tom Chappell, Conchita Paz, Buford Rolin, and Joe Kaczmarczyk (Staff).

Absent: Bill Fair

Additional Attendance: See attached list of observers who signed in

After a discussion of the relevant issues, the members of the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) Discussion Group #4 made the following **draft** policy recommendations:

- There should be national educational standards for CAM modalities, therapies, and practices established by professional and educational institution organizations linked with a proposed Federal CAM coordinating entity/office. These standards should include exposure to not only a variety of commonly utilized CAM modalities, therapies, and practices, but also conventional medicine. In addition, a professional role of a "Care Navigator," as envisioned by Richard Miles, should be created [for RNs, LCSWs, and others] to listen and coach the consumer on referral in such a way as to preserve consumer choice.
- There should be scholarship and loan repayment programs available to CAM students and students of emerging professions.
- There should be a minimal level of postgraduate training (i.e., residency) for non-allopathic and non-osteopathic physicians established by professional and educational institution organizations. These residencies should have parity with allopathic residencies in terms of equal access and right to funding. A proposed Federal CAM coordinating entity/office should facilitate this process, for example, by identifying resources and models.
- There should be use of the term "Traditional Healer" for those individuals designated by native communities.
- There should be preservation of "Traditional Healing" by communities and when appropriate, with the assistance of the Indian Health Service (IHS).

Summary of WHCCAMP Discussion Group #4
Breakout Session Two February 23, 2001

Present: Linnea Larson (Chair), Tom Chappell, Conchita Paz, Buford Rolin, and Joe Kaczmarczyk (Staff).

Absent: Bill Fair

Additional Attendance: See attached list of observers who signed in

Following a discussion of relevant issues, the members of the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) Discussion Group #4 made the following **draft** policy recommendations:

- Every CAM practitioner should have a minimal level of knowledge and understanding of other CAM systems of care, modalities, therapies, and practices. This should be accomplished with a national core curriculum standard defined by CAM specialty professional organizations and facilitated by a proposed Federal CAM coordinating entity/office.
- Every CAM practitioner should have a minimal level of knowledge and understanding of conventional medicine and referring to conventional physicians or conventional health care providers as determined by professional and educational institution organizations with the assistance of a proposed Federal CAM coordinating entity/office.
- The role of continuing education for CAM practitioners should be to enhance learning and knowledge on an ongoing basis for all CAM practitioners.
- Self-determined organizations representing a modality, therapy, or practice from disparate perspectives should form a dialogical "community" for common ground. Community formation should be consistent with a wellness orientation and facilitated by a proposed Federal CAM coordinating entity/office.

Summary of WHCCAMP Discussion Group #4
Breakout Session Three February 23, 2001

Present: Linnea Larson (Chair), Tom Chappell, Conchita Paz, Buford Rolin, and Joe Kaczmarczyk (Staff).

Absent: Bill Fair

Additional Attendance: See attached list of observers who signed in

Following a discussion of pertinent issues, the members of the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) Discussion Group #4 made the following **draft** policy recommendations:

- There should be national standards or certification to provide CAM practices and products developed and implemented by certification bodies/entities. While consumer confidence can be enhanced by certification, consumer confidence should be enhanced further by disclosure about practitioner qualifications and products (at a minimum). Furthermore, while referrals for CAM practices and recommendations of CAM products should be supported, sales of CAM products by practitioners should not be supported particular when done for profit.
- In the absence of health services research, condition-specific or modality specific practice guidelines should be avoided, while long-term research should focus on the best interests of consumers.
- In terms of quality of CAM practices and products, the recommendations of the Agency for Healthcare Research and Quality (AHRQ) should be considered: (1) Quality should be defined using the IOM definition. There would not seem to be a good reason to develop a new definition. (2) CAM should be held to the same standards as Western Medicine and quality measurement must include a wide array of outcomes including ones that are patient-oriented. Quality of CAM should be measured just as we are measuring the quality of Western Medicine. It should be measured by those familiar with CAM, but who are also skilled in appropriate research methods. Effectiveness and cost-effectives should be measured. Patient outcomes that include physical and psychosocial functioning and quality of life should be included in the equation. The evidence base for CAM treatments should be developed. It should be noted that some of this work is now taking place as a result of NCCAM and AHRQ funding and also in the Cochrane Collaborative, but much more needs to be done. (3) What should consumers be told about CAM? BUYER BEWARE! The truth as it is currently known: That the evidence base for CAM is lacking in many areas and very weak in others. That certain botanical products and dietary supplements may be harmful/dangerous for some people. Although a product may be natural, this does not ensure safety. Standards of quality related to purity and consistency need to be developed. That certain other types of treatments may be harmful as well. Finally, that many treatments may not be harmful or dangerous, but they may also not be efficacious or effective and may be costly.

- There should be bilateral exchange of information between conventional and CAM practitioners, even when a consumers self-refers to a CAM practitioner. As recommended by Dr. Marty Rossman, communication of information about a patient must always depend on the patient's willingness to release that information. Provided that proper informed consent is obtained by the referring practitioner, the referral should include information about the patient's diagnosis and basic medical condition, why the referral is being made, specific concerns for safety, any other information that can help the practitioner understand the issues that the patient is facing and what information the referring practitioner wants to hear back about the outcome of.... therapy.
- There should be a mechanism to address consumer concerns or grievances about the quality of CAM practices and products in the form of a "Consumer Concerns or Grievances Board" that should be independent of any Federal or State control, but should be created through the assistance of the proposed Federal CAM coordinating entity/office.

