Jim Albertin
Univ. Club 1135 16th St, NW

Groft, Stephen (WHCCAMP)

From: Blanks, Robert [rhblanks@uci.edu]
Sent: Tuesday, July 31, 2001 12:41 PM
To: 'sg18b@NIH.gov'
Cc: 'JAlbert729@a0l.com'; 'tarondberg@home.com'; 'cbkent@ix.netcom.com'; 'Veronicapgdc@aol.com'; Blanks, Robert
Subject: RE: subluxation-based proposal

WCA.DOC

Dear Dr. Groff:

It was suggested that I send you an outline of the research proposal that we are planning to discuss on Thursday at the University Club in Washington. We appreciate your joining us, and look forward to receiving your advice on how to best proceed with the project. Please find a draft outline of the proposal attached.

Our proposal will evaluate the health and wellness benefits of subluxation-based chiropractic using two research designs: 1) a large, practice-based health outcomes study to evaluate general wellness benefits (quality of life, DNA repair enzymes, measures of autonomic, somatic, and immune systems) and not specific disease entities or end points per se.- these changes will be evaluated across a large sociodemographic and socioeconomic population allowing us to evaluate the health economics of this intervention, develop statistical models of health behavior, and to evaluate the cross cultural aspects of health, i.e., race/ethnic beliefs about health and health behaviors. 2) in subsequent years, we propose to evaluate this particular CAM intervention in randomized, controlled longitudinal studies.

We believe that the project, although ambitious in scope, will be successful given the credentials of the assembled multidisciplinary research team, the strength of the accumulated pilot data to support the hypotheses, and the overwhelming support being provided by the health professionals themselves and the organizations representing all these subluxation-based practitioners (World Chiropractic Alliance, Council of Chiropractic Practice). Moreover, we believe that the research methodologies being employed, and the generalized health and wellness outcome measures, will be of considerable assistance to the mission and objectives of NCCAM and other federal agencies, because they can be utilized to evaluate other CAM modalities in the future which similar holistic (vitalistic) health objectives.

I look forwarding to our discussions.

Robert Blanks, Ph.D.
Professor of Anatomy and Neurobiology
University of California Irvine
(949) 824-7991

-----Original Message-----
From: Terry Rondberg [mailto:tarondberg@home.com]
Sent: Monday, July 30, 2001 1:24 PM
To: Blanks, Robert
Subject: FW: Steve Groff at lunch

-----Original Message-----
From: JAlbert729@aol.com [mailto:JAlbert729@aol.com]
Sent: Monday, July 30, 2001 1:09 PM
To: tarondberg@home.com; cbkent@ix.netcom.com
Subject: Steve Groff at lunch

Drs Rondberg and Kent, Dr. Steve Groff, will be joining Dr. Blanks and myself
for lunch on Thursday. Thanks to DR. V for helping to set this up! Dr. Rondberg, could please ask Dr. Blanks to share his proposals with Dr. Groff at e-mail sg18b@NIH.gov before the lunch. Thanks. Best, Jim Albertine

"Outcomes Assessment of Health Disciplines Operating in the Wellness Model: Subluxation-Based Chiropractic"

Purpose: The purpose of this grant is to provide a large, practice-based evaluation of the general health and wellness benefits of subluxation-based chiropractic, as distinct from specific medical symptom relief (e.g., low back pain, headaches, etc.). The practice-based design will allow us to collect a large statistical sample (in excess of 30,000 patients under care) to control for sociodemographic, prior existing condition, co-therapies, etc. and, using standardized, patient-centered, health/wellness questionnaires, to directly examine cross-cultural health beliefs and behaviors. This begins to address the Presidential and Department of Health and Human Services (DHHS) Initiative on health disparities, and the five-year strategic Research Plan by the National Institutes of Health (NIH) to reduce and ultimately eliminate health disparities. The investigators are expert in all aspects of the proposed research, and have partnered with the international organization representing Subluxation-based chiropractic, the World Chiropractic Alliance (WCA).

Scope of project: 4-5 million total direct cost (TDC) over the five-year grant period for research costs, and $300,000 to $400,000 to set up the research infrastructure (electronic data capture network , web-based training to standardize the outcome assessment protocols, intervention and research/clinical records documentation.

Funding Source: NIH program project grant (NCCAM, NIA, Heart, Lung, Blood) and possibly Small Business Improvement Research (SBIR) grants. The program project grants will pay for data collection and analysis, and SBIR will pay for commercial development of web-based technology/training through cooperative interaction with an existing for-profit or not-for-profit corporate entity.

Investigators: Investigators at several major US research Institutions, in affiliation with the World Health Organization (WHO) and the international association representing the chiropractic profession, the World Chiropractic Alliance (WCA).

Performance sites: A practice-based study representing 1,000 subluxation-based chiropractic offices in the United States, 200 offices internationally, and the out-patient clinics of two United States-based colleges of chiropractic (Sherman College of Straight Chiropractic, Parker College of Chiropractic) where the practice and theory of subluxation-based chiropractic is taught and practiced clinically.

Experimental Design: Years 1-3, health outcomes research on existing data (retrospective design) using a cross-sectional design, i.e., survey of all patients undergoing care. Year 4-5, longitudinal study design using time varying series with control population.

Survey population: Representative multicultural populations of men, women, and children in the United States. Subsamples will be obtained from international populations in relative proportions to their cultural representation in the United States (e.g., Europe, Middle-East, Africa, Central and South America, Asia). The latter will be accomplished through on-line/ Web-based sampling in the native language of the country in conjunction with standardized statistical methodologies, and carefully-designed cross-training protocols for each of the data collection sites; national and international training will be accomplished through web-based and regional seminars.

Outcome Measures: To objectively evaluate the impact of subluxation-based chiropractic on the bio-, psycho-, social- and spiritual-dimensions of health, the following measures will be utilized:

1) Standardized, Patient-centered measures of health, wellness and quality of life.
2) Immune system assessments. This includes Natural Killer cell activity, CD3/CD16+56, cytokine concentrations, and cortisol levels.
3) DNA repair enzymes, or a surrogate such as serum thiol levels.
4) Autonomic tests, such as skin temperature analysis (thermography) and heart-rate variability.
5) Somatic assessment, including postural muscle tone using surface EMG

SPECIFIC AIMS

1. Evaluation of subluxation-based chiropractic using general wellness outcome measures: including health/wellness/quality of life questionnaire, immune system assessment, DNA repair enzymes, tests of autonomic (skin temperature and heart rate regularity) and somatic motor (surface EMG) systems.

