DRAFT RECOMMENDATION ON COLLABORATIVE RESEARCH ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

MORE EVIDENCE BASED ON RESEARCH IS NEEDED ON CAM PRODUCTS AND PRACTICES.

Because the public in large numbers is using complementary and alternative medicine (CAM), research on CAM products and practices is an important public health and safety issue. To address the need for dependable information on CAM products and procedures, research that meets high standards of design and execution is required. For many CAM products and practices there is little reliable information about safety and efficacy. Anecdotes, observations by individual practitioners, and small studies are important first steps in pursuing the development of the critical mass of objective, high quality data on the safety and efficacy of CAM practices and products.

PUBLIC SAFETY REQUIRES IMPROVED DIALOGUE AND COOPERATION BETWEEN THE CONVENTIONAL MEDICAL COMMUNITY AND THE CAM COMMUNITY.

Greater communication, understanding, and cooperation need to be fostered between the conventional medical community and the CAM community. The conventional medical research community and the CAM community should:

(1) reduce negative stereotyping;
(2) work on strengthening the dialogue between them;
(3) increase collaboration; and
(4) include each other on interdisciplinary advisory committees and at conferences designed to facilitate communication.

Because CAM is important to many members of the public, the conventionally-trained medical community needs to:

(1) be better trained and more knowledgeable about CAM;
(2) discuss patients' use of CAM products and procedures to be better informed about patients' total care and to avoid adverse reactions and drug/herb interactions; and
(3) be open and receptive to communication with CAM practitioners in a joint interest to improve patient care.

The CAM community needs to:

(1) understand the concerns of members of the conventional medical community about CAM practices and products;
(2) strengthen their professional organizations in the areas of training and credentialing;
(3) improve their ability to recognize complications and adverse interactions; and
(4) pursue the skills needed to collect reliable, objective data; serve on research teams, and learn the research skills and rigorous requirements of competing for research dollars,

AS IS THE CASE WITH CONVENTIONAL MEDICAL RESEARCH, GOOD SCIENTIFIC EVIDENCE ABOUT CAM MODALITIES REQUIRES CREATIVITY IN RESEARCH METHODOLOGY AND FLEXIBILITY IN IDENTIFYING PRELIMINARY DATA.

Randomized, controlled clinical trials (RTC) should be the method of choice whenever possible. As in challenges posed by conventional medical research questions, methodological adjustments to the study of CAM questions are possible, few are insoluble. CAM studies may be different in detail and types of complexity, but should adhere to the same basic elements–a hypothesis that can be tested, a good study design and research team, verifiable data, and objective conclusions. Findings should be as reproducible as possible. Individualized therapy and practitioner affect on outcome can be examined inside studies.

Pursue follow-up studies to increase the strength of the evidence.

Use a broad spectrum of data when studying herbs. Consider historical data in addition to practice-based and other more current data sources. (Also see section on industry below.)

Pursue ways to access international data (European and Asian), but evaluate the quality and objectivity of the data.

RESEARCH ON THE SCIENTIFIC BASIS OF CAM AND THE DEVELOPMENT OF AN ADEQUATE POOL OF WELL-TRAINED CAM RESEARCHERS REQUIRES STRONG COMMITMENT BY THE FEDERAL GOVERNMENT.

The Federal government should:

continue to strengthen support for

(1) rigorous research on the scientific basis of CAM and the training of conventional researchers to develop well designed and conducted studies;
(2) the training of CAM professionals to collect reliable and objective data, serve as members of collaborative research teams, and become fully trained investigators; and
(3) the infrastructure needed to carry out CAM research and the training of CAM researchers at both conventional medical research institutions and state-approved CAM educational facilities, and to stimulate cooperation between the conventional researchers and credentialed, licensed members of the CAM community. (Also see section below on academic health centers.)

ensure the appropriate inclusion of experts on CAM practices and products on peer review and advisory committees and institutional review boards (IRBs).

encourage more NIH Institutes to collaborate with the National Center for Complementary and Alternative Medicine (NCCAM), as good grant application opportunities arise, and to develop programs similar to the best case series program of the National Cancer Institute (NCI).

give strong support to the Office of Dietary Supplements (ODS), NIH, which is supporting studies in such areas as the synergistic properties of blended compounds, and encourage collaboration with NIH Institutes, such as the collaborations between the ODS and the National Institute of Environmental Health Sciences (NIEHS).

create incentives to motivate basic scientists to partner with CAM practitioners in areas relevant to both, such as the mechanisms of action of acupuncture or the study of complete biological systems.

support clinical research on promising products and modalities that are not patentable and are therefore not likely to attract the expenditure of research dollars by the pharmaceutical, biotechnology, or medical device industries. (Also see section on government agencies below.)

fund research on the top 20 most popular herbs, first to establish their safety and then in more depth to establish their efficacy.

revisit Medicare rules barring payment for treatments not normally covered, including many CAM modalities, which pose a significant obstacle for including elderly people on Medicare in CAM clinical trials.

invite the public to give their views in setting CAM research priorities, and invite CAM professionals to be included in research policy efforts.

leverage funds through collaboration with philanthropic and private organizations; invite representatives from these two sectors as well as CAM professionals to join advisory committees considering CAM research activities; and issue a list of meritorious grants that have not received support. (Also see section on private and philanthropic organizations below.)

increase opportunities to study CAM approaches to improving lifestyle, disease prevention, and quality of life, especially given an aging society, the prevalence of chronic diseases, and the need to strengthen health maintenance in younger people. Many people with chronic disorders turn to CAM.

encourage funding to universities to develop or strengthen programs that bring CAM clinical research into academic health centers, such as those at the University of Pennsylvania, Harvard, Duke, and the University of Maryland. (Also see academic health centers below.)

MAKE CAM PART OF THE MISSION OF ALL RELEVANT FEDERAL AGENCIES.

Strengthen CAM-related activities among the Federal agencies through a government-wide interagency committee that considers all aspects, other than research, that are relevant to the integration of CAM and collaborations with the private and not-for-profit sectors.

STRENGTHEN SUPPORT FOR CAM RESEARCH AS APPROPRIATE IN ALL AGENCIES WITH RESEARCH-RELATED RESPONSIBILITIES IN THEIR MISSION.

Adequately support CAM-related surveillance programs on utilization (CDC, HRSA) and adverse reactions (CDC, FDA), demonstration projects (NIH, HRSA, VA), and health services and cost effectiveness studies (HRSA, HCFA, AHRQ) and by other appropriate Federal agencies.

For example, support demonstration projects or outcomes studies to answer questions about the clinical effectiveness and cost effectiveness of CAM modalities as compared to conventional care.

Use a mechanism, similar to the Centers of Excellence Program in the Health Services and Resources Administration's Bureau of Health Professionals to help jumpstart the research efforts of licensed CAM professionals and institutions.

Support schools of public health to carry out research on CAM services.

GOVERNMENT REGULATORY AGENCIES (FEDERAL AND STATE) SHOULD HELP FACILITATE CAM RESEARCH IN THE PUBLIC INTEREST.

State Medical Boards

While recognizing that protecting the public from unqualified practitioners is of the utmost importance, the U.S. Federation of State Medical Boards should develop a process for meeting with CAM practitioners who believe in practice-based research but whose treatments are considered nonstandard to guide them to collaborative research environments that allow thinking outside the box, such as the best-case series program of the National Cancer Institute (NCI). State medical boards might also help researchers involved in CAM/conventional research efforts to navigate the institutional review board process and help IRB's to better evaluate CAM research protocols. (Also see section on academic health centers below.)

Explore what regulatory changes might be made to strengthen such CAM research efforts as the NCI program which can succeed only if practitioners feel secure in sharing their observations with a government entity.

Food and Drug Administration

Increase FDA funding to add adequate staff, who are well-versed in CAM and able to communicate well with the CAM community, in order to address the safe integration of CAM products into the broader regulatory process.

Consider regulatory changes in combination-product regulations to promote CAM research on botanicals. The product that is shown, through scientific evidence, to be clinically effective no

longer has to play the label game. However, the current FDA's drug development system's regulatory framework is tailored to single entity and synthetic drugs and thus poses a barrier to research on CAM products. The FDA guidance document on how to study botanicals and deal with the approval process is a good start, but it takes the single-entity paradigm and overlays it with botanical requirements..

Encourage FDA to promulgate additional chemistry and manufacturing standards to accommodate the reproducibility, stability, and constant dose issues related to CAM products.

Because it is so difficult to give exclusive rights to products that have been used for centuries, there is little research on these products.

In addition to providing support for research on CAM products, the Federal government should provide assistance to CAM companies for drug review costs. Small manufacturers, more often than not, do not have the money to support clinical trials. If the few companies that might be able to support clinical studies did so with positive results, they would be faced with the additional expenses associated either OTC, IND, or NDA reviews. In addition, while manufacturers who took the trouble and went to the expense of gaining approval would have the right to make a medical claim, other manufacturers could sell similar products as dietary supplements. Also, pharmaceutical companies that are increasing their involvement in the sale of dietary supplements are not investing in research on these products.

Establish a mechanism for reviewing problems CAM researchers may have getting INDs. Support a staff at the FDA to assess the appropriate classification of botanicals as treatments, and support more forceful advertising of FDA's health advisories on health interactions.

ACADEMIC HEALTH CENTERS SHOULD OVERCOME TABOOS ABOUT CAM AND HELP BRING ABOUT THE SAFE INTEGRATION OF CAM INTO MEDICAL PRACTICE THROUGH RESEARCH, RESEARCH TRAINING, AND MEDICAL EDUCATION.

Address education, clinical practice and research in any plan that incorporates CAM, and develop all three simultaneously.

Create steering committees that include individuals knowledgeable about CAM to advise IRB's on applications that require such input.

Integrate core knowledge about CAM modalities into the educational curriculum.

Sponsor meetings with institutions engaged in CAM research that want to exchange ideas and explore cooperation. Address the need to improve research capabilities at CAM institutions by partnering with institutions that have a research focus.

When creating a program or division that will include CAM, invite people representing opposing positions to join the planning panels.

Provide training programs, including pre- and post-doctoral opportunities and career tracks for capable individuals interested in the integration of CAM.

THERE IS A NEED FOR GREATER COVERAGE OF CAM RESEARCH RESULTS IN MEDICAL JOURNALS SO THAT ALL PRACTITIONERS AND THE PUBLIC ARE MORE AWARE OF BOTH THE POSITIVE VALUE OF CAM THERAPY AND ANY HARMFUL EFFECTS.

Mainstream medical journals need to publish carefully and fairly reviewed research results of CAM practices and products because many people use CAM products and visit CAM practitioners and medical students are expressing increased interest in gaining knowledge about CAM.

Recognizing that impartial review and the expectation of the highest research standards are required practice for all quality academic publications, the fine line between these requirements and publication bias must be carefully navigated and, if present, overcome.

Encourage mainstream journal editorial boards to consider the distinction between adhering to sound scientific principles and the design methodology itself in order to allow the flexibility that may be needed in evaluating the examination of a CAM question.

Ensure that the review of CAM research submissions include reviewers with knowledge about CAM.

Peer-reviewed journals should consider papers on any topic relevant to the practice of medicine and their physician/practitioner readers.

Continue to increased Federal support for CAM research and training of CAM researchers so that more high quality research articles are submitted for review.

ENCOURAGE GREATER INVOLVEMENT ON THE PART OF THE PRIVATE AND PHILANTHROPIC SECTORS IN RESEARCH ON CAM. FOR THE CAM INDUSTRY, ADEQUATE FUNDS AND RESEARCH COLLABORATIONS ARE ISSUES. FOR THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES, PROPRIETARY AND MARKET CONCERNS ARE ISSUES. FOR BOTH, REGULATORY ISSUES EXIST.

Create a model for coordination among the Federal, private and philanthropic sectors.

Encourage the CAM industry to

(1) submit studies to peer-reviewed journals; provide data from unpublished studies to assist in the selection of therapies for further study; and contribute to study design;

(2) cosponsor, symposia or conferences to provide networking opportunities for communication among practitioners, researchers, and industry; and
(3) develop a clinical trials guidance document outlining the standard components and proper design of study protocols.