DRAFT

Report of the White House Commission on Complementary and Alternative Medicine Policy

Letters of transmittal
- The President
- Congress
  - President of the Senate
  - Speaker of the House
- Secretary Department of Health and Human Services

Prologue – Chairman's Summary – 1 page vision
Acknowledgements
Commission Members
Commission Staff
Working Groups (Planning)

Executive Summary (10 pages)
- Conclusions
- Recommendations (a) Administrative Actions
  (b) Legislative Proposals

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(A) Legislative and Executive Actions
(B) Other Federal and State Activities
(C) CAM Integration Efforts to Date

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(2) Private Sector Initiatives
(3) Not-For Profit Support of CAM Research

(D) Barriers to Progress
(E) Public Input to Identify Research Opportunities
(F) Interface Between CAM Research and Regulatory Agencies
  (1) Practice-Based Research
  (2) CAM Research and Experimental
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  (4) Facilitating CAM Research and Regulatory Challenges
(D) The need to Coordinate CAM Research and Development Efforts
  (1) Collaborative Efforts
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(E) Support for Research
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  (5) Existing Sources of Funding
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  (8) Peer Review of CAM Research Proposals

Part V. Gaining Access to the Delivery of CAM Interventions and Products
(Dr. Joe Kaczmarczyk)

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(A) Financing CAM Interventions, Services and Products
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(D) Reimbursement/coverage in the Managed Care Setting
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(B) Research Training and Career Development of CAM Practitioners
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(1) Undergraduate Education
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(2) Patients
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(D) Sources of Information
(1) Public Sector
(2) Private Sectors
(D) Access to Information
(1) Media, (a) TV (b) Press (i) Professional (ii) Public
(2) Internet

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(A) Building the Scientific Basis of Understanding CAM Interventions
(B) Overcoming the Bias against CAM Practices
(C) Increasing Public Awareness of Safe and Effective Interventions
(D) Ensuring Access and Delivery of CAM Intervention and Products

Research Challenges: Tieraona Low Dog; Breakout Session IIIA; May 16, 2000

Evaluating Research Literature

Need for adequate training: An area of concern identified by the Commissioners is the ability of CAM practitioners to read critically published research regarding CAM practices and products, as well as conventional medical research. Another area of concern is the ability of CAM practitioners to serve on review teams for medical journals, research proposals, etc. The Commissioners feel that an infrastructure needs to be built to address the problem.

Barriers:

- Lack of research educators – In CAM educational institutions, there is a paucity of educators/trainers with knowledge and skills in research methodologies and related areas (e.g. biostatistics). As a result, CAM-specific curricula do not address research and CAM students are not trained in this area.
- Funding – CAM educational institutions do not have the endowments or other financial capability to develop curriculum and infrastructure in research, to bring in conventional medical researchers to serve as faculty, to train their own faculty (through additional basic or continuing education) , to establish library support, or to make computers/computer laboratories available.

Recommendations:
All practitioners (CAM and conventional) must be trained through professional educational programs, and through continuing education, in the critical evaluation of published research.

Encourage the development and continued support for training CAM professionals who can then teach research methodology and evaluation.

Encourage collaboration between conventional (medical/health) academic institutions and CAM schools for the training of CAM professionals in research methodologies and evaluation.

Funds must be made available to support and sustain the educational infrastructure necessary for training in research methodologies and evaluation, including libraries (journals, texts, etc.), computers, and Internet access.

Funds must be made available to support and sustain the development of educational training in the scientific process, research methodologies, and research evaluation for CAM-specific educators and students, including collaborative efforts with conventional (medical/health) academic settings.

Publication of Research

Increase publication and participation: The commissioners are concerned about increasing CAM research and the publication of CAM articles in CAM and conventional professional journals. The Commissioners are also concerned about translating published research information in a manner that is accessible and understandable by the public.

Barriers:
Small pool of expert CAM researchers (see above)
Who are the peers performing the peer review?
Lack of publication sources, i.e. not enough journals for publishing CAM (or conventional) research
CAM does not have an equal footing in conventional medical journals
Lack of good information resources for the public

Recommendations
Peer-reviewed journals should involve at least one reviewer with experience in the CAM modality being studies or considered for publication.

Agency publications should include CAM evaluations (trials) in their reports (HCFA, ODS, CDC, NCI, NLM.

Encourage NCCAM to consider producing a publication of the "Year's Best" in CAM research and include it on their web site..

Foundation Support for CAM Research

Disparate information: The Commission is concerned that sources of funding for CAM research are not readily known in the research or CAM communities. The Commissioners are also concerned that much of the needed CAM research, including health services research on costs and effectiveness, is very expensive – and could not be funded by a single source.

Barriers:
No single source of information on sources of research funding.
Research and demonstrations are very expensive.

Recommendations
Encourage foundations to form an affinity pool of private donors to announce and support competition for CAM research support.

Encourage foundations to form a consortium to share various types of support for CAM research and related activities, e.g., grants, conferences, dissemination of information, etc.