2. Health beliefs and Behaviors in CAM: Creation of centralized clinical and patient-centered database and infrastructure for collection, analysis and publication (peer-reviewed journals, public policy documents, legislative review, insurance reform, medical-legal issues).

3. Racial and Ethnic Health Disparities in CAM utilization: The demographics, prevalence, and patterns of subluxation-based chiropractic in the United States. Data to be collected included demographics, health and social characteristics, race/ethnicity, pre-existing illnesses, and CAM utilization by minority populations to support statistically reliable estimates of CAM patterns of use.

4. Standardized CAM protocols: for patient intake forms, discipline-specific clinical findings in subluxation-based chiropractic, standardized clinical record keeping (re.

common data input stream, Medicare compliance, etc.) to allow pooling practiced-based patient data across large numbers of health professional practices.

~~DRAFT~~ Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy
August 3, 2001

I. Introduction

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order 13147 on March 7, 2000, to develop legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public.

The President and Congress created the Commission in response to the public's interest in and use of CAM modalities and approaches and in a variety of self-care practices. The Commission is charged with submitting a final report to the President and Congress by March 7, 2002.

This Interim Progress Report provides a brief overview of CAM as well as the Commission and its activities. It also discusses the Commission's progress to date on developing recommendations around the four major topic areas outlined in the President's Executive Order. Individuals and organizations are encouraged to provide written comments on this Interim Progress Report for consideration by the Commission through its website or by letter to the Commission staff.

The Commission's Charge

The President's Executive Order (see Appendix 1) charged the Commission to consider four broad topics related to CAM:

- Coordinated research to increase knowledge about CAM practices and products;
- The provision to health care professionals of reliable and useful information about CAM that can be made readily accessible and understandable to the general public;
- Guidance for appropriate access to and delivery of CAM; and
- The education and training of health care practitioners in CAM.

The Commission's role is to recommend policies that ensure the public's health and safety when accessing CAM practices and products and the practitioners who offer them. The Commission will also recommend strategies to increase the availability of authoritative information about the safety and efficacy of CAM practices, techniques, practitioners, and products.

A. Overview of CAM

Definitions of complementary and alternative medicine (CAM) continue to evolve. CAM generally refers to modalities, practices, techniques, and systems of healing that are used together with ("complementary to") or instead of ("alternative to") conventional medicine. Among the modalities that are associated most often with the term CAM are chiropractic, acupuncture, massage therapy, mind-body techniques (e.g., biofeedback, guided imagery, yoga, and meditation), some forms of nutritional therapy, dietary supplements (including herbs), as well as homeopathy, naturopathic medicine, various forms of energy healing, and the indigenous healing systems of the many ethnic groups in the United States.

Over the past decade, several nationwide surveys have documented a substantial and growing usage of CAM practices and products by the American public.[1-4] These surveys have found that most CAM users seek out conventional medical treatment first, and then turn to CAM practitioners. Most people appear to use CAM in conjunction with, not as a replacement for, conventional medical therapy, and many seek out care that integrates the best of a variety of approaches.[1] The use of CAM modalities, practices, and products by the general population varies in the published literature, ranging from 6.5 percent[6] to 42 percent[3] depending on the population studied and the criteria used to define CAM. Other studies have documented even higher use of CAM therapies among people with chronic and life-threatening conditions.[5,7] For example, a recent study at a major cancer center indicated that 69 percent of patients included CAM approaches as part of their cancer care.[7]

B. An Overview Of The Commission: Its Membership and Activities To Date

Commission Membership

The Commission includes twenty members representing a diverse range of expertise in biomedical research, medical and CAM fields. The Commissioners include the Chair, James S. Gordon, M.D.; George M. Bernier, Jr., M.D.; David E. Bresler, Ph.D.; Thomas M. Chappell; Effie Poy Yew Chow, Ph.D.; George T. DeVries, III; William R. Fair, M.D.; Joseph J. Fins, M.D.; Veronica Gutierrez, D.C.; Wayne B. Jonas, M.D.; Charlotte R. Kerr, R.S.M., R.N., M.P.H., M.Ac.; Linnea S. Larson, LCSW; Tieraona Low Dog, M.D., A.H.G.; Dean Ornish, M.D.; Conchita M. Paz, M.D.; Joseph E. Pizzorno, Jr., N.D.; Buford L. Rolin; Julia Scott; Xiaoming Tian, M.D.; and Donald W. Warren, D.D.S. (Appendix 2)

Activities To Date

The Commission has held seven formal meetings in Washington D.C., all of which have included sessions for open public comment, and four Town Hall meetings, where hundreds of people gave testimony. In total, the Commission has heard from more than 1,000 speakers and received nearly 2,000 individual comments and recommendations from the public. In the coming months, the Commission plans to review reports from previous commissions and authoritative bodies on

the topics identified in its charge and to solicit additional written comments and suggestions from the general public by e-mail, fax, and mail.

Each of the Commission meetings have focused on one or more of the four major topics in the Presidential Executive Order, as follows:

- July 13-14, 2000: Planning Meeting
- October 5-6, 2000: Coordination of CAM Research
- December 4-5, 2000: Access and Delivery of CAM Services and Products
- February 22-23, 2001: Education, Training and Credentialing for CAM Practices
- March 26-27, 2001: Wellness, Self-Care, and Prevention and the Development and Dissemination of CAM Information to the Public
- May 14-16, 2001: Coverage and Reimbursement of CAM Services and Coordination of CAM Research
- July 2-3, 2001: Discussion of the Interim Progress Report and Draft Recommendations

At the four Town Hall meetings held in San Francisco, Seattle, New York City and Minneapolis, testimony was presented on subjects related to all four topics. Appendix 3 contains a detailed description of the subjects discussed during the Commission and Town Hall meetings. The transcripts, agenda, and other information pertaining to all Commission Meetings and Town Hall Meetings are available on the Commission's website, http://whccamp.hhs.gov. Additional information, such as Commissioner biographies and a schedule of future meetings, also is readily available at the website which is periodically updated to reflect ongoing activities. Comments, recommendations, and suggestions can be sent though the website, or to whccamp@mail.nih.gov.

II. The Commission's Progress To Date

The Commission supports the promotion of rigorous science and the appropriate use of the scientific method in research studies. The Commission recognizes the major ongoing contributions in this area by the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health. The Commission also supports making the current evidence for CAM practices and products more widely and easily available to the public and health care providers. The Commission recognizes that recommendations in the Final Report about the appropriate use of safe and effective CAM practices and products must be grounded in sound scientific and ethical principles.