The dietary supplement industry should use NIEHS National Toxicology Program data on the toxicity/carcinogenicity of these complex materials to study some of the untested dietary supplements in commerce. This is important because the basic safety and toxicity information is urgently needed and the NTP is limited in the number of (the many) products in popular use that it can test.

Consider providing pharmaceutical companies with incentives, such as process-use patents, and market protections, such as exclusivity periods, to stimulate investment in research and development of botanicals that meet the highest standards.

Convene meetings between companies and medical journal editorial boards to solicit recommendations for increasing acceptance of papers submitted by industry.

Involve industry early in the discussion and development of regulations that would affect facilitating research and research investment.

Develop a rigorous review process that would include both academic and industry scientists in the evaluation of CAM research proposals.

Increase the use of the NIH Small Business Innovation Research grant mechanism.

Stimulate the philanthropic sector to form a consortium of foundations interested in CAM and the public interest that would pool funds for the support of CAM research, which would reduce the risk for the individual organizations. The endeavor would require a scientific advisory board, a review process, and a mechanism for announcing funding competition up to so many dollars.

Encourage philanthropic organizations to (individually or cooperatively) provide seed money for or pilot studies, research training, coordinated research activities at academic health centers; the publication of research results; and the convening of conferences to assess the state of the science, and workshops on Federal and foundation grant processes and opportunities.

Encourage foundation sponsorship to convene a "think-tank" group of research methodologists and CAM professionals to discuss the methodological issues involved in CAM research.

Consider the advisability of changes in the not-for-profit law to permit grants to individuals.

Invite foundations to host face-to-face meetings with CAM professionals and make site visits to NIH-funded research centers.

draft

Recommendations

June 7, 2001
Corinne Axelrod

Draft Issues and Recommendations

CAM Information Development and Dissemination

A. Internet, Radio, Television, and Print Media

Issue 1: The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers. The NCCAM website reports receiving over half a million hits per month[1], the Ask Dr.Weil site reports up to 5 million page views per month[2], AlternativeMedicine.com reports 2 million hits per months[3], and WebMD reports 4.7 unique visits last December[4]. In addition to the many CAM sites, there are numerous general health information sites that include CAM information.

The quality, accuracy, accessibility, and timeliness of the information varies greatly. Some sites provide accurate and current information, while many others contain inaccurate, misleading, or outdated information. The ability to control the quality of information on the internet is extremely limited, due to both the nature of the technology and the First Amendment protection of free speech.

Recommendations:

A) Bring together leaders in the field of CAM internet information, including for- profit, non-profit, academia, researchers, clinicians, state and local sponsors of CAM internet sites and general health information sites, and other interested parties, for a public-private partnership to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites. These standards should include disclosure of any conflict of interest.

Once the voluntary standards are established, develop a process to review sites based on the established criteria. This could be done through a government- sponsored advisory board, with public members rotating for a specified period of time. No site will not be required to have a rating, and sites that have been reviewed and found in compliance with

[1] - Irene Lui, WHCCAMP testimony, March 26, 2001, p16

[2] - Andrew Weil, WHCCAMP testimony, March 26, 2001, p56

[3] - Burton Goldberg, WHCCAMP testimony, March 26, 2001, p

[4] - Susan Detwiler, WHCCAMP testimony, March 26, 2001, p210

the criteria can state so on their site (similar to the American Heart Association labels or the Good Housekeeping Seal of Approval). This would be an ongoing system with periodic reviews of sites to assure that they continue to be consistent with the standards.

B) Conduct a public education campaign that teaches people how to evaluate CAM information on the internet. This would be part of a larger public education campaign on CAM.

Discussion: There are several organizations that have developed standards for health sites on the internet. A non-profit membership organization called Hi-Ethics, Inc. has defined a set of criteria for health information on the internet that addresses quality, privacy, and disclosure. Membership is $20,000 annually, although membership will not be required to participate in their upcoming "E-Health Seal" program. Health on the Net, a Swiss - based organization, also has a list of ethical standards for health sites that address issues such as advertising, sponsorship, etc. and does not charge for membership. The Internet Healthcare Coalition charges $50 per year for membership and has more emphasis on the quality of the information. However, none of their Board of Directors or Advisory Board members listed on their internet site have any CAM credentials.

A public-private partnership between the government and industry to develop and implement voluntary standards is proposed because 1) many of the sites that are listed as members of one or more of these groups are the very sites that have been used as examples of the problems in CAM related web sites such as quality, accuracy, accessibility, timeliness, etc.; 2) these programs have not made an impact on consumers; and 3) most of these programs are focused on ethics related issues such as privacy, financial sponsorship, etc. and not on content, and the one that does address content is composed exclusively of representatives from conventional medicine. A government sponsored partnership could bring more exposure, credibility, and balance to this effort and bring more focus to CAM. These organizations could participate in this effort.

A public education campaign is also necessary because, regardless of all efforts to improve the quality of CAM information on the internet, there will always be some information that is inaccurate, misleading, or out of date. Consumers need to be able to recognize indications that a site is less than reputable, and individuals have a responsibility to evaluate or validate the information they get on the internet.

Issue 2: About 60 million American adults have used the internet for health information[5]. Some studies show that 70 % of health seekers search for illness-related information, compared to only 13% for health or wellness related information[6]. There is concern that employers or insurance companies can track which sites a person visits and could use this information to make decisions

[5] - Harrison Lee Raine, WHCCAMP testimony, March 26, p195

[6] - Susan Detwiler, WHCCAMP testimony, March 26, p204

regarding health insurance coverage, employment opportunities, etc. Some 85% of health seekers on the internet say they are concerned about their insurance company finding out such information and changing their insurance status or rates[7]. While there is no documented evidence that this is occurring, the possibility exists and steps should be taken to prevent this from becoming a problem.

Recommendations:
A) Encourage CAM sites to disclose if users are tracked and ~~what~~ how that information is utilized.

B) Explore the necessity of developing or amending current legislation or regulations to assure the protection of privacy of CAM health information seekers on the internet.

Discussion: Concerns about the privacy of health information has been a priority in Congress and the DHHS. Some of the organizations previously mentioned were formed in response to either the need for standards or the fear of restrictive legislation. Current legislation and regulations should be reviewed to determine if they are adequate to protect the privacy of health information seekers on the internet, and if these protections extend to users of CAM internet sites.

Issue 3: As part of its 1998 legislative mandate, NCCAM contracts with a clearinghouse to provide information on research findings to the public. However, there is no other centralized source of CAM information in the Federal government that provides information on other CAM topics such as training, licensure, access, reimbursement, wellness, self-care, herbs, botanicals, legislation, diseases, etc.

Recommendations:
A) Form a task force to determine how the Federal government could provide comprehensive CAM information to the public. This may include:

i) Expanding the scope of NCCAM's clearinghouse activities;
ii) Requiring other agencies such as the FDA, CDC, HRSA, etc. and other Departments such as the Department of Education and the Department of Agriculture to provide CAM information relevant to the mission and activities of those organizations;
iii) Establishing a centralized source of CAM information in DHHS to coordinate and develop CAM information for the public; etc.

Discussion: In several of the Town Hall meetings, people have recommended the establishment of a government clearinghouse for information on CAM. NCCAM has invested a substantial amount of time and resources to develop a clearinghouse for CAM information related to research. Other agencies, such as the FDA, also have a

[7] - Harrison Raine, WHCCAMP testimony March 26, p201

clearinghouse for consumer information, but doesn't specifically address CAM. The task force should look at what approach would be in the best interests of the public to provide comprehensive CAM information, either through expanding the current NCCAM clearinghouse or establishing another, more comprehensive clearinghouse, or creating a link between the NCCAM clearinghouse and other government clearinghouses specifically addressing CAM.

Issue 4: 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.[8]

Recommendations:.
A) Create a centralized office in the Office of the Secretary, DHHS, for information on CAM, with links to other resources such as the NCCAM.

Discussion: The news media works on very short timelines and when they have a breaking story related to CAM, they need to have a centralized 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.

Recommendations:
a) 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[9]. This effort could be enhanced to include more training and more focus on CAM.

Note: See also "Access"

Issue 6: According to the 1992 National Adult Literacy Survey, 48% of U.S. adults, or close to

---

[8] - David Schardt, WHCCAMP testimony, March 26, p.228

[9] - Sheldon Kotzin, WHCCAMP testimony March 24, p28

100 million Americans, have very limited literacy skills[10]. Factors that contribute to this are 1) lack of English skills, 2) reading disabilities, and 3) under-education[11]. While the use of CAM among this population is unknown, it is believed that a substantial number use CAM.[12].

Recommendations:
A) Promote the development of CAM information materials at a level that the general public can understand and utilize.

Issue 7: 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.

Recommendations:
A) Promote the development of CAM information that is targeted to different population groups.

Note: See also "Access"

Issue 8: There are many government agencies that provide information on diseases, conditions, or products and do not include any information on CAM in their fact sheets or internet sites.

Recommendations:
A) Have the Secretary, DHHS, direct all government agencies involved with health to include CAM- related information on their fact sheets and internet sites as appropriate. This could include information on wellness and CAM, CAM preventive and therapeutic measures, information relevant to specific diseases or conditions where appropriate, advise for patients to tell their physicians about any vitamins, herbals or botanicals they may be taking, etc. This information should emphasize CAM as part of the whole person wellness and healing process in concert with conventional care.

B) Where appropriate, encourage government sites that provide CAM information to describe both benefits and cautions.

Discussion: There has been some discussion to having the government develop a new web site that would list pros and cons of various therapies and interventions, much like a voter pamphlet provides both sides of an issue. While the concept has some merit, it may

---

[10] - U.S. Department of Education, National Center for Education Statistics,1992

[11] - ibid

[12] - Elmer Huerta, WHCCAMP testimony March 26, p.142, and Frances Brisbane, WHCCAMP testimony, March 27, p191

be more cost-effective and acceptable to have existing government web sites utilize this format to provide balanced information.

Issue 9: Consumers have no easy way of determining the training and ~~quality~~ qualifications of people offering CAM services or products.

Recommendations:
A) Government internet sites should provide information describing the training and certification requirements of CAM professionals, and link to states to provide information on licensure.

A) Government internet sites should have links to state licensing and disciplinary information sites.

Note: See also "Education and Training"

Discussion: There are numerous types of CAM providers with different levels of training and it is difficult for the public to understand the differences between them and make informed choices. This is due to several factors, including the variability of state scope of practice acts, the lack of definition of some professions (e.g. "Herbalist"), and the use of the same title by people of different levels of training (e.g. professional acupuncturists and physicians can both be called "acupuncturist"). To help assure public safety, information should also be available on any disciplinary actions against a practitioner.

Issue 10: Lack of information on effectiveness of CAM therapies is often cited as reason to not provide or reimburse for these services, but there is a significant amount of high quality CAM information published in other countries that is not available in English.

Recommendations:
A) Provide funding to i) identify barriers to identifying and translating relevant articles, reports, and other materials, ii) develop a strategy to overcome these barriers

Note: See also "Research"

B. Advertising, Marketing, and Labeling

Issue 1: The Federal Trade Commission (FTC) oversees advertising of products and services and brings actions against false and deceptive claims in the marketplace. To address what they call "an epidemic of health fraud on the internet"[13], the FTC established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims on the internet. Yet, they are only able to pursue a small percentage of the fraudulent claims identified.

Recommendation:
A) Provide additional support to the FTC to identify false and deceptive CAM-related health claims on the internet and to take appropriate action to minimize the occurrence of these claims.

Discussion:
Operation Cure.all is not looking exclusively at CAM related health sites, but many of the fraudulent claims are related to CAM products and services, often claiming to cure cancer, AIDS, and other diseases. In one afternoon of internet surveillance, 400 clearly fraudulent health claims were identified. After sending an email warning, 80 of these sites either dropped the questionable claim or took down the site down. Of the 320 that did not respond to the email warning, the FTC was able to take action on only 2. If the perception exists that less than one percent of identified fraudulent claims are pursued, it is likely that there will be even more deceptive CAM advertising.