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Wayne Jonas May 16, 2001
Breakout Session IIIB

Research Important
High Quality
Multimethods

Systematic Reviews Meta Analyses	Health Serv Res including cost	
Randomized controlled Clinical Trials	Outcomes/ Observational Research	
Basic	Qualitative	

Causal Proof

Utility
Coordination/
Qualitative value

Prioritization?

Multidisciplinary Teams

Experts science
CAM experts
Public participation

Qualitative Outcomes measures

Quality of Life
Patient Satisfaction
Adverse effects
Other Subtle or special CAM outcomes

(unexpected/serendipity)

Safety

Stakeholders

FDA
CDC (MMWR)
NEIHS
USP
Industry

DSHEA
modification?
implementation?
Substance **monitoring of adverse effects**
Competency of training
Quality assurance of products
Evidence stratification by risk

Meaning of epistemological information

NEH
Culturally relevant information
Anthropology and social science

Stimulation and Support of Research

Stakeholders

HRSA	
NAS	
NIH	Encourage, fund, stimulate more federal agency
CDC	involvement in research
AHRQ	RFA's review group. $ confers future budge considerations
HCFA	
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VA	
USDA	
NSF	

Stimulation of Research

(1) Academic Health Centers — infrastructure, critical mass.
Integrative/CAM research
- training
- equipment
- methodology
- research teams
- informatics

(2) Foundations Coordination of support: philanthropic, private, government sectors

(3)Private Sector

Market protection, patents, DHSEA, tax incentives
(like orphan drugs, small business innovative research)

Training

Regional Collaboration — Conventional/CAM/Integrative

Local and state governments

Repository of research support, organization, information

Wayne Jonas May 16, 2001
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Wayne Jonas May 16, 2001
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FTC

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Research training

Regional collaboration — Conventional/CAM/Integrative

Role of local and state governments

Repository of research support, organization, information

Chang, Michele (NCCAM)

To: Steve Groft (E-mail); Corrine Axelrod (NCCAM) (E-mail); Joe Kaczmarczyk (E-mail); Gerry Pollen (E-mail); Ken Fisher (E-mail)
Subject: Commissioner Calls

Here is the deal of the deck:

Corinne:
Donald Warren
Dean Ornish
David Bresler
Julia Scott

Dr. Joe:
Linnea Larson
George DeVries
Wayne Jonas
Joe Pizzorno

Gerry:
Tieraona Low Dog
Bill Fair
Joe Fins

Ken Fisher:
Tom Chappell
Veronica Gutierrez
Buford Rolin

Michele:
Effie Chow
Conchita Paz
Charlotte Kerr

Steve:
George Bernier
Ming Tian

Please cover:

(1) What themes or key issues do you feel are emerging?

(2) What issues do you feel will require further input and/or discussion (e.g., licensing, regulation)? How would you prefer to process this issue? (e.g., expert testimony, small group breakouts, large group discussion, background reading material--from whom?)

(3) What do you hope to accomplish at the July (and October) meetings? What process suggestions do you have? (large vs. small group discussions, advance reading, etc) Cover what our proposed process is (June 18 package of recommendations, etc)

(4) Would you be available and willing to participate in a Sunday, July 1 informal dinner to discuss the potential for the report (commissioners' expectations and hopes) and potential pitfalls and traps?

Thanks!

Michele M. Chang, MPH, CMT
Executive Secretary
White House Commission on
Complementary and Alternative Medicine Policy
tel: 301-435-6232
fax: 301-480-1691
website: whccamp.hhs.gov

White House Commission on Complementary and Alternative Medicine Policy Meeting on July 2-3, 2001

I. Review of Interim Report - Contents
   - A. History of Commission
   - B. Schedule of Meetings - General and Town Hall
   - C. Issues/Subjects Discussed at Meetings
   - D. Major Themes for Report - e.g., Full Implementation of DSHEA; CAM Education of all Health Care Providers, General Public, and Children; Permanent Presence of Office to Implement Recommendations of the Commission
   - E. Other Recommendations - Specific, Inexpensive to Implement, Short-term Success, Ease of Implementation

F. Development and Review of Issue-Specific Recommendations - Executive .Order categories; Master List Provided Around June 18; Brief Analysis of Recommendations

G. Review of Draft Chapters of Report - 2 Audiences of Those Knowledgeable and Those Unfamiliar with CAM
   - A. Introduction/History of Commission
   - B. Literature Review of CAM/Historical Perspectives
   - C. World View

H. Identify Missing Information for Future Meeting Discussion or Data Collection

All Inclusive — Menus detail

Either way is OK — Menus Home Cooked

July 1 { Either Way — Hotel
Stay in Hotel

George Berner - Comfort in Proceeding
Adherence to Evidence based learning
Blue Cross / Blue Shield - No Coverage under licensing

BWI - (BWI 6:00) - 7:00 — Sunday Night

Groft, Stephen (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Tuesday, May 22, 2001 4:39 PM
To: Groft, Stephen (NCCAM); Axelrod, Corinne (NCCAM); Kaczmarczyk, Joseph (NCCAM); Pollen, Geraldine (NCCAM); Fisher, Ken (NCCAM)
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Buford Rolin

Michele:
Effie Chow
Conchita Paz
Charlotte Kerr

Steve:
George Bernier 409-744-0160
Ming Tian 301-530-5328

Please cover –at minimum, but let them say what is on their minds...:

(1) What themes or key issues do you feel are emerging?