Other principles that will guide the Commission in its deliberations include: an emphasis on health promotion and wellness in addition to disease prevention and the treatment of illness; a recognition that the body has a remarkable capacity for healing that can be facilitated by addressing the underlying causes of illness and suffering; an attention to all aspects of life that can impact health—physical, mental, emotional, environmental, and spiritual; an understanding that each person has unique needs that must be attended to in every therapeutic setting and encounter;

and a belief that self-care is integral to our nation's healthcare and should be taught to health professionals and the public.

The Commission also is focused on maximizing the potential benefits of CAM by considering recommendations that promote collaborations between conventional and CAM health care professionals and researchers, and by encouraging the integrated delivery of CAM along with conventional medicine, where appropriate. Furthermore, the Commission recognizes that consumers have a basic right to choose freely among qualified CAM practitioners and safe products they believe are beneficial to their health, and must be included as partners in any policy or regulatory decisions about CAM access, delivery, and research.

The Commission's recommendations will be formed by the evidence presented and gathered during its deliberations. The diverse perspectives reflected in the testimony heard from advocates, critics and other expert witnesses will be considered in the context of these principles and the potential benefits and risks of CAM use in this country. This interim report provides an overview of the issues presented to the Commission, including the need for Federal efforts to ensure access by the public to safe and efficacious CAM services and products, and for reliable and timely information.

A number of speakers noted that many CAM systems of practice place an emphasis on promoting wellness in addition to treating illness and dysfunction. There was considerable public support for the Federal government to help shape health promotion initiatives and disseminate information to the public on CAM as well as conventional approaches to wellness and disease prevention.

A. Coordination Of Complementary And Alternative Medicine Research

Americans are seeking out and using CAM practices and products. In many cases, people are using these practices and products without the scientifically-based information necessary to make informed choices about their safety and efficacy. Individuals who testified, from both the CAM and conventional medical communities, agreed that the public's health and safety calls for more rigorous scientific research and more readily available information on the results of CAM research that already exist. Underlying all research is the paramount goal of producing dependable and relevant information for practitioners and the public.

Testimony to the Commission described a growing interest in and support for CAM research, not only on the part of the CAM community and the public, but also at the Federal level, in academic health centers, in community hospitals, and in mainstream private practices. This interest has further stimulated CAM professional schools and manufacturers of CAM products to enhance their own research capacity. The importance of public input into the research agenda was discussed often during testimony.

Speakers identified several types of evidence-based medical research they believe are needed, such as studies on the basic mechanisms of action; clinical safety and efficacy; treatment

outcomes; and health services, including cost-effectiveness and health care delivery. Speakers and Commissioners agreed that to be methodologically sound, CAM-related studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. There was general agreement that the research should meet high standards of design and execution consistent with the type of information being sought; that strategies be applied that appropriately incorporate step-wise approaches to research sequence and design, as is done in many areas of conventional medical research; and that clinical research comply with human subject protections and appropriate institutional review board guidelines.

Many of those who testified agreed that CAM research might be best served by collaborations between conventional and CAM researchers and clinicians. One goal of these collaborations is to produce research results that meet the rigorous publication requirements of published and on-line peer-reviewed journals that already set standards for the conventional medical community. Testimony also emphasized the need for continued support for training conventional and CAM researchers to study CAM therapies; increased support for developing research infrastructures at accredited CAM and conventional institutions; and for developing funding initiatives to study promising nonpatentable products

Support and coordination of CAM activities by agencies of the Federal government were seen as essential to ensure the types and quality of studies needed as key elements in achieving research progress in these areas. Numerous speakers identified strong and continued support for agencies involved in CAM research and related activities and support for all other Federal agencies with research or related responsibilities. (See Appendix 4) In addition, there was considerable public support for encouraging the private sector--foundations, product manufacturers, and pharmaceutical companies--to support CAM research and collaborate with the Federal sector in strengthening research efforts.

Regulatory Activities

Effective regulations serve and protect the public by ensuring compliance with standards that are shaped by good research, and removing harmful products from the marketplace. Public testimony supported the importance of the Federal government's role in ensuring that CAM products are safe. Testimony also expressed concern that the content and purity of some CAM products, such as dietary supplements, is inconsistent and could potentially have negative health consequences. Testimony indicated that the Food and Drug Administration (FDA) has authority, through the Dietary Supplement Health and Education Act (DSHEA), to ensure product safety but FDA's resources have not been commensurate with these responsibilities. In the testimony, there was strong support to fully implement DSHEA, provide adequate funding for its full implementation, and ensure that the FDA has adequate professional staff with expertise in dietary supplements, particularly botanical products.

A number of speakers, including many from the dietary supplement industry, asked that the FDA establish regulations on Good Manufacturing Practices (GMPs) for quality control and

standardization as a minimum standard for the safety and integrity of all products. They also called upon Federal agencies and the private sector to coordinate efforts to establish and implement guidelines standardizing the composition and purity of products, and to address possible contaminants and adulterants. Researchers asked for standards that will result in a readily available supply of products with consistent composition to assure reliable research results. There was also support for the establishment of a dedicated CAM-related office and/or CAM-related core review teams to facilitate the regulatory review of CAM products.

Although the number of adverse events reported from the use of dietary supplements is relatively small, any adverse event can become a public health issue. Several speakers asked for a strengthening and expansion of the FDA's adverse event reporting (AER) system and for this information to be made widely available. This is consistent with a recent report from the Office of the Inspector General of the Department of Heath and Human Services that describes the current limitations of the AER system for all products and provides recommendations to improve it.[9]

Testimony focused on the need for manufacturers to make information on the benefits and risks of herbs and dietary supplements readily available to consumers and health care professionals through methods such as improved labeling, package inserts, and information at points-of-sale. This information should include any limitations; known interactions with drugs, foods, and other health products; and possible risks to vulnerable populations, including children, the elderly, pregnant and nursing women, and those with certain health conditions or compromised immune systems. [10]

B. Providing Reliable, Useful Information on CAM to Healthcare Professionals and the Public

The Commission heard testimony that the quality, accuracy, accessibility, and timeliness of information on CAM practices and products vary greatly, and there is a significant need for accurate, authoritative, and up-to-date information about CAM. People want to know which CAM approaches might work for them, where they can find professionals qualified to provide these services, and how CAM therapies might interact with their conventional treatments. Clinicians, likewise, need information on the safety and efficacy of various CAM approaches so that they can converse with their patients about CAM and make appropriate and authoritative recommendations and referrals.

Internet, Radio, Television, and Print Media

The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and health care providers. The Federal Trade Commission predicts that 30 million Americans will seek health information online in 2001 and that this number is increasing dramatically.[11] There are numerous CAM-specific websites as well as a variety of general health information sites that include some CAM information. According to

public testimony, some of these sites provide accurate and current information, while many others contain inaccurate, misleading, self-serving, or outdated information.