Issue 2: Some populations, such as the recently arrived Hispanic immigrant populations, other immigrants and non-English speaking persons, the elderly, etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television.[14]

Recommendations:
A) Provide additional support to the FTC to monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations.

B) Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

---

[13] - Michele Rusk, WHCCAMP testimony, March 26, p.276

[14] - Elmer Huerta, WHCCAMP testimony March 26, p.145

Discussion: Due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, and other similar factors, certain 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.

Note: See also "Access"

Issue 3: Legitimate companies that comply with current anti-deception and substantiation standards can lose market share and suffer financially as a result of companies using deceptive advertising[15].

Recommendation:
A) Provide adequate funding to the FTC to enforce current requirements for substantiation of advertising and marketing claims.

B) Increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

Discussion: Companies that invest their resources to comply with FTC regulations and provide truthful information to the public should not be put at a disadvantage in the marketplace.

Issue 4: People providing CAM therapies can have significant differences in their level and type of training and it is difficult for consumers to understand the differences and make informed choices.

Recommendation:
A) Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

B) Encourage States and local governments to make information on state guidelines, requirements, and licensure of CAM providers readily available to the public.

Discussion: People can advertise themselves as a practitioner of a CAM therapy, yet licensing requirements, certification, scope of practice, regulations, and even definitions vary considerably from state to state. An herbalist may have years of training or no training at all. Acupuncture can be practiced in some states by practitioners of other

[15] - Sara Taylor, WHCCAMP testimony, March 26, p.288

health modalities (e.g. physicians, dentists, podiatrists, etc.) with no additional training, or by someone who has spent several years in acupuncture-specific training. Some practices require licensure, others do not. Information that explains a person's level and scope of training will help consumers to make informed choices in their selection of a practitioner.

Note: See also "Education and Training"

Issue 5: The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies mostly on its adverse event reporting system to identify safety problems. The system is entirely voluntary, and events can be reported by both consumers and health professionals. However, a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with dietary supplements[16].

Recommendation:

A) Strengthen the adverse event reporting system so that serious or clinically significant adverse events[17] related to dietary supplements can be identified and contained in a timely manner and associated morbidity and mortality can be reduced. This may include requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs), requiring manufacturers to register with the FDA so that the FDA can identify and contact them if an adverse event is reported, developing a data base of manufacturers and product ingredients, etc.

B) Strengthen outreach activities to health professionals and consumers regarding the importance of reporting adverse events and how to use the system.

Discussion: In April, 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it "an inadequate safety valve". This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary supplements and provides numerous recommendations to improve the system. Some of these recommendations are included in the FDA's 10- year strategic plan. Recommendations to require manufacturer and product registration and mandatory manufacturer reporting of adverse events may require legislative authority, while most recommendations can be implemented administratively with additional funding. The recommendations do not appear to be in conflict with the intent of DSHEA, and would be beneficial in protecting public health and safety.

---

[16] - DHHS, OIG, Adverse Event Reporting for Dietary Supplements, April 2001

[17] - These terms are defined under Medwatch and in the FDA's Standard Operating Procedures of 1999.

Note: See also "Research"

Issue 6: Some dietary supplements do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain ingredients other than those listed on the label. If 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.

Discussion: ConsumerLab testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and phenol levels that they claimed the product contained.[18] Testing of 13 SAMe products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable level).[19] Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies[20]. There are numerous other examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. 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

---

[18] - ConsumerLab.com, September 2000

[19] - ConsumerLab.com, January 2000

[20] - FDA

purity of herbal ingredients[21].

Discussion: In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. In April, 2001, Solgar Vitamin and Herb Company recalled some dietary supplements due to salmonella contamination of raw materials supplied by American Laboratories. 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[22]. 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.

---

[21] - Dennis Awang, WHCCAMP testimony, December 3 2000

[22] - University of California, Cooperative Extension, Environmental Toxicology Newsletter, Vol. 19, No.1, 1999

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.

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 CAM products.

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.

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]. or publicly available source

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 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.
- 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 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) graduate education training opportunities.

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.
- 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.

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.

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.

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.

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.

Recommendations on Coverage and Reimbursement of CAM Services

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 – often only with Congressional approval -- makes decisions regarding the health benefits for Medicare, Medicaid (although this authority is shared with States), the military, veterans, Federal employees, etc. and helps provide a safety net for the uninsured and underinsured. States enhance the benefits available under Medicaid and for the medically indigent.

Presentations at the recent meeting on coverage and payment identified key issue areas and recommendations. Payers and purchasers generally expressed openness to coverage of CAM services that demonstate 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
- 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).

Related to these are issues of practitioner qualification for coverage and reimbursement: education, training, licensure/certification, and credentialing.

Another common thread among the presenters were the need for not only biomedical research but more clinical research, health services research, and health services demonstrations, particularly on the cost and efficacy of CAM services, comparative studies with allopathic medicine, and the value of health (non-disease oriented) regimens.

The recommendations that follow were drawn from the May meeting as well as other Commission meetings and Town Hall meetings.

Health Services/Cost Effectiveness Research and Demonstrations

Congress could instruct public agencies (e.g., NIH, AHRQ, HCFA, DOD, VA, HRSA) to fund research and demonstrations on the clinical effectiveness of various CAM approaches and on the relative costs of more conventional allopathic treatments and of CAM treatments for the same condition.

- Investigate the outcomes and value of CAM networks and the use of complementary/integrative teams of practitioners.

Develop a unified data tracking system for clinical outcomes and costs that allows research from public and private sectors to be aggregated across institutions.

Fund the needed clinical and health services research/demonstrations from both public and private sources. For example: NIH, AHRQ, CDC, FDA, HCFA, DOD, VA, insurance companies, managed care companies, employers, health care business entities (such as pharmaceutical companies) associations, foundations, etc.

Encourage HCFA to develop a HCFA demonstration project with selected HMOs:

- Cover reimbursement for evidence-based CAM procedures as part of comprehensive case management of persons with chronic disease.
- Utilize Medicare+Choice organizations (M+COs) – i.e., Medicare HMOs – and Medicaid managed care plans, selecting those HMOs whose physician leadership has demonstrated a commitment to evidence-based medicine and pursuit of excellence in high quality case management.
-

WHCCAMP and Congress could encourage one or more Fortune Top 50 companies to callaborate with HCFA by creating its own demonstration project, examining the feasibility of using this approach with a broad-based employee population and testing the impact on overall medical costs.

WHCCAMP and Congress could encourage HCFA to set up an additional 5-year demonstration project that reimburses Medicare enrollees within a single state or area of a state for costs of services provided by certified CAM practitioners or for herbs and supplements. There would be a cap on reimbursements equivalent to current proposals for prescription drug relief. The project would compare total Medicare costs for that demonstration area with costs incurred by an equivalent Medicare population of similar size elsewhere.

Conduct research to evaluate the effectiveness of CAM services in improving health outcomes. The impact of CAM services on improving health and moderating costs must be studied and proven to be of value, based on clinical evidence. Such studies should use metrics that will withstand the legal and professional scrutiny to which plans are subject.

- Study how CAM care relates to and supports conventional biomedical services. Can CAM services substitute appropriately for some biomedical services, or will CAM always be additive?
- The impact of CAM services on improving health and moderating health care costs should be studied before consumers become entrenched in new patterns of care.

<u>Federal and State</u>

Establish within the federal bureau that funds [community] health centers an Integrative Medicine and Alternative Health Practices – or IMAHP Initiative to

provide information and track the use of alternative therapies within these health centers.

Address the funding barrier. At DHHS, increase funding and/or earmark funds for identified populations to benefit from CAM therapies, not only at the Bureau of Primary Health, but also the Indian Health Service, Maternal and Child Health Program, Ryan White AIDS Program, among others.

- Open the National Health Service Corps to CAM practitioners.

Medicaid and the Child Health Insurance Program should provide coverage for appropriate CAM therapies.

CAM practitioners should apply to become members of various committees, working groups, professional panels, etc. (such as the Medicare Coverage Advisory Committee) in order to assure that CAM interests are represented and to help influence coverage, payment, and research decisions within the broader health care industry.

Explore approaches to expanding Medicare coverage other than through demonstrations or national coverage decisions, e.g., work with local carrier review committees, explore coverage under Medicare's "incident to" policy.

Explore approaches to expanding coverage for federal employees under FEHBP, the military, and veterans to clinically effective CAM services.

Creating a Level Playing Field

Information [on the clinical and cost effectiveness of various allopathic and CAM treatments for the same condition], supplemented by other information found in peer-reviewed journal, should be brought together and made available in an easily accessible website.

- The website should be updated constantly as new data becomes available.
- The public agency responsible for this website should be instructed to draw this information to the attention of insurance companies, managed care organizations, HCFA, and the continuing medical education programs of medical schools on an ongoing basis.
- Information should be made available not only for professionals, but also for consumers.

Congress could amend the tax laws to allow performance-based tax credits to businesses that provide disease-prevention and health-improvement programs to their employees. As part of this legislation, Congress could encourage work-site wellness programs to include relevant complementary and altenatitive health ingredients as part of these wellness services.

Develop tax policy that gives consumers of CAM therapies an equivalent "pre-tax benefit" as consumers have with health insurance.

Insurers and "purchasers" of health plans (e.g. employers, Medicare, Medicaid, etc.) should be educated in CAM and encouraged to treat CAM practitioners and CAM services equitably with conventional practitioners and allopathic medicine.

Address appropriately the obstacles to including CAM services in health plan packages.

- Contracted benefits must be clinically and legally defensible. Does the CAM service(s) meet contractual definitions, or investigational and medical necessity criteria? This would require outcome measures and data, expert consensus panels, and criteria on the indications for particular services (usually developed by professional organizations, government bodies such as NIH or AHRQ, academic centers, or consulting organizations).
- Are there data on local CAM providers and the substitution between biomedical and CAM services that would be necessary to project a premium for an open-ended benefit?
- For coordinated, high quality care, how would CAM utilization information be shared with allopathic physicians (e.g., a PCP)?
- How do licensure and scope of practice laws affect coverage of CAM? What is the health plan liability associated with credentialing unlicensed CAM providers for network participation?

Analyze the coding issues for CAM services, including the impact of HIPAA. (These coding issues affect progress on research and demonstrations, as well as reimbursement.) The coding system should recognize the time, training, and experience of CAM providers and CAM approaches to health care, and should not be solely based on allopathic parameter or disease-based diagnoses.

Develop strategies for achieving consistent national standards for education, training, and licensure that are appropriate for the various CAM therapies. Develop a strategy for informing purchasers of health care, and health insurers, of progress toward these standards with specific therapies.

Insurers should offer a partial "cash-out" for patients with catastrophic or terminal illnesses (with written consent) to allow them to use CAM services.

<u>Coverage and Reimbursement</u>

Providers and third party payers should consider cultural diversity and standards in their efforts to improve cultural competency of their health care delivery system.

Purchasers of health care (employers, HCFA, OPM, DOD, etc.) and health insurers should consider reimbursement for clinically effective CAM services and products. (Some recommendations were made for specific services such as, second opinions by CAM practitioners, acupuncture and Oriental medicine, non-prescription substances prescribed by licensed providers, etc.)

Three Top Research Issues/Recommendations

1. High quality, evidence-based research on CAM leads to credibility and credibility leads to acceptance and integration into medical practice.

Public safety requires better communication between the conventional biomedical research community and the CAM community.

In the public's interest, all Federal agencies that have research and research-related responsibilities should be supported in their activities in carrying out their responsibilities related to CAM.

Top 3 issue for Information Development and Dissemination:

1) Fund FDA to fully implement DSHEA to strengthen the adverse event reporting system, implement the GMPs when they are released by OMB, and increase staff with expertise in botanical products.

2) Increase funding to the FTC to identify false and deceptive CAM-related health claims.

3) Create a centralized office in the Office of the Secretary, DHHS, to coordinate CAM activities throughout the department and provide a centralized place for information on all aspects of CAM for the public, health care professionals, and the media.

Top 3 issue for Self-care, Wellness, and Prevention:

1) Develop a public information campaign to promote and teach self-care, wellness, and prevention practices, starting in elementary schools.