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recommendations, etc)

(4) Would you be available and willing to participate in a Sunday, July 1 informal dinner to discuss the potential for the report (commissioners' expectations and hopes) and potential pitfalls and traps?

Deadline:

We agreed to complete these calls while the last meeting was still fairly fresh in Commissioners' minds. Please try to finish or at least initiate your calls by this Friday, ready to report back by Tuesday.

Come talk to me or Steve if you are feeling at a loss as to why we are doing this :-)

Thanks!

Michele M. Chang, MPH, CMT
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Complementary and Alternative Medicine Policy
tel: 301-435-6232
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In May 2001, Natural Organics recalled several dietary supplements, also due to salmonella contamination of raw materials supplied by American Laboratories. The University of California, Cooperative Extension, has found toxic levels of mercury in some pills from China[7]. While the extent of contamination of dietary supplements is not known, steps should be taken to assure that these products are free of contaminants.

Issue 8: Dietary supplements can make structure and function claims, but only approved drugs can make claims about preventing, treating, curing, or mitigating a disease. Since drug approval is a labor intensive process that requires substantial research, time, and money, most manufacturers of dietary supplements do not seek drug status for their products. The unintended effect is that in some instances where there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Information that may be beneficial to consumers is therefore limited and sometimes confusing.

Recommendations:
A) Include package inserts that explain current information on the product, as well as the limitations of that information.

Discussion: The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to "diagnose, treat, prevent, cure, or mitigate" a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent , and any realized benefits will apply to all manufactures, not just the one who prepared the application. While consumers need to have accurate and truthful information, they should also have access to available data to assist them in their decision making.

The U.S. Court of Appeals for the District of Columbia, in the matter of *Pearson v. Shalala*, ordered the FDA to clarify its significant scientific agreement (SSA) standard, reevaluate some previously denied claims, and permit health claims that do not meet the SSA standard if a disclaimer can ensure that the claim will not mislead consumers. It is too early to assess how this will change health claims information.

Issue 9: Consumers may be unaware of possible risks of using one or more dietary supplements.

Recommendations:
A) Include warnings in dietary supplements regarding interactions with other dietary supplements, drugs, OTCs, foods, or other products with which interactions may occur, or with certain health conditions. If this information is not available, the labels should state so.

B) Warnings for pediatric use, use by pregnant or nursing women, and those whose immune system is compromised should be included.

helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to "diagnose, treat, prevent, cure, or mitigate" a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent , and any realized benefits will apply to all manufactures, not just the one who prepared the application. While consumers need to have accurate and truthful information, they should also have access to available data to assist them in their decision making.

The U.S. Court of Appeals for the District of Columbia, in the matter of *Pearson v. Shalala*, ordered the FDA to clarify its significant scientific agreement (SSA) standard, reevaluate some previously denied claims, and permit health claims that do not meet the SSA standard if a disclaimer can ensure that the claim will not mislead consumers. It is too early to assess how this will change health claims information.

Recommendations:
A) Include warnings in dietary supplements regarding interactions with other dietary supplements, drugs, OTCs, foods, or other products with which interactions may occur, or with certain health conditions. If this information is not available, the labels should state so.

B) Warnings for pediatric use, use by pregnant or nursing women, and those whose immune system is compromised should be included.

Discussion: Many people have the misconception that so-called "natural" products are inherently safe. While much information is not known about safety, interactions with other drugs or foods, or the effect on various conditions or diseases, consumers should be made explicitly aware that these are all possibilities until proven otherwise. However, even when information becomes known, such as St. John's Wort decreasing the efficacy of some drugs, that information is not included in the product.

Issue 10: Oversight of the composition, quality, safety, labeling, and adverse events of botanical products should be performed by professionals with expertise in botanical products.

Recommendations:
A) Assure an adequate staff of professionals within the FDA with expertise in botanical products. This could include hiring people with these specific skills, and/or providing training to current staff.

Discussion: There have been recommendations to establish an Office of Botanical Products within FDA, and recommendations to establish an Office of Botanical Products outside of FDA. These recommendations stem largely from real or perceived concerns that the FDA will either not do its job in a timely, effective, or fair manner, or that it will overstep its authority and limit the access and availability of these products. Establishing another office within or outside of FDA would not address the lack of sufficient expertise in the government oversight of botanical products. The use of all dietary supplements, including botanicals, has grown remarkably since DSHEA was enacted in 1994, yet the FDA has not received appropriations commensurate with its new responsibilities. To provide greater leadership in the oversight of botanical products, FDA needs additional funds to hire qualified expertise and train existing staff to meet the increasing and ongoing demands of assuring both public access to and safety of botanical products.

Training, Education, Credentialing, and Licensure

Training and Education

The need for a national, basic CAM curriculum for all conventional health care professions at the undergraduate, graduate, and continuing education levels is evident. Curricula on CAM fundamentals should be developed in conjunction with CAM practitioners, professionals, and educators. Simultaneously, a national, basic curriculum for CAM institutions and training programs is needed, as is development and availability of continuing education for CAM practitioners. Curricula for CAM students and practitioners should include information on other CAM modalities, therapies, practices, and systems of health care, as well as conventional health care. CAM professions and practitioners are seeking parity with conventional health care in terms of access to funding and other resources for faculty, curricula, and program development. In addition, CAM professions and CAM students are seeking inclusion in student loan forgiveness and scholarship programs. While non-allopathic and non-osteopathic physicians desire postgraduate training, this type of training generally is not currently available. Instead of developing new postgraduate training programs, joint and/or cross training of CAM and conventional health care professionals can be a more feasible means of providing postgraduate training. Joint and/or cross training and faculty-exchange can be applied to undergraduate training and provide a foundation for future collaborative and pluralistic health care.