The Commission heard that for people without access to the Internet or the skills to use the Internet, the National Library of Medicine and the public libraries, through the American Library Association, are training librarians to help people gain access to health information on the Internet. It was suggested that these efforts also could be used to help people gain access to information on CAM practices and products.

Similarly, the Commission heard testimony that television, radio, and print media coverage of CAM benefits and safety issues is often uneven, incomplete, or biased. Media representatives, health professionals, and the general public said that several Federal agencies provide important and useful resources for information on the benefits and safety of CAM. However, they said they are still hampered in their efforts to obtain objective, comprehensive information about CAM by the lack of a central, authoritative resource within the Federal government that can quickly and reliably answer questions on a variety of CAM issues.

Many people from the conventional and CAM professional communities, the public, and the media asked the Federal government to assume a greater leadership role in providing and coordinating authoritative information about CAM practices and products in an easily accessible form that ensures consistent, quality information.

Public testimony described indigenous systems of healing and the use of culturally based CAM therapies among people of different racial and ethnic groups. Community leaders called for the development and promotion of information on the appropriate use of CAM therapies that would be targeted to diverse population groups in the United States.

Public testimony suggested that the Federal government establish a public education campaign that teaches consumers how to evaluate and assess information on treatments that have not been evaluated by the FDA. It also was suggested that a public-private partnership be created to establish a voluntary code of standards for information available on the Internet and through other media, including standards for ethics and disclosure of conflicts of interest.

Advertising, Marketing, and Labeling Regulatory Activities

Advertising, marketing, and labeling are important mechanisms for disseminating information to the public about products. The Commission heard testimony that there is a significant amount of false and misleading advertising, marketing, and labeling of CAM products and practices, especially herbal and dietary supplements. Of particular concern is the marketing of products or services that may be unnecessary, harmful, or otherwise detrimental to the general public, including low-income populations, the elderly, and non-English speaking people. False and misleading advertising may lead people to seek treatments that are not only costly, but also may delay or interfere with more appropriate or effective treatments.

The Commission heard about the role of the Federal Trade Commission (FTC) in identifying false and deceptive CAM-related health claims, and their efforts to minimize the occurrence of these claims. There was public support for sufficient resources for Federal agencies such as the FTC and the Consumer Product Safety Commission to improve oversight of CAM products and services. Testimony also underscored the need for increased consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising, and the importance of involving trusted community leaders in developing successful strategies to prevent consumer exploitation.

C. Access to and Delivery of Complementary and Alternative Medicine

Access to and delivery of health care services affect health care utilization and health outcomes. Many factors influence access to and delivery and utilization of health care services. These factors may include quality of care; distribution and availability of local providers; licensing, certification, and credentialing of providers; coverage and reimbursement; characteristics of the health care delivery system; and consumer outreach, education, and satisfaction., The Commission heard testimony that, as with conventional care, these factors often are more problematic for rural, uninsured, underinsured, and diverse populations.

Consumers, health care professionals, and representatives of professional organizations and educational institutions told the Commission that Americans want to be able to choose from among conventional and CAM practices and products, and they want assurances that practitioners are qualified and products are safe. According to testimony, many Americans have neither this choice nor these assurances.

Testimony described how States regulate health care practitioners by helping to assure quality and accountability of professions and providing a process for professional conduct review and disciplinary action. Information provided to the Commission illustrates State-by-State variability in regulatory approaches to licensure and scope of practice. This information shows that chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 41, 30, and 11 states, respectively. These variations impact access to and delivery of CAM by limiting practitioners' ability to practice lawfully and obtain malpractice insurance.

While some CAM professions endorse licensure and certification to participate more fully in the health care delivery system, several witnesses testified that licensure or certification is not feasible for some categories of CAM practitioners such as Native American and other traditional healers. Some CAM practitioners consider their disciplines to be educational (Alexander Technique) or spiritual (Reiki) and have expressed concerns about licensing as health professionals. The Commission also heard from several conventional practitioners who incorporate CAM modalities in their practices and are concerned that their integrative approach does not lend itself to the

licensure process. Some, but not all, of the conventional practitioners who testified recommended that scope of practice laws be broadened to allow latitude for CAM modalities to be used.

The Commission heard about several models of delivery of CAM services. These included solo CAM practitioners, freestanding CAM facilities offering multiple CAM approaches; collaborative models that support referrals, consultation, and co-management; and a variety of integrative models in which CAM practitioners work with conventional practitioners. There has been little evaluation of the effect on access, clinical outcomes, or cost-effectiveness of these models.

While many of those testifying supported integrative models of delivery, a perspective of some CAM practitioners was that the integrity, philosophy, and standards of CAM disciplines may be compromised, and the effectiveness of CAM practices may be diminished or lost, as various integrative approaches are explored. Other CAM practitioners suggested that if integration occurs, it should include entire systems of care and healing rather than only selective incorporation of CAM modalities that fit into the biomedical model. The importance of educating conventional practitioners in the philosophical and historical roots of CAM disciplines was cited as an important step in preserving the integrity of these other systems of care and healing.

Testimony indicated variation in use of CAM among people of different racial, ethnic, and cultural backgrounds, as well as geographic, economic, and condition-specific variations. However, testimony provided little information regarding factors that determine consumer choice of CAM practices and products. Obtaining this information is important in the appropriate design, development, and implementation of policies and programs.

Coverage And Reimbursement Of CAM Practices And Products

The Commission heard from a spectrum of experts on health care financing, the insurance and managed care industries, and other issues regarding coverage and reimbursement of CAM practices and products. Employers and other health plan sponsors are the major purchasers of health coverage and, in conjunction with insurance companies and managed care organizations, they determine which health benefits are covered and how the services are reimbursed for most Americans.

Testimony indicated increasing interest in and coverage of CAM services by employer-sponsored health plans in direct response to employee requests. They also are increasingly adding CAM benefits to attract and retain employees, improve health, and comply with State mandates. Various employer-sponsored health plans were described, including: limited coverage for certain CAM services (e.g. chiropractic care) as part of a basic benefit package; information-only programs (e.g. Internet-based programs related to CAM modalities); on-site services (e.g. yoga classes); a CAM benefit account (e.g. a $500 annual maximum benefit, with employee co-payments), discount programs (employees may receive CAM services and pay a discounted fee by using a pre-screened panel of CAM providers), or benefit riders (employees may opt to participate in a CAM managed care plan that offers certain services through a credentialed network of CAM providers and with utilization controls).