2) Fund Medicare and Medicaid demonstration programs for self-care, wellness, and prevention programs.

3) Establish a Wellness Center at NIH to support research in self-care, wellness, and prevention.

Kaczmarczyk, Joseph (NCCAM)

From: Kaczmarczyk, Joseph (NCCAM)
Sent: Monday, June 11, 2001 2:39 PM
To: Groft, Stephen (NCCAM)
Cc: Chang, Michele (NCCAM)
Subject: Top Three Issues

11 June 10

Steve,

As requested, here, in my opinion, are the top three issues.

Overarching: Permanent Presence

Access and Delivery:

- Balance of consumer choice and public health/safety (particularly "unguided" self-care)
- Integration vs. CAM Autonomy (to integrate or not to integrate) [N.B., Conventional health care carries out integration by incorporating selected CAM modalities, while CAM espouses integration that includes pluralism and preservation of entire systems of healing.]
- Reduction/elimination of health disparities through CAM access for uninsured and underinsured populations (e.g., adequate funding of community and migrant health centers to provide CAM/integrative services)

Education, Training, Licensing, and Credentialing:

- National basic CAM undergraduate, graduate, and continuing education curricula (for licensed conventional health care professionals as well as CAM practitioners) that include cross-training
- Parity with conventional health care professions in terms of CAM professions/practitioners access to eudcational/trainig funding and other resources
- Licensure (to license *v* not to license)

Joe

Commissioner's

Comment

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

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

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

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

Issues Before the Commission

Coordination of CAM Research - Opportunities, Obstacles, and Solutions

Access and Delivery of Cam Practices and Products - Clinical effectiveness, Cost effectiveness, Integrating CAM Practices in Service Delivery

Training, Education, Credentialing, and Licensing of CAM Practices - Assuring Quality and Accountability

Development and Dissemination of CAM Information for Health Care Providers and the Public

CAM in Wellness - Nutrition , Children, Families, Communities

CAM and Self-Care

Reimbursement and Coverage of CAM Practices and Products

Discussion

Issues Not Considered that Should Have Been Considered

Controversial Topic Areas

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

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

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

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

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

Table of Contents

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

Part IV. Coordination of CAM Research
(Gerry Pollen)

(A) Current Efforts and Status of CAM Research

(1) Federal Efforts
(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
  (3) Research in the Regulatory Framework
  (4) Facilitating CAM Research and Regulatory Challenges
(D) The need to Coordinate CAM Research and Development Efforts
  (1) Collaborative Efforts
  (2) Research Areas in Need of Coordinated Efforts
  (3) Underutilized Coordinating Bodies
  (4) Evaluation of Interventions by non-traditional Research methods

(E) Support for Research
  (1) Basic Research
  (2) Clinical Research
  (3) Health Services Research
  (4) Epidemiological/Follow-up Long Term Studies
  (5) Existing Sources of Funding
  (6) Research Opportunities In Waiting
  (7) The Research Community; Perceptions and Realities of Support for CAM Research
  (8) Peer Review of CAM Research Proposals

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

(A) The Availability of CAM Interventions and Products
(B) Concerns About Liability
(C) CAM Delivery Systems
  (1) Private Sector
    (a) Private Practice Based
    (b) Community Hospitals
    (c) Academic Health Centers
    (d) Managed Care Organizations

(8) State and Local Government Supported
Washington
Minnesota
Ohio
(9) Federal Sector Activities

(H) Cost Effectiveness of CAM Interventions

Part VI. Reimbursement for CAM Interventions and Products **(Maureen Miller) (to be expanded after meeting)**
(A) Financing CAM Interventions, Services and Products
(B) Medical Insurance Industry, Criteria for Reimbursement
(C) Eligibility Requirements for Medical and Medicare
(D) Reimbursement/coverage in the Managed Care Setting
(E) Gaps in Reimbursement and Coverage

PartVII. The Education and Training of CAM Researchers and Health Care Practitioners **(Dr. Joe Kaczmarczyk) (to be expanded after meeting)**
(A) Attracting and Retaining CAM Research Investigators
(B) Research Training and Career Development of CAM Practitioners
(C) Emerging CAM Professions
(D) Introducing CAM Intervention Theory to the Research Community and to Healthcare Practitioners
(1) Undergraduate Education
(2) Graduate Education
(3) Continuing Education of Health Care Providers
(E) Licensure, Certification and Credentialing of CAM Practitioners

Part VIII. Development and Delivery of Information on CAM Interventions and Products **(Corinne Axelrod) (to be expanded after meeting)**
(A) The need for Information
(1) Public
(2) Patients
(3) Health Care Providers
(4) CAM Practitioners
(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

Part IX. A Vision for the Future
(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

DRAFT

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

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

Part IV. Coordination of CAM Research
(Gerry Pollen)

(A) Current Efforts and Status of CAM Research

(1) Federal Efforts
(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
  (3) Research in the Regulatory Framework
  (4) Facilitating CAM Research and Regulatory Challenges
(D) The need to Coordinate CAM Research and Development Efforts
  (1) Collaborative Efforts
  (2) Research Areas in Need of Coordinated Efforts
  (3) Underutilized Coordinating Bodies
  (4) Evaluation of Interventions by non-traditional Research methods

(E) Support for Research
  (1) Basic Research
  (2) Clinical Research
  (3) Health Services Research
  (4) Epidemiological/Follow-up Long Term Studies
  (5) Existing Sources of Funding
  (6) Research Opportunities In Waiting
  (7) The Research Community; Perceptions and Realities of Support for CAM Research
  (8) Peer Review of CAM Research Proposals

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

(A) The Availability of CAM Interventions and Products
(B) Concerns About Liability
(C) CAM Delivery Systems
  (1) Private Sector
    (a) Private Practice Based
    (b) Community Hospitals
    (c) Academic Health Centers
    (d) Managed Care Organizations

(8) State and Local Government Supported
Washington
Minnesota
Ohio
(9) Federal Sector Activities

(H) Cost Effectiveness of CAM Interventions

Part VI. Reimbursement for CAM Interventions and Products **(Maureen Miller) (to be expanded after meeting)**

(A) Financing CAM Interventions, Services and Products
(B) Medical Insurance Industry, Criteria for Reimbursement
(C) Eligibility Requirements for Medical and Medicare
(D) Reimbursement/coverage in the Managed Care Setting
(E) Gaps in Reimbursement and Coverage

PartVII. The Education and Training of CAM Researchers and Health Care Practitioners **(Dr. Joe Kaczmarczyk) (to be expanded after meeting)**

(A) Attracting and Retaining CAM Research Investigators
(B) Research Training and Career Development of CAM Practitioners
(C) Emerging CAM Professions
(D) Introducing CAM Intervention Theory to the Research Community and to Healthcare Practitioners
(1) Undergraduate Education
(2) Graduate Education
(3) Continuing Education of Health Care Providers
(E) Licensure, Certification and Credentialing of CAM Practitioners

Part VIII. Development and Delivery of Information on CAM Interventions and Products **(Corinne Axelrod) (to be expanded after meeting)**

(A) The need for Information
(1) Public
(2) Patients
(3) Health Care Providers
(4) CAM Practitioners
(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

Part IX. A Vision for the Future

(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

Groft, Stephen (NCCAM)

From: Kaczmarczyk, Joseph (NCCAM)
Sent: Monday, June 11, 2001 1:39 PM
To: Groft, Stephen (NCCAM); Chang, Michele (NCCAM); Pollen, Geraldine (NCCAM); Axelrod, Corinne (NCCAM); Miller, Maureen (NCCAM); Fisher, Ken (NCCAM)
Subject: FW: FW: Commissioner Calls

11 June 01

Here is Wayne's response.
Joe

-----Original Message-----
From: WBJonas@aol.com [mailto:WBJonas@aol.com]
Sent: Friday, June 08, 2001 12:52 PM
To: Kaczmarczyk, Joseph (NCCAM)
Subject: Re: FW: Commissioner Calls

Joe,

Finally had a breather to look at these and my suggestions are straight forward. I have inserted them below. Call me if you need to (pager 877-395-4899) otherwise take them for what they are worth. ($0.02) My resonses are underlined.

Best,

Wayne

Commission Questions.

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

More and better research is needed which will only be addressed with longterm strategies. There should be an investment in an infrastructure development of research. This means special efforts for building research facilities, training investigators and stimulating basic science research.

The public must be more integrally involved in setting priorities and directing Integrative health services. Methods of assuring educated public involvement and power are needed such as training and funding priority input.

Ways to provide incentives for the private sector to move into research, education and services in integrating CAM into the health care system are especially important.

> (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?)

It would be good to get some specific input for federal agencies as to how the commission report and federal can facilitate their involvement in integration of CAM into the health care. What do they need from the government?

>

> (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)

>
I hope the July meeting can be reviewing a draft of the commission recommendations that have been listed by all so far and that a facilitator can be available to help us prioritize these recommendations.

Large group work would be most appropriate for the above if a skilled facilitator and a summary of potential recommendations is available.

1. Summaries of previous meetings with key points (as done for the initial research meeting and some of the town meetings) would be especially helpful.
2. A print out of the names, addresses and topical summaries (or simply a reminder title) of each presenter over the last year would also help us see an overview of what we have seen and are dealing with.
3. A clear summary of our charge, the agencies we are making recommendations to and their primary mission would be the final background material that would be helpful.

> (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?

Yes

Groft, Stephen (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Friday, June 08, 2001 11:31 AM
To: Albrecht, Joan (NCCAM); Axelrod, Corinne (NCCAM); Fisher, Ken (NCCAM); Gerry Pollen (E-mail); Jim Swyers (E-mail); Joe Kaczmarczyk (E-mail); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Mylene Huynh; Steve Groft (E-mail)
Subject: Joe's Calls to Commissioners

FYI for our staff meeting on Monday (9:00 a.m.)

-----Original Message-----
From: Kaczmarczyk, Joseph (NCCAM)
Sent: Thursday, June 07, 2001 8:24 PM
To: Chang, Michele (NCCAM)
Subject: Callss to Commissioners

7 June 01

Michele,

Here is a summary of my calls to the Comissioners. Please distribute this to the appropriate persons.

Emerging Themes and Key Issues:
1. Permanent Office
2. Licensure
3. Level the playing field for CAM (Resource and funding comparability with conventional health care)
4. Portable national standards (including credentialing) developed by CAM professional organizations
5. Integration

Issues Requiring Further Discussion:
1. Licensure
2. Permanent Office
3. Integration
4. Public information dissemination (framed in the context of safety)

Expectations Future WHCCAMP Meetings:
1. Becoming individually and collectively more politically astute in topics discussed and recommendations made
2. Reslove licensure issues
3. Produce 6 key legislative recommendations for the Interim report to be used subsequently by Congress for appropriations

Process Preference:
Small group discussions preferred by 2, while large/plenary group process preferred by 1.

Thank you,
Joe

Tom Chappell (interviewer: Ken) May 31, 2001

Key Issues and Recommendations Emerging

1. Provide equal opportunity for CAM practitioners in terms of research support, access and delivery to consumers, licencing, and reimbursement. Concept of level playing field in health care delivery.

2. Enhanced support system in regard to government funding of CAM research, training, and education.

3. Integration and promotion thereof for the entire health care system. (Integration should be voluntary, but integrative medicine and health care should be promoted).

4. Build greater scientific credibility for CAM by better research protocols and study designs, guidelines on research, focus on outcomes research, collaborative team efforts.

5. Federal policies must be committed to assurance of the safety of botanicals and like products. Government (and the WHC) represents consumers in the area of safety.

6. Efficacy is in the eyes of the beholder; it is not a Federal government function. Federal policies should be driven by protection of the public, not by issue related to efficacy of products.

7. Start education on wellness, self care and health early including access to CAM (Adopt the world view of CAM)

Specific Ways to Address these Key Points

1. Initial thrust to develop and expand partnership models such as the work in Seattle and the Aetna(?) efforts. Identify a number of integrative service delivery efforts that are successful and build, test, or do demonstration projects using these as model approaches.