Credentialing and Licensure

Meaningful national standardization of CAM credentialing can be achieved by inclusive processes which should involve those organizations which represent CAM professions, practitioners, and educational institutions, along with other stakeholders. Licensing of CAM practitioners is clearly a function of the individual States and an issue characterized by a variety of views and absence of consensus. The impact of individual state licensing boards on conventional health care providers and CAM practitioners through promulgation, interpretation, and enforcement of regulations on CAM is significant, although these boards frequently lack CAM expertise. The collective power of state licensing boards is magnified in national organizations such as the Federation of State Medical Boards which can create national policy on CAM in the form of practice guidelines on integration of CAM by conventional physicians. Several different models for credentialing or licensing of CAM providers based on the interest and needs of individual states were offered as examples.. These options include mandatory licensure; voluntary registration, exemption from licensure such as the Minnesota model, or some variation or combination of these options.

Many providers want licensure to gain legitimacy and avoid liability under state licensure procedures and laws. Not all CAM practitioners believe licensure of the individual practitioner is the most appropriate process. These practitioners believe licensure is not appropriate for many

practices and would diminish the heart and soul of CAM practice. It is recognized that some of the interventions considered as CAM practices do not lend themselves to a licensure process. However, all practitioners are encouraged to disclose to the public their qualifications, education, training, certification or licenses to practice and to provide CAM services. The Commission has endorsed the need for accountability of all practitioners to the public.

Information Development and Dissemination

Internet, Radio, Television, and Print Media

The quality, accuracy, accessibility, and timeliness of the information on CAM practices and products varies greatly. Some media outlets provide accurate and current information, while many others contain inaccurate, misleading, or outdated information. The ability to control the quality of information available from many of these sources is extremely limited. The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers. In addition to the many CAM sites, there are numerous general health information sites that include CAM information.

Leaders in the field of CAM information, including foundations, academia, researchers, clinicians, private sector developers of CAM and general health information should consider the need for a public-private partnership to develop voluntary standards to promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM. A public education campaign that teaches people how to evaluate CAM information. A government sponsored partnership could bring more exposure, credibility, and balance to this effort and bring more focus to CAM. A public education campaign is also necessary because, regardless of the many efforts to improve the quality of CAM information, there will always be some information that is inaccurate, misleading, or out of date. Consumers are encouraged to evaluate or validate the information they get on all proposed treatments. In addition to the efforts of the National Center for Complementary and Alternative Medicine and their information center/clearinghouse activities, all Federal agencies should provide information on other CAM topics such as training, licensure, limitations to access and reimbursement, wellness, self-care, herbs, botanicals, legislation, diseases and so forth on relevant to the mission and activities of those organizations.

Media coverage of CAM benefits and cautions is often uneven, incomplete, or biased, and the availability of objective, comprehensive information about CAM from the Federal government is hampered because the government does not have a central place for the media to contact for information on CAM. The news media works on very short timelines and when they have a breaking story related to CAM, they need to have a source in the government to verify the information and provide balance to their stories. This would also include referrals to experts in different areas of CAM.

Issue 5: While the use of the internet has proliferated, there are still many people, especially elderly and low income people, who do not have personal access to the internet or knowledge of how to use the internet for CAM information. Public libraries exist in most communities and are a source of both internet access and guidance. However, many librarians lack training on how to access CAM information on the internet.

In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the

internet.

Discussion: The NLM has begun working directly with public libraries through the ALA to train local librarians to use the internet to find health information[3]. This effort could be enhanced to include more training and more focus on CAM.

Even for those without difficulty reading, there is a lack of CAM information that is targeted to specific population groups, despite the numerous indications that there is great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups.

Promote the development of CAM information that is targeted to different population groups.

Advertising, Marketing, and Labeling

Federal agencies with oversight of advertising of products and services need sufficient resources to identify false and deceptive CAM-related health claims and to take appropriate action to minimize the occurrence of these claims in all media. Of particular concern are the elderly and the non-English speaking multi-ethnic populations who may be particularly vulnerable or targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental. All populations are particularly susceptible to advertisements of CAM products or services that promise to cure health and other problems that are not being addressed through the conventional health care system or through legitimate CAM providers. This not only takes money away from people who have very little, but also can delay treatment of serious conditions until they become emergencies. The involvement of community leaders that are trusted by the populations they represent is essential to successfully educate vulnerable consumers and develop strategies to prevent their exploitation. Increased consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising is needed.