Federal and State governments are also major purchasers of health care. The Federal government, often through Congressional legislation, makes decisions regarding the health benefits for Medicare, Medicaid, the military, veterans, Federal employees, and others, including funding for the State Children's Health Insurance Program. Some Federally-sponsored sites, such as military and veterans' treatment facilities, are beginning to make some CAM benefits available. States establish health plans for their employees and share responsibility with the Federal government for the Medicaid program and the State Children's Health Insurance Program. States usually enhance the Federally mandated benefits available under Medicaid and extend Medicaid coverage to the medically indigent.

Despite such programs, an overwhelming majority of Americans do not have coverage or reimbursement for CAM services or products. They must pay out-of-pocket for CAM treatment of diseases and for prevention and wellness services. Thus, access to CAM products and practices appears to be limited largely by the ability to pay. Other witnesses noted that limited access to CAM practices and products is part of the larger problem of limited access to all health care.

Representatives of the insurance and managed care industries told the Commission that they are interested in adding covered benefits provided that the services and products are safe, of consistently high quality, are no longer investigational, and that criteria exist for determining medical necessity. They also want standards of practice to guide utilization, assure quality care, and manage financial risk (in view of the potential for malpractice/medical liability suits). Another requirement they specified is that practitioners are adequately educated, trained, and qualified by licensure and/or certification.

Those health care purchasers who are interested in offering CAM services often must base their decisions on incomplete information on safety, efficacy, and cost-effectiveness. They also expressed a strong interest in research on determining whether CAM services and products would be replacements for or additions to conventional services and products. Purchasers testifying before the Commission identified a need the development of appropriate coding for CAM services, improvement of the collection of claims data, and the development of databases for managing information and conducting research on the cost-effectiveness and utilization of CAM. It was suggested that public agencies and private organizations co-sponsor conferences on the development of data on CAM services and products to address issues of coding and building claims databases, and to identify what decision-makers need regarding utilization and cost information.

Public testimony recommended that health services research and demonstration projects be funded by public, private and joint public-private sources to provide information on the efficacy, cost-effectiveness, and cost-benefits of CAM practices and products. It was also requested that the Federal government establish and adequately fund efforts to make CAM research results more available and accessible to the public and to industry, particularly employers, insurers, and policymakers at the Federal and State levels.

D. The Education and Training of Health Care Practitioners in CAM

Testimony underscored the importance of increasing the knowledge and understanding of CAM among conventional health care practitioners to enhance and protect the public's health. It was suggested that a basic or core CAM curriculum for conventional health care professionals be developed at the professional schools, in postgraduate training programs, and at continuing education programs. It also was suggested that these curricula in CAM fundamentals and principles should be developed in conjunction with CAM experts. The curricula should establish, to the extent possible, an evidence-based foundation for conventional health professionals to discuss CAM use with their patients, to make referrals to appropriately trained CAM professionals, and to develop an understanding of the interactions, either therapeutic or harmful, between conventional and CAM treatments to improve and safeguard their patients' health.

Consumer testimony revealed that many people are reluctant to disclose their CAM use to their conventional health care providers whom they believe are not knowledgeable about CAM or interested in CAM approaches to healing. This represents a potential health hazard because conventional practitioners often do not know that their patients may be taking dietary supplements or using CAM practices and products which may interact with medical treatments, [9,12,13] or perioperative care associated with anesthesia or surgical procedures.[13,14,15]

Another issue that emerged during testimony was the need to educate CAM practitioners in the basics of conventional health care so that they can recognize the limits of their clinical expertise and potential complications of their interventions, and make appropriate referrals to conventional health care providers. It was suggested that a basic curriculum for CAM students and practitioners should include information about evidence-based conventional medicine, conventional health care, and other CAM modalities and systems of heath care. The Commission learned about innovative models of cooperative and collaborative CAM training programs, which expose conventional medical and CAM students to each other's philosophies and practices. Continuing education programs exist for audiences composed of both conventional and CAM practitioners.

A number of CAM representatives reported that there is a need for access to funding and other resources for faculty, curricula, and program development as well as for student access to loan and scholarship opportunities. Testimony also suggested that training of CAM professionals should include high quality postgraduate and continuing education programs that resemble those currently available to conventional health care providers.

E. Coordinating And Centralizing Federal CAM Efforts

The Commission heard testimony recommending a centralized process at the Federal level to coordinate CAM activities to ensure optimal access to safe and effective CAM products, services and modalities. The Commission will continue to consider a range of administrative options to promote this level of coordination, including the creation of a centralized Federal office. The Office of Women's Health, or the Office of Minority Health, both established within the Office of the Secretary for Health and Human Services, may provide useful models from which the

Commission can develop an operational proposal. These Offices primarily serve to coordinate, support, and enhance ongoing and new Federal efforts relevant to their missions at all levels of the Federal sector. Thus, a centralized coordinating entity for CAM would neither preempt nor supplant those Federal efforts already in place, particularly the research activities or agenda of the NIH's National Center for Complementary and Alternative Medicine. Nor would it supplant the responsibilities of regulatory agencies, such as the Food Drug Administration and the Federal Trade Commission.

F. CAM In Wellness, Self-Care, Health Promotion And Disease Prevention

The role of CAM in wellness, self-care, health promotion and disease prevention was a frequently emphasized topic throughout the testimony provided to the Commission, including areas where CAM may assist in achieving the Nation's health promotion and disease prevention goals. Since the publication of *Healthy People: The Surgeon General's Report on Health Promotion and Disease* in 1979, goals and objectives for the Nation's health have been defined and monitored. The most recent report, *Healthy People 2010*, includes the involvement of all of the agencies within the Public Health Service, as well as State and local health departments and a wide range of private sector health organizations. Witnesses testified that the integration of CAM in health promotion and disease prevention could have profound positive consequences for the wellness and quality of life of individuals, and may impact on the health care delivery system of the United States.

Many CAM disciplines are derived from cultural traditions and practices that are rooted in connections between the body, mind, and spirit and between individual health and the community's well being. Public testimony recommended that CAM principles and practices of health promotion be taught at all levels of the educational system, and that methods be explored to integrate CAM principles (e.g. connection of body, mind and spirit) and practices (e.g., stress reduction techniques and nutrition) into a national health and wellness initiative.

In the testimony presented to the Commission, the current health care system was described as primarily disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating diseases and conditions. Some who testified believe that the incorporation of CAM principles and practices into the current health care system would improve the emphasis on wellness, self-care, health promotion and disease prevention. Many feel that one of the most important and enduring contributions of CAM will be its emphasis on maintaining wellness and the important role of self-care.