2. Develop strategic demonstration projects to transfer their approaches to the health care delivery system; for example, use the Eisenberg model.

3. In the above efforts, stress building of public/private models and programs as a way to strengthen partnerships.

Topics Needing More Input

1. We have had enough hearings, now it is our responsibility to put it all together. WHC needs more time to discuss and develop major recommendations.

2. A major thrust should include creation of partnership models using the strengths and resources identified in the testimony to forge stronger integrated/programmatic partnerships. Be entrepreneurial!

Process for July and October Meetings

July - focus on closure of concepts and recommendations (general concurrence rather than consensus).

October- develop implementation strategies

Feb

Availability July 1st?

"If fellowship is the goal, then family comes first". If the whole WHC agrees, I'll be there.

(No need for a private or closed meeting; I for one will say what I think- private or public)

<Chappell.Fisher.wpd>

Interview Overlapping/Common Issues/Recommendations
(Chappell; Gutierrez: Rolin)

1. Research support from public and private resources

2. Improved research protocols and demonstration projects that integrate CAM

3. Develop role of Federal and States in more communication of qualifications of practitioners as well as guidelines on competency

4. Safety and quality(composition, consistency) of products is a Government responsibility; i.e. consumer protection.

5. Consider special needs or aspects of different cultures.

6. Greater communication among CAM professionals

7. Greater emphasis on early education

8. Demonstration projects, especially integrative medical ccare delivery

Veronica Gutierrez (interviewer: Ken) May 30, 2001

Key Issues and Recommendations Emerging

Veronica identified a large number of issues and recommendations, so the presentation is via bullets, rather than text.

1.Research:

- need for model protocols applicable to CAM beyond DBPCRCT (these should be out-of-the-box models with wide applicability)
- in the above, promote interdisciplinary approaches and methodology
- identify the current policies that restrict CAM research
- promote research that includes quality of life, psycho-social, and wellness endpoints
- increase research on the needs of culturally diverse groups

CAM colleges and universities should be encouraged to be research centers with emphasis or favor towards interdisciplinary teams

-need for more and better information from public and private sources of research funding and grant requirements for CAM research

-need review of CAM grants to date by Federal agencies to determine areas and balance of current and past funding of research

-identify by line item in appropriations, dollars earmarked for CAM research on quality of life, wellness research, especially interdisciplinary projects

-increase efforts to regionalize research awards, i.e. spread the wealth around the USA

-more emphasis on research that focuses on social, cultural, dietary, ethnic, etc needs and factors that impact wellness and prioritize these for future emphasis in not only research but in education and self-help and care

- research on determining if wellness is cost effective

2. Information Dissemination

- need for more and better information on dietary supplement quality and product consistency, as well as food and drug interactions with dietary supplements
- more and better information on intent and purpose of health care procedures (across the board, not just CAM)

-more information to public on level of training and credentialing. Maybe even Federal guidelines or recommendations to States on minimum credentials

-greater efforts at health care awareness, including CAM, starting at the preschool level

-establish a Federal Office(?) Agency(?) Outside FDA to address CAM issue and information dissemination

-all CAM professions should publicly state what they do so that everyone knows what they do in prevention and treatment

-make publicly available a listing of State laws and regulations by profession in regard to educational requirements, licencing, credentialing, regulation of practice, etc.

-all professions and practitioners should have and use a consent for care and disclosure form (Is there a need for a Federal model guideline, regulation, or law here?)

-begin education on health care at preschool level. Get junk food machines out of schools

- reconsider requirements for mandatory vaccinations and allow full freedom in health care choices

3. Access and Delivery

- full disclosure by all practitioners
- more demonstration project for CAM using 2 or 3 states or the military as models
-tax incentives for employers that agree to participate in demonstration projects
-expand office hours and teaching sites by tax incentives (across the board in all health care)
-promote freedom of choice for all citizens in health care (related to information dissemination and definition of what CAM is being available publicly and understood
-approach integration of professions and individual modality practice as equally acceptable approaches
- need more detailed and improved billing codes for general use
- examine use of teaching clinics with the view of greater utilization of them as resources

4. Education

-student loan forgiveness for students going into CAM modalities and integrated practices as in PHS training programs

- at the Federal level, develop model laws or regulations to define minimal competency; states could then develop higher levels if they wanted (this would also address the fact that the several professions are currently poorly educated or aware of the competencies of the other professions)
- use this effort to remove existing barriers restricting movement from state to state
-regional accreditation for minimal or optimal standards of education and training for professions seeking or holding licensure
-what do regional or professional accrediting agencies do? How do the chiropractic accrediting agencies work? Are there accrediting agencies for other CAM practices? Is there a common set of principles that can be developed out of these efforts?
-invite professional organizations to develop and publish (submit to WHC) model guidelines or regulations or laws defining minimum competency

5.Reimbursement

- need improved and expanded billing codes system
-need to establish what is cost effective
- need to establish guidelines where licenced professionals are or are not reimbursed, and where non-licenced professionals are and are not reimbursed (but later she indicated non-licenced practitioners should not be eligible for reimbursement)
-need to establish regulations on reimbursement of wellness care rather than just disease care

-co-payment should be the model for all reimbursement (patient buys in)

-revisit the Washington State model as a demonstration project for expanding practice guidelines

Topics Needing More Input

- could we get some more information and background on regional and professional accrediting agencies and how they work?

- no other gaps in testimony, need to review, discuss, and condense

-politics of health care transcends CAM

Process for July October Meetings

-leaning toward small group discussions and reporting back the full WHC

Availability July 1st?

-yes

Buford Rolin (interviewer: Ken) May 31, 2001

Key Issues and Recommendations Emerging

1. Access, Delivery, and Reimbursement

Major points discussed reflected the orientation of cultural differences among population subsets. Specifically, there are cultural differences in practicing health care delivery. Of particular concern was the cultural differences in Hawaiian and Native North American Tribes where primary health care delivery involves individuals who may or may not have formal training, but have the traditional, cultural mandate to serve the population as the source of health information. Related issues were: a) Tribes made the decision as to who is the health information source for the tribe; 2) opportunities for continuing education of these individuals; 3) often they are not compensated (bartering), so this raises questions about licencing, credentialing outside the tribe, reimbursement, etc.; and, 4) the Hawaiian and Native North American approaches to health care access and delivery are different and within the latter, the tribes themselves differ. Dr. Rolin is getting several references form the IHS for us on this issue.

A case might be made that Native North American and Hawaiian on-site health care delivery is more a cultural aspect of the population and thus outside CAM. A similar case might be made for spirituality and other culturally and ethnically difference groups.

2. Licencing, Credentialing

See item above, but across the board, opportunities for continuing education will be essential. Compare and contract the current situation of MDs, DOs, Chirop, Naturop, Acupuncture, massage therapy in terms of the evolution and maturation of the profession. E.G., Osteopaths are today where MDs were a decade ago: chiropractors are today, where Osteopaths were a decade or two ago, and so on. Health care professions are dynamic and evolving.

3. Regulation: State and Federal

More public information needed about State's guidelines, regulations, and licencing of the several CAM modalities. (final report should address matter of state responsibilities in these areas). There is an interface between CAM regulation and CAM research.

4. Research and Education

Need for greater support for CAM research by both private and public sectors. Need for more education in both public and private colleges (undergrad and grad) about CAM.

Topics Needing More Input

1. Not enough discussion on spirituality approaches to prevention and treatment; may not need testimony, but references and discussion

Process for July and October Meetings

July should focus on the interim report issues and recommendations. Then identify the issues for further effort and discussion for October meeting. Expressed no preference as to process, (small groups vs. entire WHC discussions)
October, no suggestions as yet

Availability July 1st?

-yes

Julia Scott

Issues:

These are issues that the Commission needs to discuss and come to consensus on:

1) Evidence based research - what should be required of CAM

2) DSHEA - she's for increased funding, but there may be people who want to amend it

3) Should more oversight (e.g. botanicals) be given to FDA or a separate office

4) Will licensing and credentialing be required for reimburement?

5) Access – do we recommend Medicare funding of CAM? Require CHCs to provide CAM?

Process:

Have staff develop issues as much as possible and provide to Commissioners before the meeting.

Include recurring themes and suggested recommendations

Start with the whole group, then break into smaller groups, then return to larger groups

Additional speakers not needed

Look at what's do-able in the short term and the long term

Dean Ornish

Issues:

He believes there is consensus among the Commissioners on:

- the importance of science to justify or study CAM and that we need to take a scientific approach

- that there is a double standard, not a level playing field, regarding funding, publishing, research, reimbursement, and clinical recommendations

His suggests that the Commission recommendations should be incremental, there should be increased funding for NCCAM, and we should take a science-based approach.

Process:

The Chair should go around the table and give everyone 5 minutes to talk about the issues they feel are important and to get their opinions. This will force the people who never say anything to more actively participate.

July meeting - start with the whole Commission together, everyone summarize the issues they feel need further discussion. In the afternoon break out into smaller groups to address specific issues.

He would also like to see the administration more involved.

Donald Warren

Emerging themes/issues:

- He is very concerned that the independence and essence of CAM will be lost if it becomes medically oriented and if the medical side has too much control of CAM. He does not believe that there is much true integration, or that integration is always necessary or ideal. The Commission may need to discuss and clarify what we mean by integration.

- He does not believe that we need double blinded RCTs for all of CAM and that outcome studies where there is a preponderance of evidence should be sufficient.

- He would like some discussion regarding states setting up umbrella CAM boards to oversee CAM practitioners in the state. In practices that are not licensed, these boards could serve to register practitioners. He also mentioned the issue of reimbursement and that not every CAM practice needs to have 3rd party reimbursement.

Topics not yet addressed:

- Osteopaths have become indistinguishable from MDs and we have lost the manipulative aspect of their practice.

- There is no consistency in how the Federal government classifies mercury (EPA and OSHA consider it toxic, the FDA considers it a medical device and is therefore exempt from establishing safety).

- Dentists should have the option of using other therapies such as nutrition and cranial manipulation to treat problems such as TMJ and cervical spine problems. The state dental boards need to expand the Scope of Practice to give dentists more latitude. This applies to all practitioners.

- Pharmacists are underutilized in CAM and are just starting to get more involved. They should be able to recommend products such as herb, nutritional supplements, etc., as well as therapies such as massage.

- Use of muscle testing as a diagnostic technique

July meeting:

- He would like the Commission to come to agreement that a permanent CAM office be established at the Secretary's level

- He would like the Commission to reach agreement on the definition of CAM.

- He would like the Commission to discuss implementation and education issues.

Dinner Discussion:

- He is available and willing

Tieraona Low Dog (Interviewer: Gerry)
Key issues and recommendations emerging or requiring further discussion

1. Get more of a handle on reimbursement. In cases where evidence shows effectiveness, how is this incorporated into coverage. Some private insurance companies are already incorporating some CAM modalities indicating movement in the direction of coverage. Greater concern about low income (Medicaid) and the elderly (Medicare).

2. Emphasize education.

Recommend that medical schools include minimum (core) overview of CAM.. Essential to mandate that this be required, not voluntary in order to happen.

Recommend heavily marketed, government-supported dependable information out-reach program to practitioners (including pharmacists) and the public. Develop a government-supported web site clearinghouse; collaborate with public libraries nationally to make it accessible to all citizens; arrange for public health advertisement of the existence of site through radio, TV, newspapers, pamphlets in public malls, super markets, libraries, etc., and include information on how to use the site. Include guidance on how to access or link to other dependable information.

3. Importance of consistency of standards. Recommend standardization of requirements state to state regarding licencing, certification, educational standards for practitioners; acupuncturists, message therapists, etc.

4. DSHEA: Revisit?? At least recommend adequate support (funding) to carry out its provisions as currently written. Also, Commission should look at the Report of the Commission on Dietary Supplement Labels (Ken Fisher).

5. Too soon to support CAM under NHSC in rural areas when we're not able to get nurse practitioners yet. Conventional care needs to come first.

6. Report should be "conservative," well thought out, with carefully chosen and focused recommendations.

Process for discussion of report

Recommend large group discussion so all Commissioners hear everything and can respond. Not enough time and less efficient to depend on small groups followed by large group discussion. Jim Gordon will have to draw out members that tend to be quiet during full Commission discussions and make sure their ideas are heard.