Access to and Delivery of CAM Practices and Products

Conventional medicine and practicing physicians' resistance to and lack of acceptance of CAM is cited as the basis for non-disclosure of CAM use by patients and as a barrier to access to CAM services. While the current reimbursement system is influenced by an evidenced-based approach, CAM generally lacks the type and amount of western scientific evidence on safety, indications, clinical effectiveness, and cost effectiveness sought by the current reimbursement system. Moreover, data on systems of care, multiple modalities, combination therapies, various delivery systems, and diverse populations are not available. The balance of consumer choice and public safety is evident in utilization of CAM as part of self-care, particularly in women's health, and is dependent on information which can be difficult to obtain, contradictory, and of questionable accuracy. Access to CAM by special populations such as HIV/AIDS, elderly, pediatrics, and cancer patients is characterized by more numerous and significant barriers than the general population. Cultural and linguistic barriers to access to CAM are associated with recent immigrants, native peoples, and an increasingly diverse population especially in the context of traditional healing.

Although there is strong support for integrating CAM practices and conventional or western medicine to form what is frequently termed "integrative medicine," there also is strong interest in maintaining CAM as a separate system of care. The CAM community is fragmented and does not possess unifying infrastructure or global consensus. Many of the problems of CAM service delivery are magnified by the challenges of service delivery to the growing numbers of uninsured and underinsured.

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- Place a major focus on wellness and recommend policies for reimbursing CAM providers for health promotion.

- Encourage the FDA to require nutritional supplement and herbal remedy manufacturers to label their products with warning against possible adverse effects or toxicity, and recommendations for proper usage.

- Institute a system, such as that proposed by the World Health Organization, to establish guidelines for the assessment of herbal products to ensure proper identity and quality of both raw materials and finished products.
- Involve well-trained herbalists in the scientific study of safety and efficacy of herbs.

- Require the FDA to recognize a "traditional medicines" category that would take into account the historical and traditional uses of herbs and permit manufacturers to put this information on the label.
- Develop "peer" education programs to disseminate credible information on CAM to minority and ethnic communities.

Coverage and Reimbursement of CAM Practices and Products

The authority to decide what health care services are covered and reimbursed is spread among a number of purchasers. Employers, in conjunction with insurance and managed care companies, determine what health benefits are covered for most Americans. The Federal government, with Congressional approval, makes decisions regarding the health benefits for Medicare, Medicaid (although this authority is shared with States), the military, veterans, Federal employees, and others. These benefits help provide a safety net for the uninsured and underinsured. States enhance the benefits available under Medicaid and for the medically indigent.

Payers and purchasers generally expressed openness to coverage of CAM services that demonstrate several factors:

- The services or products were no longer investigational;
- The services or products were proven safe and of consistent high quality;
- Criteria were available to determine when such services or products should be paid, such as medical necessity criteria; and
- Standards of practice were available for the service or product (not only for guiding utilization and treatment plans, but as a prospective defense against potential malpractice/medical liability suits).

Major considerations of practitioner qualification for coverage and reimbursement are related to education, training, licensure/certification, and credentialing discussed in another section of this report.

Another common thread identified to address the issue of coverage and reimbursement was the need for not only biomedical research but more clinical research, health services research, and health services demonstration projects, particularly on the cost effectiveness of CAM services, comparative studies with allopathic medicine, and the value of health, wellness(non-disease oriented), and prevention regimens.

CAM in Wellness, Self-Care and Prevention

The role of CAM in self-care, wellness, and prevention, like the role of CAM in illness and disease management, is an evolving phenomenon with boundaries that are sometime difficult to define. The areas where CAM in self-care, wellness, and prevention merge can have important consequences for the health and well-being of individuals, and can greatly impact the way that health care is delivered in this country.

The current health care system is disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating disease. Self-care, wellness, or prevention activities that are incorporated into the conventional health care system are, for the most part, disease screening (e.g. pap smears, mammograms, etc.), or offered in response to an already identified illness or condition (e.g. physical therapy, nutrition counseling, etc.) Self-care, wellness, and prevention activities frequently take place outside of the conventional health care system, and are reliant upon a person's initiative and ability (education, finances, availability of resources, etc.) to access and incorporate them into their life.

Many CAM therapies come from a holistic tradition of integrating body, mind, and spirit, and focus on optimal functioning to prevent, deter, or minimize illness and disease, and maximize one's potential to live life to the fullest. These qualities are the foundation of much of the interest in self-care, wellness, and prevention, which cover a wide range of activities such as support groups for people with cancer; meditation, yoga, or tai chi for relaxation and stress reduction; foods and dietary supplements to retain and enhance function and vitality; palliative care for the end of life; etc. All of these have a CAM component whose benefit is just beginning to be realized.

CAM-related self-care, wellness, and prevention activities need to be taught, promoted, and encouraged at all levels of the education spectrum, including the workplace, as part of a national health and wellness initiative for the entire population.

Schedule of Commission Meetings and Material Subjects Reviewed

July 13-14, 2000 - Planning Meeting

- Discussion of Vision, Issues and Concerns of the Commission Members on Issues Presented in Executive Order
- Development of Meeting Schedule
- Discussion of Website Development and Content

October 5-6, 2000 - Coordination of CAM Research & Achievements, Opportunities, Obstacles and Solutions

- Public Input and Research Priorities
- Federal Support for CAM Research
- Academic Centers and Support for CAM Research
- Research Support and Collaborations at the NIH
- Facilitating CAM Research and Regulatory Challenges
- Research in the Regulatory Framework
- Outcomes Research - Interface between CAM Research and Regulatory Agencies
- Outcomes Research - CAM Research and Experimental Study Design
- Guiding Principles of CAM Perspectives and Practices
- Support for CAM Research - The Not-for-Profit Sector
- Support for CAM Research - The Private Sector
- Support for CAM Research - Federal Agency Support

December 4-5, 2000 - Access and Delivery of CAM Services

- Utilization of CAM Services and Products
- Cost Effectiveness of Selected CAM Services
- Clinical Effectiveness of Selected CAM Services
- Use of CAM for Selected Health Conditions
- Issues in Integrating CAM in Service Delivery
- Meeting Public Needs: Systems of CAM Delivery at Community Health Clinics, in Private Practice and Hospital Based Centers, in Hospice Care, at Academic Research Centers and in Managed Care Organizations.