Witnesses described programs in schools, the workplace, geriatric centers, and other institutions that are integrating CAM approaches to wellness, self-care, and prevention into their activities, and recommended that these programs be studied and expanded. It was also emphasized that conventional health professionals need to have some training in the role of CAM in wellness, self-

care, and prevention, and that a multi-disciplinary team approach, with CAM and conventional providers working together, may be a very effective way to promote health and enhance self-care and wellness.

III. Conclusion

The Commission continues to deliberate on all of the issues discussed in the Interim Progress Report and others to fully comply with the Executive Order. The Commission continues to study working models from many sources, including those from other countries. The Final Report will provide detailed recommendations regarding the four topics identified in the Executive Order: coordinating research on CAM; providing access to and delivery of CAM practices and products; developing and providing reliable information on CAM; and educating all health care practitioners in CAM. The recommendations will reflect principles that guide good health care; promote sound scientific inquiry related to CAM; maximize access and delivery of safe and efficacious health care; and promote health and prevent illness by encouraging the well-being of the whole person. As the Commission develops final recommendations and proposals for legislative and administrative actions, it will continue to solicit and consider the advice of the public.

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Appendix 1

THE WHITE HOUSE

EXECUTIVE ORDER 13147

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to establish the White House Commission on Complementary and Alternative Medicine Policy, it is hereby ordered as follows:

Section 1. Establishment. There is established in the Department of Health and Human Services (Department) the White House Commission on Complementary and Alternative Medicine Policy (Commission). The Commission shall be composed of not more than 15 members appointed by the President from knowledgeable representatives in health care practice and complementary and alternative medicine. The President shall designate a Chair from among the members of the Commission. The Secretary of Health and Human Services (Secretary) shall appoint an Executive Director for the Commission.

Sec. 2. Functions. The Commission shall provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine. The recommendations shall address the following:

(a) the education and training of health care practitioners in complementary and alternative medicine;

(b) coordinated research to increase knowledge about complementary and alternative medicine practices and products;

(c) the provision to health care professionals of reliable and useful information about complementary and alternative medicine that can be made readily accessible and understandable to the general public; and

(d) guidance for appropriate access to and delivery of complementary and alternative medicine.

Sec. 3. Administration. (a) To the extent permitted by law, the heads of executive departments and agencies shall provide the Commission, upon request, with such information and assistance as it may require for the purpose of carrying out its functions.

(b) Each member of the Commission shall receive compensation at a rate equal to the daily equivalent of the annual rate specified for Level 1V of the Executive Schedule (5 U.S.C. 5315) for each day during which the member is engaged in the performance of the duties of the Commission. While away from their homes or regular places of business in the performance of the duties of the Commission, members shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701-5707).

(c) The Department shall provide the Commission with funding and with administrative services, facilities, staff, and other support services necessary for the performance of the Commission's functions.

(d) In accordance with guidelines issued by the Administrator of General Services, the Secretary shall perform the functions of the President under the Federal Advisory Committee Act, as amended (5 U.S.C. App.), with respect to the Commission, except that of reporting to the Congress.

(e) The Commission shall terminate 2 years from the date of this order unless extended by the President prior to such date.

WILLIAM J. CLINTON

THE WHITE HOUSE,
March 7, 2000.

THE WHITE HOUSE

September 15, 2000

EXECUTIVE ORDER

AMENDMENT TO EXECUTIVE ORDER 13147, INCREASING THE MEMBERSHIP OF THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to increase the membership of the White House Commission on Complementary and Alternative Medicine Policy from not more than 15 members to up to 20 members, it is hereby ordered that the second sentence of section 1 of Executive Order 13147 of May 7, 2000, is amended by deleting "not more than 15" and inserting "up to 20" in lieu thereof.

WILLIAM J. CLINTON

THE WHITE HOUSE,
September 15, 2000.

Appendix 2

White House Commission on Complementary and Alternative Medicine Policy

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Appendix 3 Schedule of Commission Meetings and Material Subjects Reviewed

Commission Meetings

July 13-14, 2000 - Planning Meeting

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

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

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

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

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

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

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

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

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

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities
- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

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

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

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

July 2-3, 2001 – Discussion of Interim Progress Report

Town Hall Meetings

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

Topics Discussed

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems
- Dietary Supplements and Herbal Products
- Education of CAM Providers

- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

Future Meeting Dates of the Commission

- October 4-6, 2001 Bethesda, MD
- December 6-7, 2001 Washington, DC

Appendix 4

FEDERAL AGENCIES WITH HEALTH RESEARCH AND/OR RELATED ACTIVITIES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

DEPARTMENT OF AGRICULTURE

DEPARTMENT OF DEFENSE

DEPARTMENT OF EDUCATION

DEPARTMENT OF LABOR

DEPARTMENT OF VETERANS AFFAIRS

INDEPENDENT AGENCIES

Consumer Product Safety Commission
Environmental Protection Agency
Federal Trade Commission
National Science Foundation

Maureen

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

REPORT TO CONGRESS CLEARANCE

Report OS#: 082820010027 *DATE CLR DUE:* 08/12/2001

Prepared By: NIH *Date to Clearance:* 08/29/2001

Full Title: Interim Progress Report to Congress of the White House Commission on Complementary and Alternative Medicine Policy - Letters attached for signature

Short Title: White House Commission on Complementary and Alternadve Medicine Policy

This is clearance number 1 for this document.

For:	Referred to the Office of:	
CLEAR	PPO	
CLEAR	OPHS	
CLEAR	OGC	
CLEAR	ASPE	
CLEAR	ASPA	
CLEAR	ASMB	
CLEAR	ASL	Concur with comment*:
CLEAR	SAMHSA	Carol S. Cook 9/5/01
CLEAR	NIH	Signature Date
CLEAR	IHS	
CLEAR	HCFA	
CLEAR	FDA	* CDC believes it may be premature to establish a CAM office
CLEAR	CDC	in HHS/OS at this time.
CLEAR	AHRQ	

Instructions: **Report to Congress is returned to Exec Sec 10 business days from today (August 29, 2001)**

-Lorraine Fishback

Please send your clearance response via the SWIFT System. If you have any questions, please contact Alford, Erica at (202) 690-7699.

Lorraine Fishback
Policy Coordinator

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Thomas, Michelle (HHS/OS)

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Subject:	CC: Interim Progress Report to Congress of the White House Commission on Complementary and Alternative Medicine Policy - Letters attached for signature
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Deadline:	None
DocType:	Reports to Congress
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TaskID:	082820010027-024

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

NIH Clearance comments supplied by NCCAM (Jane Kinsal for Dr. Straus)

The report identifies major issues related to complementary and alternative medicine and captures much of the controversy surrounding it. It deals with issues beyond the purview of the National Institutes of Health and makes no specific recommendations at this point.