How to use July and October meetings
Base October meeting on discussion of draft report in July and the follow-up items that are identified.. July 1 dinner availability: Yes

Bill Fair (Interviewer: Gerry)
Key issues and recommendations emerging or requiring further discussion

1. Concern about what will happen after the Commission's report is released; its important to avoid its relegation to a shelf somewhere.

2. Strong argument to support the study of the effectiveness of CAM products and practices, and elevate the philosophy of disease prevention; for example, there is growing concern about the increasing number of young adults developing diabetes. As has been shown with cardiovascular disease (Ornish data), life style changes would likely go a long way in reducing the incidence of diabetes cases. Include health education in the public school curriculum as a continuum from pre-kindergarten through senior high school.

3. Because of participant turnover, commitment on the part of HMO's and other insurance companies to disease prevention is weaker than it should be. Medicare is a good place to start because of its stable participation.

4. Before reimbursement can be considered, the issue of quality must be addressed. CAM professional societies must set standards and states must license and oversee CAM practice. The CAM community must be represented on state Boards.

5. Education is key. Educational requirements must ensure quality, not only justify reimbursement.

6. Growing consensus of among the Commissioners that herbal supplements are in need of more oversight; e.i., standards of quality, absence of contamination (purity), and truth in labeling. Also, greater emphasis on tracking of adverse reactions by FDA requires attention.

July 1 availability: Yes

Joe Fins (Interviewer: Gerry)
Key issues and recommendations emerging or requiring further discussion

1. Overwhelming issue is protecting public safety. Consensus is emerging on the Commission that dietary supplements require more oversight. This view is consonant with public perception.

2. To ensure public safety, establish a surveillance system for adverse reactions. Involve FDA, the CDC (MMWR), FTC. Many CAM practitioners need training to recognize complications and report them to the appropriate public health agency, and allopathic practitioners need to recognize the medical history or etiology of complications related to CAM.

3. Promote research in the context of true scientific discovery. NCCAM and its collaborative efforts with other NIH Institutes should be viewed as a gateway to increased research support by all NIH Institutes (NCI example); i.e., integrate, not segregate.

4. Emphasize adequate support for research training that will produce the pool of researchers capable of designing sufficiently competitive applications for funding, which in turn will produce the critical mass of evidence needed to integrate CAM into medical practice.

5. In addition to the need for data from hypothesis-driven collaborative scientific studies of safety, efficacy, and mechanism of action, data on health services delivery, which are needed to assess the basis for access and for reimbursement, are not available. Recommend support for health services research; e.g., demonstration projects and small pilot studies supported by ARHQ, HRSA, to answer questions about the clinical effectiveness and cost effectiveness of CAM modalities as compared to standard conventional care.

6. To ensure public safety, recommend national standards for accreditation, and licensing of practitioners in all states as consistent with Federalism and the role of states in regulating medical education and licensing.

7. Support demonstration projects to look at the scientific basis for the diagnosis and treatment paradigms employed in various CAM practices before moving toward assignment as primary care physicians in underserved and rural areas so that these populations receive the same quality of medical care as other members of the public. There is a difference between the question of whether the training of nurses prepares them to diagnose and provide primary care, and the need to ascertain both the scientific basis of the CAM practice and the practitioner's competency, which is complicated by variations in standards and licensing.

8. The Commission needs to identify the key elements of an infrastructure or a process for moving the safe and effective integration of CAM into medical practice; demonstration projects are needed for such model as hospice programs.

Comments on report process

1. Commission needs another meeting. Too much time elapses between meetings. The process for hammering out differences, especially among a divergent group is very difficult and will require the Commissioners to interact more instead of sending in separate comments/changes. The completion timeline is too short for the number of meetings scheduled. There is not adequate time to respond to the text in a day and a half.

2. There needs to be provision for dissenting opinion should this be necessary. Interim report or final report?

3. Brevity and focus are important targets to pursue in developing the interim report. The report's objective should be the support of well-thought-out guidance for incremental change and building the infrastructure for the future.

July 1 dinner availability: Yes, late lunch or early dinner to give us time.

Pollen, Geraldine (NCCAM)

From: Joseph Fins [jjfins@med.cornell.edu]
Sent: Friday, June 01, 2001 8:25 PM
To: Pollen, Geraldine (NCCAM)
Subject: Re: Phone Interview Follow-up

Importance: High

Gerry,
Good job. Pls see my additions in BOLD.
Have a good weekend.
Best,
Joe

>Joe:
>
>Here are my notes taken during our conversation. Please make
>additions/changes in ALL CAPS and send back to me by "return mail." Please
>no later than cob Monday, June 4.
>
>Thanks,
>Gerry
>_____
>Joe Fins (Interviewer: Gerry)
>
>Key issues and recommendations emerging or requiring further discussion
>
>1. The overwhelming issue is protecting public safety. Consensus is
>emerging that dietary supplements require more oversight. HOW THIS
>SHOULD BE DONE IS BEYOND THE COMMISSION BUT WE AGREE THAT .
>REGULATION IS NEEDED. WHETHER DSHEA OR NEW MECHANISM WILL BE
>REQUIRED IS AN OPEN QUESTION. ALSO NOTE THAT THE BLENDON ARTICLE
>SUGGESTS THAT THIS VIEW IS CONSONANT WITH PUBLIC PERCEPTION-- NOT
>NECESSARILY THE ADVOCATES WHO ATTENDED OUR MEETINGS.
>
>2. To ensure public safety, recommend the establishment of a surveillance
>system for adverse reactions. Involve FDA, the CDC (MMWR), FTC.
>THIS IS MADE COMPLEX BY THE FACT THAT MANY CAM PRACTITIONERS MAY NOT
>BE TRAINED TO RECOGNIZE COMPLICATIONS OF THEIR THERAPIES AND REPORT
>THEM TO PUBLIC HEALTH AUTHORITIES AND BY THE FACT THAT ALLOPATHIC
>PRACTITIONERS MAY NOT APPRECIATE THE HX OR ETIOLOGY OF COMPLICATIONS
>RELATED TO CAM. SEE EDUCATION BELOW.
>
>3. Promote research in the context of true scientific discovery. NCCAM and
>its collaborative efforts with other NIH Institutes should be viewed as a
>gateway to OTHER NIH Institutes (NCI example);
>i.e., integrate, not segregate.
>
>4. Emphasize adequate support for research training that will produce the
>pool of researchers capable of designing sufficiently competitive
>applications for funding, which in turn will produce the critical mass of
>evidence needed to integrate CAM into medical practice. THE LEVEL OF
>EXCELLENCE REQUIRED AT OTHER NIH INSTITUTES SHOULD PREVAIL AT NCCAM
>
>5. In addition to the need for data from hypothesis-driven collaborative
>scientific studies of safety, efficacy, and mechanism of action, data on
>health services delivery, which are needed to assess the basis for access
>and for reimbursement, are not available. Recommend support for health
>services research; e.g., demonstration projects and small pilot studies
>supported by ARHQ, HRSA, to answer questions about the clinical
>effectiveness and cost effectiveness of CAM modalities as compared to
>standard conventional care. THIS DATA WILL BE ESSENTIAL PRIOR TO THE
>ESTABLISHMENT OF ANY NEW ENTITLEMENTS. AGAIN, AT THE RISK OF BEING

>REDUNDANT SUPPORT OF AN UNPROVEN OR UNVALIDATED CAM MODALITY IN THE
>SETTING OF A LACK OF A CONVENTIONAL DRUG BENEFIT WOULD BE ETHICALLY
>AND LOGICALLY UNTENABLE.
>
>6. To ensure public safety, recommend national standards for accreditation,
>and licensing of practitioners in all states.---CONSISTENT WITH
>FEDERALISM AND THE ROLE OF STATES IN REGULATING MEDICAL EDUCATION
>AND LIC.
>
>7. Support demonstration projects to look at the scientific basis for the
>diagnosis and treatment paradigms employed in various CAM practices before
>moving toward recognition as primary care physicians in underserved and
>rural areas so that these populations receive the same quality of medical
>care as other members of the public. A HELPFUL ANALOGY WOULD BE TO
>NOTE THAT THIS IS DIFFERENT QUESTION THAN WHETHER NURSE PRACTIONERS
>CAN PROVIDE PRIMARY CARE. THEY TOO ARE ALLOPATHICALLY TRAINED AND
>THE QUESTION IS NOT WHAT INTERVENTION THEY MIGHT PRESCRIBE FOR
>CONGESTIVE HEART FAILURE BUT WHETHER THEIR TRAINING PREPARES THEM TO
>MAKE THE PROPER DX AND RECOMMEND THE PROPER TREATMENT. WITH
>NATUROPATHIC PRACTIONERS WE HAVE TWO ISSUES: THE FIRST IS THE
>SCIENTIFIC BASIS OF THEIR PRACTICE; THE SECOND IS THEIR COMPETENCY.
>THIS IS FURTHER COMPLICATED BY THE VARIABILITY OF STANDARDS ACROSS
>THE NATION.
>
>8. The Commission needs to identify the key elements of an infrastructure
>or a process for moving the safe and effective integration of CAM into
>medical practice; [example: integrating CAM into end-of-life care].
>EOL CARE MAY BE A MODEL THAT IS MOST EVOLVED AND THERE SHOULD BE
>FUNDING FOR ADDITIONAL DEMONSTRATION PROJECTS HERE TO SUPPORT
>HOSPICE PROGRAMS.
>
>Comments on report process
>
>1. Commission needs another meeting. Too much time elapses between
>meetings. The process for hammering out differences, especially among a
>divergent group is very difficult and will require the Commissioners to
>interact more instead of sending in separate comments/changes. The
>completion timeline is too short for the number of meetings
>scheduled. I DO NOT THINK WE WILL HAVE ADEQUATE TIME TO RESPOND TO
>THE TEXT IN A DAY AND A HALF.
>
>2. There needs to be provision for dissenting opinion. SHOULD THIS
>BE NECESSARY Interim report or final report?
>
>3. Brevity and focus are important targets to pursue in developing the INTERIM
>report. The report's objective should be to support well-thought-out
>guidance for incremental change. AND BUILDING THE
>INFRASTRUCTURE FOR THE FUTURE.
>
>July 1 dinner availability: Yes, late lunch or early dinner to give us time.

Interview with Conchita Paz and Michele Chang
June 7, 2001

Conchita feels that all the issues raised thus far are equally important. She mentioned in particular: regulation, licensing, quality control, research, reimbursement, and making information available to the public.

Of these, she identified licensing as particularly "emotional," i.e., people seem to range themselves "really for" or "really against" it. More testimony is NOT needed, but we should definitely be prepared for in-depth discussion on this issue.

Conchita further identified health coverage, i.e., reimbursement as being "the whole crux of the thing." She is concerned that we need to have sufficient "ammunition" to attack this issue. Our recommendation needs to demonstrate a comprehensive approach to the "effectiveness question" of modalities; address quality control of therapies; and improve the accessibility of effective, safe CAM to the general public.

In this regard, Conchita felt strongly that our reimbursement recommendation should address health disparities and provide strategies for serving the uninsured and underserved. Unfortunately, this is the one area of reimbursement about which Conchita feels we have provided the least information. She is convinced that this area is in most need of policy guidance, but feels at a loss on how to "go about doing it" vis-a-vis a recommendation.

Finally, Conchita spoke several times about the dire need for better quality control. She would like to see a recommendation that enables modalities to develop their own standards to assure the quality of their products or practices. She feels that the issue of licensing is integral to this expectation.

Conchita is comfortable with the "game plan" and relieved that she will see recommendations before the meeting. She is prepared for the breakfast meeting and had some questions about the difference between the July and October agenda. She prefers the discussions to be in small group because "there are so many people and so much stuff. In the smaller groups, more people open up and there is more time." (She is prepared that we may not have that luxury in July.)

Conchita had some questions about the political situation with the recent changes in the Senate. She is feeling optimistic about the environment for the interim and final report.