February 22–23, 2001 - Training, Education, Credentialing and Licensing of CAM Practices

- CAM Education and Training: Establishing Educational Programs
- Continuing CAM Education and Training - Building Knowledge and Skills
- CAM Credentialing and Licensure - Assuring Quality and Accountability in CAM Practices

March 26-27, 2001 - Development and Dissemination of CAM Information

- CAM in the Media - Newspapers, Magazines, Television and Radio
- CAM in the Media - The Internet
- Evaluation of available CAM Information
- Marketing and Advertising of CAM Services and Products

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities

- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

- Not-for-Profit Support for CAM Research
- Investigating the Scientific Bases of CAM Practices
- Approaches to Evaluating CAM Research Literature
- Challenges of CAM Research and Research Training
- Peer Reviews of CAM Research Results in the Published Literature

May 15-16, 2001 - Coverage and Reimbursement of CAM Services

- Health Care Financing in the United States
- Federal Purchasers
- State Perspectives
- Employer Coverage
- The Underinsured, Uninsured and Minorities
- Health Plans and CAM Benefits
- Healthcare Insurance - Providers Perspectives
- Evolving Health Care Systems

Town Hall Meetings

September 8, 2000 - San Francisco, CA
October 30-31, 2000 - Seattle, WA
January 23, 2001 - New York City, NY
March 16, 2001 - Minneapolis, MN

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems
- Dietary Supplements and Herbal Products
- Education of CAM Providers
- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

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Summary and Analysis of Themes and Recommendations on Education, Training, Licensing, and Credentialing

This is a summary and analysis of themes and recommendations derived from written and oral testimony from the February 22-23, 2001 meeting of the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) on Education, Training, Licensing, and Credentialing of Complementary and Alternative Medicine Practice, town hall meetings, and other topic-specific WHCCAMP meetings. In particular, the February 2001 WHCCAMP meeting--which included not only a significant outreach to CAM, conventional, and integrative professional organizations, but also three breakout session for the initial attempt at formulating draft policy recommendations--was used as the primary information source.

The following education and training themes have been identified:

- Need for national, basic undergraduate, graduate, and continuing education CAM curricula
- Parity of CAM professions and practitioners with conventional health care professions in access to educational and training funding and other resources
- Joint and cross training of CAM and conventional health professions in undergraduate and graduate programs.

The need for a national, basic CAM curriculum for all conventional health care professions at the undergraduate, graduate, and continuing education levels is evident. Curricula on CAM fundamentals should be developed in conjunction with CAM practitioners, professionals, and educators. Simultaneously, a national, basic curriculum for CAM institutions and training programs is needed, as is development and availability of continuing education for CAM practitioners. Curricula for CAM students and practitioners should include information on other CAM modalities, therapies, practices, and systems of health care, as well as conventional health care. CAM professions and practitioners are seeking parity with conventional health care in terms of access to funding and other resources for faculty, curricula, and program development. In addition, CAM professions and CAM students are seeking inclusion in student loan forgiveness and scholarship programs. While non-allopathic and non-osteopathic physicians desire postgraduate training, this type of training generally is not currently available. Instead of developing new postgraduate training programs, joint and/or cross training of CAM and conventional health care professionals can be a more feasible means of providing postgraduate training. Joint and/or cross training and faculty-exchange can be applied to undergraduate training and provide a foundation for future collaborative and pluralistic health care.

Similarly, the following credentialing and licensing themes have been detected:

- Potential for organizations representing CAM practitioners and CAM educational institutions to contribute to development of CAM credentialing standards
- Conflicting views on whether or not to endorse licensure of CAM practitioners
- Preeminent role of States in licensing

- Impact of state licensing boards and their national organizations (e.g., Federation of State Medical Boards) on policy and practice patterns.

Meaningful national standardization of CAM credentialing can be achieved by inclusive processes which should involve those organizations which represent CAM professions, practitioners, and educational institutions, along with other stakeholders. Licensing of CAM practitioners is clearly a function of the States and an issue characterized by a variety of views and absence of consensus. The impact of individual state licensing boards on conventional health care providers and CAM practitioners through promulgation, interpretation, and enforcement of regulations on CAM is significant, although these boards frequently lack CAM expertise. The collective power of state licensing boards is magnified in national organizations such as the Federal of States Medical Boards which can create national policy on CAM in the form of practice guidelines on integration of CAM by conventional physicians.

The following draft policy recommendations are the result of an iterative condensation process. The recommendations on education and training have been stratified into conventional health care professionals and CAM and further subdivided into undergraduate, graduate, and continuing education categories. The recommendations on credentialing and licensure have been grouped together. Recommendation on Traditional healing have not been included in any of these recommendations, since they are contained in the staff summaries of the three breakout session from the February 20001 WHCCAMP meeting which follow the recommendations below.