We look forward to reviewing a draft of the Commission's Final Report to determine how their recommendations would impact on NCCAM or NIH regarding research, research training, and information dissemination.

I suggest that Section II.A. (page 4) include a sentence noting that NIH expects to fund over 220 million for CAM research and research training in Fiscal Year 2002.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

September 4, 2001

MEMORANDUM

TO: Lorraine Fishback, ES

FROM: Scott Whitaker, ASL

SUBJECT: Control No. 082820010027 – Interim Progress Report of the White House Commission on Complementary and Alternative Medicine Policy – CONCUR WITH COMMENTS

We concur with the submission of the above-captioned interim report to congressional leadership and to members of Congress who have expressly stated an interest in receiving an interim progress report from the Commission, which was established under Executive Order 13147 and is scheduled to issue its final report by March 7, 2002. While we have no comment on the substance of the report, we do note that the following edits should be made:

1. The article cited at endnote 8 is never referenced in the report. Either a reference should be made, or the note should be removed and the subsequent endnotes renumbered.

2. Page 5, first full paragraph needs a period at the end.

3. Page 25, AHRQ is the Agency for Healthcare (not Health) Research and Quality.

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CDER/OFFICE OF DRUG EVALUATION V

Date: 09/11/2001
From: Shaw T. Chen, M.D., Ph.D., Associate Director, ODE-V, HFD-105
Through: Director, ODE-V, HFD-105
To: Office of Executive Secretary

Subject: Comments on Interim Report of the White House Commission on Complementary and Alternative Medicine

In "Regulatory Activities", starting from Page 5 of the Report, the Commission seemed to be content with maintaining regulation of CAM as dietary supplements. The Report emphasized the need of strengthening implementation of the DSHEA, and called for adequate FDA resources to regulate and ensure the quality and safety of CAM as dietary supplements. It also described the need to expand the current adverse event reporting system in FDA to accommodate CAM products. These are all urgent issues in the regulation of CAM, but curiously, no one asked about the quality of evidence that supports the claims of benefits. Yes, it noted that "the manufacturers need to make information on the benefits and risks readily available to consumers and health care professionals through improved labeling", but did not suggest that the "information of benefits" needs to be verified by regulatory authorities. While the latter is not required by DSHEA, it is somewhat disappointing that neither the Commission nor the public testimony cited in the Report showed any interest in upgrading the CAM to the same class as conventional prescription drugs to treat serious diseases (thus subject to rigorous clinical testing and regulatory review).

There is a great expectation and potential for CAM products to be developed as new therapies to fill the medical need currently unmet by conventional approaches. Restricting the use of CAM as dietary supplements and not advocating further upgrading to the level of prescription drugs does not appear to fulfill the missions of "maximizing the benefits to American public of complementary and alternative medicine". This issue should be addressed in the final report.

/09/07/2000

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
IMMEDIATE OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

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- ___ Ekaterini Malliou
- ___ Martina Varnado
- ___ Thomas Yatsco
- ___ Ann Stallion

Sender's Fax #s: (202) 205-2135 or (202) 205-8870
Office #: (202) 690-7753

MESSAGE: Clearance comments from FDA, NIH, CDC, ASL Several are still out but I think these are the main points.

Printed:9/10/01 11:20 am

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

REPORT TO CONGRESS CLEARANCE

Report OS#: 082820010027 *DATE CLR DUE:* 09/12/2001

Prepared By: NIH *Date to Clearance:* 08/29/2001

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CLEAR	SAMHSA	Carol S. Cook 9/5/01
CLEAR	NIH	Signature Date
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CLEAR	FDA	* She believes it may be premature to establish a CAM office
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Thank you

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PUBLIC HEALTH SERVICE
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To: Office of Executive Secretary

Subject: Comments on Interim Report of the White House Commission on Complementary and Alternative Medicine

In "Regulatory Activities", starting from Page 5 of the Report, the Commission seemed to be content with maintaining regulation of CAM as dietary supplements. The Report emphasized the need of strengthening implementation of the DSHEA, and called for adequate FDA resources to regulate and ensure the quality and safety of CAM as dietary supplements. It also described the need to expand the current adverse event reporting system in FDA to accommodate CAM products. These are all urgent issues in the regulation of CAM, but curiously, no one asked about the quality of evidence that supports the claims of benefits. Yes, it noted that "the manufacturers need to make information on the benefits and risks readily available to consumers and health care professionals through improved labeling", but did not suggest that the "information of benefits" needs to be verified by regulatory authorities. While the latter is not required by DSHEA, it is somewhat disappointing that neither the Commission nor the public testimony cited in the Report showed any interest in upgrading the CAM to the same class as conventional prescription drugs to treat serious diseases (thus subject to rigorous clinical testing and regulatory review).

There is a great expectation and potential for CAM products to be developed as new therapies to fill the medical need currently unmet by conventional approaches. Restricting the use of CAM as dietary supplements and not advocating further upgrading to the level of prescription drugs does not appear to fulfill the missions of "maximizing the benefits to American public of complementary and alternative medicine". This issue should be addressed in the final report.

/09/07/2000

Michele

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

REPORT TO CONGRESS CLEARANCE

Report OS#: 082820010027 *DATE CLR DUE:* 09/12/2001

Prepared By: NIH *Date to Clearance:* 08/29/2001

Full Title: Interim Progress Report to Congress of the White House Commission on Complementary and Alternative Medicine Policy - Letters attached for signature

Short Title: White House Commission on Complementary and Alternative Medicine Policy

This is clearance number 1 for this document.

For:	Referred to the Office of:	
CLEAR	PPO	
CLEAR	OPHS	
CLEAR	OGC	
CLEAR	ASPE	
CLEAR	ASPA	
CLEAR	ASMB	
CLEAR	ASL	Concur with comment*;
CLEAR	SAMHSA	
CLEAR	NIH	Carol S. Cook 9/5/01
CLEAR	IHS	Signature Date
CLEAR	HCFA	
CLEAR	FDA	* One believes it may be premature to establish a CAM office in HHS/OS at this time.
CLEAR	CDC	
CLEAR	AHRQ	

Instructions: **Report to Congress is returned to Exec Sec 10 business days from today (August 29, 2001)**

-Lorraine Fishback

Please send your clearance response via the SWIFT System. If you have any questions, please contact Alford, Erica at (202) 690-7699.