Overall, Conchita does not appear to have any pressing concerns or opinions regarding expectations for the upcoming meetings, the proposed agenda or format of that meeting, or regarding either the interim or final report. She feels ready to proceed to developing recommendations.

Interview Overlapping Issues/Recommendations:

Reimbursement–requirements to be met and process; role of Medicare

Education–medical schools, public, research training

Standards, credentialing, and licensing

Dietary supplements oversight (DSHEA/FDA?)

Research; science base and health services

CAM practitioners in underserved and rural areas

Design of report; use of report

The White House Commission on Complementary and Alternative Medicine Policy was created March 8, 2000, by executive order. The 2-year commission will ultimately report to the president on legislative and administrative recommendations for ensuring that US public policy maximizes the benefits of complementary and alternative medicine. In this column, the chair of the commission will offer his thoughts about the goals and work of this key advisory body.

COLLABORATION, CONSENSUS, AND CHALLENGES: A PROGRESS REPORT

James S. Gordon, MD

James S. Gordon chairs the White House Commission on Complementary and Alternative Medicine Policy and directs the Center for Mind-Body Medicine in Washington, DC. He is the author, most recently, of *Comprehensive Cancer Care: Integrating Alternative, Complementary, and Conventional Therapies* (Perseus Press, 2000).

Collaboration, consensus, and challenges. These are the words that come to mind as the White House Commission on Complementary and Alternative Medicine Policy begins its 10th month.

COLLABORATION

The work of the commission depends on 3 groups: the 20 commissioners, the commission staff, and those who provide information, commentary, and analysis to us. They are clinicians, researchers, educators, policy makers, business people, and those who have found, or been unable to find, help from complementary and alternative medicine (CAM). In the last 3 months, the level of activity and commitment from these 3 groups has increased exponentially, and the interaction among them has grown progressively richer and more rewarding.

The number of commissioners now stands at 20, up 5 from the 15 who were initially appointed by President Clinton. All of the commissioners have been participating actively in formulating the agenda for full commission meetings, in reading and commenting on the huge volume of material that's been offered to us, in participating in small group discussions, and in making recommendations.

The staff, led by our executive director, Stephen Groft, PharmD, has coordinated these activities, discovered the most appropriate speakers, issued invitations, and formulated a range of wonderfully useful questions to those who testify at commission meetings as well as those whom we've asked to submit written testimony.

The response has been extraordinary. At the New York town hall meeting on January 23, 2001, a total of 140 people—the regulators and the regulated, clinicians and patients, scholars and activists, enthusiasts and skeptics—spoke to us.

At the last full commission meeting on professional education, licensure, and credentialing (February 22-23, 2001), more than 100 organizations—from the American Medical Association and the Association of American Medical Colleges to the American Massage Therapy Association, the National Breast Cancer Coalition, and the American College of Acupuncture and Oriental Medicine—submitted testimony. We had plenary session presentations and 4 working groups that read through and discussed the state-of-the-art positions we received, the catalogues of institutional concerns, and the vast array of thoughtful proposals. We concluded with a full commission 4-hour discussion of all this material and a list of possible recommendations.

CONSENSUS

Our charge from the White House and Congress was—and is—to offer recommendations for legislation and administrative action, and to make at least some of these recommendations—about CAM research, services, reimbursement, professional education, and public information—in our interim report in July 2001. In March 2002 we will present to the president a final report that we hope will include a wide perspective on the field, the most important lessons we've learned and the vision they've given us of the future of CAM, and the relevance of CAM to healthcare for all Americans. These will form the basis for further long-term policy recommendations.

As we begin to develop a consensus about interim report recommendations, we've been discussing with increasing energy possible areas we want to address. At the same time, we're keeping the process as open as possible to those who want to communicate with us (and there have been well over 1000 organizations and individuals so far), as well as among ourselves. Coming to a consensus and making specific recommendations for the interim report is the work of the next 4 months.

There are, however, some themes that are emerging, and some areas of general, if not unanimous, agreement among commissioners. Following are several:

- A need for CAM education to be available to all professionals at every stage of their training process. For conventional professions—medicine, nursing, psychology, social work, and so on—this means

inclusion in undergraduate, postgraduate, and continuing education programs. For CAM professionals this means an understanding of conventional as well as other CAM principles and approaches in all parts of their training.

- These parts of the curriculum must be tested, along with basic science and conventional clinical practice, on National Board examinations.
- A guarantee that all supplements, herbals, and so on, that are marketed and sold to the public have good manufacturing practices and honest and truthful labeling, as well as a mechanism for calling to account and prosecuting those who violate these standards.
- An emphasis on the central role of self-care and the CAM practices that contribute to it, in all aspects of medicine and healthcare, including services offered and covered by government programs and private reimbursement mechanisms.
- An understanding that integrative practitioners—those who use CAM therapies along with conventional care—and CAM practitioners, as well as the public, must be represented on all boards that regulate integrative and CAM practitioners and their practices.
- The development of research strategies that respect the integrity of CAM practices and the traditions on which they are based.
- The provision of reliable and authoritative information about CAM approaches and practices to the public and professionals.
- Mechanisms to make effective CAM practices available to all Americans, not just those who have discretionary income to spend on them.
- A respect for the unique needs of traditional communities—American Indian tribes as well as immigrant communities—and of their systems of healthcare.
- An understanding that education of all Americans about better health practices and wellness, including nutrition, exercise, and stress reduction, is a part of the CAM agenda and must be advanced.
- Coordination of federal interdepartmental CAM activities at the highest level.

I mean this list to be suggestive rather than exhaustive. And, of course, there is no guarantee that any or all of these will be included as we move ahead in formulating our legislative and administrative recommendations in our interim report. However, I think this is a fair summary of some of the themes that most commissioners agree are important.

CHALLENGES

If there is substantial agreement on a number of themes and approaches, there are also many challenges that face us—areas where there is significant disagreement among those whom we've asked to testify, even, at times, among commissioners themselves. I'll touch on just a few prominent ones here.

Should the federal government have a role in recommending minimum standards for licensure for integrative and CAM practice, or should this be left entirely to the states? At our most recent meeting on professional education, credentialing, and licensure, we heard and read strong arguments on both sides, as well as pleas for an approach—"harmonization"—that would allow for diversity and promote dialogue.

What should the role of "evidence-based" studies be in determining which practices are included in the domains of the various professions, in the services made available, and in reimbursement plans? Many feel that evidence-based medicine—and in particular large population studies such as randomized controlled trials—should be the basis for inclusion. But a number of others are convinced that other research methodologies (including "outcomes based" and "N-of-1" studies and qualitative research) can be used. Still others believe that as long as informed consent is provided and no harm is done, all practices, with or without evidence, should be available.

Should all CAM practices be included in the domain of healthcare? Most CAM professional organizations want the approaches and therapies they offer to be included, desire their practitioners to be licensed, and hope for reimbursement. But others do not. Some bodyworkers, for example, would prefer that these approaches be regarded as educational, whereas others, particularly some who practice energy healing, prefer to be considered spiritual practitioners.

Should continuing education credits, and in particular continuing medical education (CME) credits, be offered for learning to do as well as learning about CAM approaches? And, if so, what should the criteria be for awarding CME credits?

This is a short list. I expect that it will grow longer as the next commission meetings unfold. The next meeting, which will have occurred by the time you read this, includes the March 26-27 sessions on public information and wellness. The second program, May 14-16, is on research and research methodologies and reimbursement and financing. At the third, on July 2 and 3, we will meet as a full commission to discuss our interim report. All meetings will be in Washington, DC.

We invite you, as always, to read the transcripts of the commission meetings and the summaries of our town hall meetings on our Web site (http://www.whccamp.hhs.gov), to communicate with us by e-mail, and to come to the meetings and tell us what you think. We look forward to hearing from you as we continue our discussions and deliberations, as well as after we publish the interim report. And I look forward, as well, to my next communication with all of you.

Int. Report

The White House Commission on Complementary and Alternative Medicine Policy: A Progress Report by the Chair

James S. Gordon, M.D.

Collaboration, consensus and challenges. These are the words that come to mind as the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) begins its tenth month.

Collaboration

The work of the Commission depends on three groups: the twenty Commissioners, the Commission staff, and those who provide information, commentary and analysis to us – clinicians, researchers, educators, policy makers, business people and those who have found, or been unable to find, help from CAM. In the last three months, the level of activity and commitment of these three groups has increased exponentially, and the interaction among them has grown progressively richer and more rewarding.

The number of Commissioners now stands at 20, up five from the 15 who were initially appointed by President Clinton. All of the Commissioners have been participating actively in formulating the agenda for full Commission meetings, in reading and commenting on the huge volume of material that's been offered to us, in participating in small group discussions and in making recommendations.

The staff, led by the executive director, Stephen Groft, Pharm.D, has coordinated these activities; discovered the most appropriate speakers; issued invitations; and formulated a range of wonderfully useful questions to those who testify at Commission meetings, and those whom we've asked to submit written testimony.

The response has been extraordinary. At the New York Town Hall, on January 23, 2001, 140 people - the regulators and the regulated, clinicians and patients, scholars and activists, enthusiasts and skeptics - spoke to us. At the last full Commission meeting, on Professional Education, Licensure and Credentialing (February 22-23rd, 2001) well over one hundred organizations - from the American Medical Association and the Association of American Medical Colleges to the American Massage Therapy Association, the National Breast Cancer Coalition, and the American College of Acupuncture and Oriental Medicine - submitted testimony. We had plenary session presentations and four working groups which read through and discussed the state of the art positions we received, the catalogues of institutional concerns, and the vast array of thoughtful proposals. We concluded with a full Commission four hour discussion of all this material and a list of possible recommendations.

Consensus

Our charge from the White House and Congress was, and is, to offer recommendations for legislation and administrative action, and to make at least some of these

recommendations - about CAM research, services, reimbursement, professional education, and public information - in our Interim Report in July 2001. In March 2002 we will present the President with a Final Report which we hope will include a wide perspective on the field, the most important lessons we've learned, and the vision they've given us of the future of CAM and its relevance to healthcare for all Americans. These will be the basis for further long term policy recommendations.

As we begin to develop a consensus about Interim Report recommendations, we've been discussing with increasing energy possible areas we want to address. At the same time, we're keeping the process as open as possible to those who want to communicate with us (and there have been well over 1000 organizations and individuals so far) as well as among ourselves. Coming to a consensus and making specific recommendations for the Interim Report is the work of the next four months. There are, however, some themes that are emerging, and some areas, of general, if not unanimous, agreement among Commissioners. Here are several:

1. A need for CAM education to be available to all professionals at every stage of their training process. For conventional professions – medicine, nursing, psychology, social work, etc. – this means inclusion in undergraduate, postgraduate, and continuing education programs. For CAM professionals this means an understanding of conventional, as well as other CAM principles and approaches in all parts of their training.

2. These parts of the curriculum need to be tested, along with basic science and conventional clinical practice on National Board examinations.

3. A guarantee that all supplements, herbals, etc., that are marketed and sold to the public have good manufacturing practices and honest and truthful labeling, and a mechanism for calling to account and prosecuting those who violate these standards.

4. An emphasis on the central role of self-care, and the CAM practices that contribute to it, in all aspects of medicine and healthcare – in services offered and covered by government programs and private reimbursement mechanisms.

5. An understanding that integrative practitioners – those who use these CAM therapies, as well as conventional care - and CAM practitioners, as well as the public, must be represented on all boards that regulate integrative and CAM practitioners and their practices.

6. The development of research strategies which respect the integrity of CAM practices and the traditions on which they are based.

7. The provision of reliable and authoritative information about CAM approaches and practices to the public and professionals

8. Mechanisms to make effective CAM practices available to all Americans, not just those who have discretionary income to spend on them.

9. A respect for the unique needs of traditional communities - American Indian tribes as well as immigrant communities - and of their systems of healthcare.

10. An understanding that education of all Americans about better health practices and wellness, including nutrition, exercise and stress reduction, is a part of the CAM agenda and must be advanced.