Licensed Conventional Health Care Professionals:

- Develop a generic national curriculum for health professionals on CAM therapies and the skills necessary to assess CAM use by patients and their families with an emphasis on therapeutic relationship and interpersonal skill development.
- Develop a train-the-trainer initiative to provide health professions faculty with the skills to teach future health care professionals about CAM therapies.
- Create an easily accessible, evidence-based data resource on CAM therapies designed for health professions educators [and clinicians].

Conventional Health Care Professionals:

Undergraduate Education:

- Convene education leadership conferences to develop standards of CAM education and position Titles VII and VIII of the PHS Act as vehicles for faculty development and curriculum development initiatives.
- Expose students to CAM early and have CAM practitioners/professionals introduce the philosophy and underlying concepts of CAM.
- Provide joint and cross training opportunities for conventional and CAM students.
- Include CAM on national board examinations

Graduate Education:

- While CAM education should be foundational at the undergraduate level, CAM education at the graduate level should provide opportunities for developing more sophisticated CAM skills in an interdisciplinary environment.
- Provide graduate education with opportunities for joint and cross training with CAM professions.

Continuing Education (CE):

- Develop CE for conventional health care professionals to provide a basic understanding of CAM and its ability to complement conventional treatment.
- Include CAM in health professions continuing education but consider financial barriers to CE.
- Require all health care professionals to receive some form of education in herbal therapies
- Involve CAM practitioners and educators in creating sources of complete information on herbs and drug interactions.
- Require course materials on herbal remedies to include the history of botanical medicines and extent of regulation of herbal products.

CAM

Undergraduate Education:

- Provide comparable access to funding and resource opportunities available to conventional health professions.
- Allow CAM students to participate in scholarship and loan repayment/forgiveness programs.
- Provide joint and cross training opportunities for CAM and conventional students.

Graduate Education:

- Provide comparable access to funding and resource opportunities available to conventional health professions.
- Require minimum levels of post-graduate education (such as residencies) for all non-allopathic and non-osteopathic physicians, leading to state certification or licensure.
- Provide joint (i.e., both CAM and conventional) and cross training graduate education opportunities.

Continuing Education (CE):

- Develop and provide appropriate CE for CAM practitioners.

Credentialing and Licensure:

- Articulate the following five principles to help guide states in developing regulations: (1) many providers want licensure to gain legitimacy and avoid criminal liability under medical license laws; (2) licensure is largely a matter of state law--states rely on the professional organizations to set standards and structures; (3) licensure has a potential dark side, in terms of diminishing the heart and soul of CAM practice; (4) several licensed CAM professions may share legal

authority to practice a given modality; and (5) adopt one of several different models for licensing CAM providers based on the state's interest: (a) mandatory licensure, (b) title licensure, (c) registration, (d) exemption, (the Minnesota model), or (e) some variation or combination of the first four.

- Promote state licensure or certification of CAM practitioners to regulate and provide a common standard of practice.
- Do not promote licensure, certification, or regulation of CAM practitioners.
- Develop consistent educational standards for CAM practitioners and accountability within the licensing and credentialing process.
- Develop national standards for CAM health care that are comprehensive, evidence-based, updated regularly, and accessible to everyone.
- Fund confidential, non-discoverable CAM quality improvement and peer review to enhance the quality of care.
- Develop incentives and an easy-to-use method(s) of reporting adverse reactions, interactions, and /or events associated with CAM products and practices and communicating this information to conventional and CAM providers as well as consumers.
- Require adequate record keeping of all providers of CAM products and practices so that outcomes can be complied and evaluated.
- Encourage full disclosure by all practitioners of their qualifications to provide CAM products and practices.

INSERT THE STAFF SUMMARIES OF THE THREE BREAKOUT SESSION FROM THE FEBRUARY 2001 MEETING ON EDUCATION AND TRAINING HERE

UNDERGOING REVISION

the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences, and erode consumer confidence.

Recommendations:

A) The FDA's Good Manufacturing Practices (GMP) for quality control, standardization, accurate labeling, should be issued and implemented.

B) Support programs (e.g.U.S. Pharmacopoeia) to assess the quality of dietary supplements and develop standards for certification of composition, quality, consistency, and safety.

The GMPs developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements. The GMPs are currently in OMB.

Issue 7: Some dietary supplements have been found to be contaminated with pesticides or infectious organisms such as salmonella..

Recommendations:

A) The FDA's Good Manufacturing Practices (GMP) for quality control, standardization, accurate labeling, should be issued and implemented.

B) Work with the Department of Agriculture and the Environmental Protection Agency, to inspect and identify sources of contamination.

C) Work with the World Health Organization to establish guidelines for to help assure the purity of herbal ingredients[2].

In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. While the extent of contamination of dietary supplements is not known, steps should be taken to assure that these products are free of contaminants.

Dietary supplements can make structure and function claims, but only approved drugs can make claims about preventing, treating, curing, or mitigating a disease. Since drug approval is a labor intensive process that requires substantial research, time, and money, most manufacturers of dietary supplements do not seek drug status for their products. The unintended effect is that in some instances where there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Information that may be beneficial to consumers is therefore limited and sometimes confusing.

Recommendations:

A) Include package inserts that explain current information on the product, as well as the limitations of that information.

Discussion: The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it