11. Coordination of federal interdepartmental CAM activities at the highest level.

I mean this list to be suggestive, rather than exhaustive. And, of course, there is no guarantee that any or all of these will be included as we move ahead in formulating our legislative and administrative recommendations in our Interim Report. However, I think this is a fair summary of some of the themes that most Commissioners agree are important.

Challenges

If there is substantial agreement on a number of themes and approaches, there are also many challenges that face us - areas where there is significant disagreement among those whom we've asked to testify, as well, at times, among Commissioners themselves. I'll touch on just a few prominent ones here:

1. Should the federal government have a role in recommending minimum standards for licensure for integrative and CAM practice, or should this be left entirely to the States? At our most recent meeting on Professional Education, Credentialing and Licensure we heard – and read – strong arguments on both sides, as well as pleas for an approach – "harmonization" – which would allow for diversity and promote dialogue.

2. What should the role of "evidence based studies" be in determining which practices are included in the domains of the various professions, in the services made available, and in reimbursement plans? Many feel evidence based medicine - and in particular large population studies like randomized controlled trials - needs to be the basis for inclusion. But a number of others are convinced that other research methodologies (including "outcome" and "N of one" studies and qualitative research) can be used. Still others believe that as long as informed consent is provided and no harm is done, all practices, with or without evidence, should be available.

3. Should all CAM practices be included in the domain of healthcare? Most CAM professional organizations want the approaches and therapies they offer to be included, desire their practitioners to be licensed, and hope for reimbursement. But others do not. Some body workers, for example, would prefer that these approaches be regarded as educational, while others, particularly some who practice energy healing, prefer to be considered spiritual practitioners.

4. Should continuing education credits, and in particular Continuing Medical Education (CME) credits be offered for learning to do, as well as learning about CAM approaches? And if so, what should the criteria be for awarding CME credits?

This is a short list. I expect it will grow longer as the next Commission meetings unfold. The next meeting, which will have occurred by the time you read this, includes the March 26-27th sessions on Public Information and Wellness. The second, May 14-16 program, is on Research and Research Methodologies and Reimbursement and Financing. At the third, on July 2nd and 3rd we will meet as a full Commission to discuss our Interim Report. All will be in Washington, DC.

We invite you, as always, to read the transcripts of the Commission meetings and the summaries of our Town Halls that are on our website (www.whhcamp.hhs.gov), to communicate with us by e-mail, and to come to the meetings and tell us what you think. We look forward to hearing from you as we continue our discussions and deliberations, as well as after we publish the Interim Report. And I look forward, as well, to my next communication with all of you.

Chang, Michele (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Monday, June 11, 2001 1:20 PM
To: Albrecht, Joan (NCCAM); Axelrod, Corinne (NCCAM); Fisher, Ken (NCCAM); Pollen, Geraldine (NCCAM); Jim Swyers (E-mail); Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); 'Mylene Huynh'; Groft, Stephen (NCCAM)
Subject: Staff followup

Hi, Everyone!

- Please remember that we are taking Joan out for her farewell lunch tomorrow, Tuesday, June 17. Her last day is this Friday. We'll leave PROMPTLY at 11:00 for early lunch at Thyme's Square in Bethesda.

- The 2-hour Discussion Sessions are as follows (also refer to attached draft agenda).

I. Coordination of Research and Regulatory Activities
II. Education, Training, Credentialing & Licensing
III. Information Development and Dissemination
IV. Access, Delivery & Reimbursement
V. Self-care and Wellness
VI. Interim Report

- Please send Steve your "Top 3 Issues" today. These will form the basis of the discussion with Peter R. on Thursday. As we agreed, these may be in lieu of the staff analyses that will be included in the BB, and are needed to give Peter a sense of the most pressing or emergent issues in the variety of topics being considered by the Commissioners.

- Please send Michele your electronic version of:

(1) revised staff analyses for the BB based on comments received no later than Wednesday.

(2) your staff report from the February 22-23 Education and Training Discussion Group no later than Wednesday.

- Attached is the proposed agenda for July; this is tentative, pending our meeting with Jim on Thursday.

Upcoming meetings:

Tuesday, June 12 @ 9:00 a.m. Topic: July 2 breakfast; proposed discussion facilitators for July

Thursday, June 14 @ 9:30 a.m. Topic: staff meeting with Jim G.
(FYI: Thursday, June 14 @ 2:00 p.m. Topic: with Peter R)

Think that is it! Great staff meeting, all!

AGENDA
I.draft.doc

White House Commission on Complementary and Alternative Medicine Policy

Jury's Hotel
1500 New Hampshire Ave, NW
Westbury Room, Washington, DC

July 2-3, 2001

PRELIMINARY AGENDA (Staff use only)

DAY ONE: MONDAY, JULY 2, 2001

8:00 – 9:45 a.m. **Breakfast with Commissioners**
Facilitator: Tom Andrews

Discussion Topic I. *(proposed)* Commissioner Expectations and Aspirations for the Final Report

Objective: (1) to elicit Commissioners' expectations for the Report
(2) to discuss the concept of a permanent presence*

Discussion Topic II. *(proposed)* Reality Check: Political and Strategic Pitfalls and Opportunities

** the proposal and concurrence discussion of a permanent presence, if raised here initially, must also be fully addressed later in public sessions...*

10:00 a.m. **Opening Remarks and Introductions**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy
- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

~~10:10~~ a.m. **Discussion Session I: Coordinated CAM Research and Regulatory Activities**
Discussion Facilitator:
Staff Lead: Gerry Pollen

12:15 -- 1:30 p.m. Lunch

~~1:30 – 3:30 p.m.~~ **Discussion Session II: Education, Training, Credentialing and Licensing of CAM Practitioners**

Discussion Facilitator:
Staff Lead: Joe Kaczmarczyk

3:30 – 3:45 p.m. BREAK

3:45 – 4:45 p.m. **Discussion Session III: Information Development and Dissemination**

Discussion Facilitator:
Staff Lead: Corinne Axelrod

6:00 p.m. Adjourn

6:30 p.m. Dinner at Nora's (proposed!)

DAY TWO: TUESDAY, JULY 3, 2001

8:00 a.m. **Opening Remarks**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy
- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

8:05 -- 10:30 a.m. **Discussion Session IV: Access, Delivery and Reimbursement of CAM Services**

Discussion Facilitator:
Staff Leads: Joe Kaczmarczyk, Maureen Miller

10:15 – 10:30 a.m. BREAK

10:30 -- 12:30 p.m. **Panel Session V: Self-care & Wellness**

Discussion Facilitator:
Staff Lead: Corinne Axelrod

12:30 – 1:30 p.m. LUNCH

1:30 – 3:00 p.m. **Panel Session VI: Interim Report**

Discussion Facilitator: Steve Groft

3:00 – 3:15 p.m. BREAK

3:15 – 4:30 p.m. **Public Comment Session**

4:30 p.m. **ADJOURN**

(1) Read Communications, Interviews
(2) Develop Paragraphs
(3) Revise Agenda
(4) Ken's Outline + Summary 78

KEN'S COMMENTS

4) Attached thick prices for BB have been marked up & highlighted to suggest what might go into interim report suitably modified.

5) Based on attached, I think YOU should draft interim report.

6) Suggested agenda

	Time	
	new	old
~~Research~~	~~BB~~	~~120~~
Education		
a) Educ & Training	60	120
b) Licensing	60	—
o Research	60	120
Regulation	60	0
o Information	60	120
Access, ~~Delivery~~	60	
Delivery	60	120
Reimbursement	60	
	480	480

Facilitator

- Time Mgt
- ~~Facilitate All Comments~~ Encourage full Participation of Members
- ~~Consensus~~ Review Issues

- Other Issues or Con not expressed in Recommendations

- ~~Other Concerns~~

Minimum Commitment of thought
Concerns Issues - Personal Agenda Aside

I. Legal - Issue focus

~~If~~ focus on agenda of commission

Established Recommendation

Contentious ones - first

Jim Summaries

White House Commission on Complementary and Alternative Medicine Policy

Jury's Hotel
1500 New Hampshire Ave, NW
Westbury Room, Washington, DC

July 2-3, 2001

PRELIMINARY AGENDA (Staff use only)

DAY ONE: MONDAY, JULY 2, 2001

8:00 – 9:45 a.m. **Breakfast with Commissioners**
Facilitator: Tom Andrews

Discussion Topic I. *(proposed)* Commissioner Expectations and Aspirations for the Final Report

Objective: (1) to elicit Commissioners' expectations for the Report
(2) to discuss the concept of a permanent presence*

Discussion Topic II. *(proposed)* Reality Check: Political and Strategic Pitfalls and Opportunities

** the proposal and concurrence discussion of a permanent presence, if raised here initially, must also be fully addressed later in public sessions...*

10:00 a.m. **Opening Remarks and Introductions**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy

- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

10:10 a.m. **Discussion Session I: Coordinated CAM Research and Regulatory Activities**

Discussion Facilitator:
Staff Lead: Gerry Pollen

12:15 -- 1:30 p.m. Lunch

1:30 – 3:30 p.m. **Discussion Session II: Education, Training, Credentialing and Licensing of CAM Practitioners**

Discussion Facilitator:
Staff Lead: Joe Kaczmarczyk

3:30 – 3:45 p.m. BREAK

3:45 – 5:45 p.m. **Discussion Session III: Information Development and Dissemination**

Discussion Facilitator:
Staff Lead: Corinne Axelrod

6:00 p.m. Adjourn

6:30 p.m. Dinner at Nora's (proposed!)

DAY TWO: TUESDAY, JULY 3, 2001

8:00 a.m. **Opening Remarks**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy
- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

8:05 -- 10:15 a.m. **Discussion Session IV: Access, Delivery and Reimbursement of CAM Services**

Discussion Facilitator:
Staff Leads: Joe Kaczmarczyk, , Maureen Miller

10:15 – 10:30 a.m. BREAK

10:30 -- 12:30 p.m. **Panel Session V: Self-care & Wellness**

Discussion Facilitator:
Staff Lead: Corinne Axelrod

12:30 – 1:30 p.m. LUNCH

1:30 – 3:00 p.m. **Panel Session VI: Interim Report**

Discussion Facilitator: Steve Groft

3:00 – 3:15 p.m. BREAK

3:15 – 4:30 p.m. **Public Comment Session**

4:30 p.m. **ADJOURN**

Groft, Stephen (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Monday, June 11, 2001 1:20 PM
To: Albrecht, Joan (NCCAM); Axelrod, Corinne (NCCAM); Fisher, Ken (NCCAM); Gerry Pollen (E-mail); Jim Swyers (E-mail); Joe Kaczmarczyk (E-mail); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Mylene Huynh; Steve Groft (E-mail)
Subject: Staff followup

Hi, Everyone!

- Please remember that we are taking Joan out for her farewell lunch tomorrow, Tuesday, June 17. Her last day is this Friday. We'll leave PROMPTLY at 11:00 for early lunch at Thyme's Square in Bethesda.

- The 2-hour Discussion Sessions are as follows (also refer to attached draft agenda).

I. Coordination of Research and Regulatory Activities
II. Education, Training, Credentialing & Licensing
III. Information Development and Dissemination
IV. Access, Delivery & Reimbursement
V. Self-care and Wellness
VI. Interim Report

- Please send Steve your "Top 3 Issues" today. These will form the basis of the discussion with Peter R. on Thursday. As we agreed, these may be in lieu of the staff analyses that will be included in the BB, and are needed to give Peter a sense of the most pressing or emergent issues in the variety of topics being considered by the Commissioners.

- Please send Michele your electronic version of:

(1) revised staff analyses for the BB based on comments received no later than Wednesday.

(2) your staff report from the February 22-23 Education and Training Discussion Group no later than Wednesday.

- Attached is the proposed agenda for July; this is tentative, pending our meeting with Jim on Thursday.

Upcoming meetings:

Tuesday, June 12 @ 9:00 a.m. Topic: July 2 breakfast; proposed discussion facilitators for July

Thursday, June 14 @ 9:30 a.m. Topic: staff meeting with Jim G.
(FYI: Thursday, June 14 @ 2:00 p.m. Topic: with Peter R)

Think that is it! Great staff meeting, all!

AGENDA
I.draft.doc

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