Lorraine Fishback
Policy Coordinator

RECEIVED
AUG 30 2001
16397
CDC EXEC SEC

R/C
OPPE-Marcia
8/29/01

Thomas, Michelle (HHS/OS)

From:	SWIFT, NIH
Sent:	Wednesday, September 12, 2001 2:33 PM
To:	Response Packets Incoming
Subject:	CC: Interim Progress Report to Congress of the White House Commission on Complementary and Alternative Medicine Policy - Letters attached for signature
Comments Attached:	0
ContactName:	Ruth L. Kirschstein, MD
ContactPhone:	301-496-3973
Deadline:	None
DocType:	Reports to Congress
Instructions:	This is the 2nd time this Clearance Task is being sent. Please remove the first Clearance Task from your Inbox. Please contact Bahar with any questions. 202-205-2499; Pager 866-397-0567 Thank you
Markedup Attached:	0
OSNum:	082820010027
SWIFTFlags:	5
TaskID:	082820010027-024

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

NIH Clearance comments supplied by NCCAM (Jane Kinsal for Dr. Straus)

The report identifies major issues related to complementary and alternative medicine and captures much of the controversy surrounding it. It deals with issues beyond the purview of the National Institutes of Health and makes no specific recommendations at this point.

We look forward to reviewing a draft of the Commission's Final Report to determine how their recommendations would impact on NCCAM or NIH regarding research, research training, and information dissemination.

I suggest that Section II.A. (page 4) include a sentence noting that NIH expects to fund over 220 million for CAM research and research training in Fiscal Year 2002.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

September 4, 2001

MEMORANDUM

TO: Lorraine Fishback, ES

FROM: Scott Whitaker, ASL

SUBJECT: Control No. 082820010027 - Interim Progress Report of the White House Commission on Complementary and Alternative Medicine Policy - CONCUR WITH COMMENTS

We concur with the submission of the above-captioned interim report to congressional leadership and to members of Congress who have expressly stated an interest in receiving an interim progress report from the Commission, which was established under Executive Order 13147 and is scheduled to issue its final report by March 7, 2002. While we have no comment on the substance of the report, we do note that the following edits should be made:

1. The article cited at endnote 8 is never referenced in the report. Either a reference should be made, or the note should be removed and the subsequent endnotes renumbered.

2. Page 5, first full paragraph needs a period at the end.

3. Page 25, AHRQ is the Agency for Healthcare (not Health) Research and Quality.

MEMORANDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CDER/OFFICE OF DRUG EVALUATION V

Date: 09/11/2001
From: Shaw T. Chen, M.D., Ph.D., Associate Director, ODE-V, HFD-105
Through: Director, ODE-V, HFD-105
To: Office of Executive Secretary

Subject: Comments on Interim Report of the White House Commission on Complementary and Alternative Medicine

In "Regulatory Activities", starting from Page 5 of the Report, the Commission seemed to be content with maintaining regulation of CAM as dietary supplements. The Report emphasized the need of strengthening implementation of the DSHEA, and called for adequate FDA resources to regulate and ensure the quality and safety of CAM as dietary supplements. It also described the need to expand the current adverse event reporting system in FDA to accommodate CAM products. These are all urgent issues in the regulation of CAM, but curiously, no one asked about the quality of evidence that supports the claims of benefits. Yes, it noted that "the manufacturers need to make information on the benefits and risks readily available to consumers and health care professionals through improved labeling", but did not suggest that the "information of benefits" needs to be verified by regulatory authorities. While the latter is not required by DSHEA, it is somewhat disappointing that neither the Commission nor the public testimony cited in the Report showed any interest in upgrading the CAM to the same class as conventional prescription drugs to treat serious diseases (thus subject to rigorous clinical testing and regulatory review).

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/09/07/2000

Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy

August 15, 2001

I. Introduction

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order 13147 on March 7, 2000, to develop legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public.

The President and Congress created the Commission in response to the public's interest in and use of CAM modalities and approaches and in a variety of self-care practices. The Commission is charged with submitting a final report to the President and Congress by March 7, 2002.

This Interim Progress Report provides a brief overview of CAM as well as the Commission and its activities. It also discusses the Commission's progress to date on developing recommendations around the four major topic areas outlined in the President's Executive Order. Individuals and organizations are encouraged to provide written comments on this Interim Progress Report for consideration by the Commission through its website or by letter to the Commission staff.

The Commission's Charge

The President's Executive Order (see Appendix 1) charged the Commission to consider four broad topics related to CAM:

- Coordinated research to increase knowledge about CAM practices and products;
- The provision to health care professionals of reliable and useful information about CAM that can be made readily accessible and understandable to the general public;
- Guidance for appropriate access to and delivery of CAM; and
- The education and training of health care practitioners in CAM.

The Commission's role is to recommend policies that ensure the public's health and safety when accessing CAM practices and products and the practitioners who offer them. The Commission will also recommend strategies to increase the availability of authoritative information about the safety and efficacy of CAM practices, techniques, practitioners, and products.

A. Overview of CAM

Definitions of complementary and alternative medicine (CAM) continue to evolve. CAM generally refers to modalities, practices, techniques, and systems of healing that are used together with ("complementary to") or instead of ("alternative to") conventional medicine. Among the modalities that are associated most often with the term CAM are chiropractic, acupuncture, massage therapy, mind-body techniques (e.g., biofeedback, guided imagery, yoga, and meditation), some forms of nutritional therapy, dietary supplements (including herbs), as well as homeopathy, naturopathic medicine, various forms of energy healing, and the indigenous healing systems of the many ethnic groups in the United States.

Over the past decade, several nationwide surveys have documented a substantial and growing usage of CAM practices and products by the American public.[1-4] These surveys have found that most CAM users seek out conventional medical treatment first, and then turn to CAM practitioners. Most people appear to use CAM in conjunction with, not as a replacement for, conventional medical therapy, and many seek out care that integrates the best of a variety of approaches.[1] The use of CAM modalities, practices, and products by the general population varies in the published literature, ranging from 6.5 percent[6] to 42 percent[3] depending on the population studied and the criteria used to define CAM. Other studies have documented even higher use of CAM therapies among people with chronic and life-threatening conditions.[5,7] For example, a recent study at a major cancer center indicated that 69 percent of patients included CAM approaches as part of their cancer care.[7]

B. An Overview Of The Commission: Its Membership and Activities To Date

Commission Membership

The Commission includes twenty members representing a diverse range of expertise in biomedical research, medical and CAM fields. The Commissioners include the Chair, James S. Gordon, M.D.; George M. Bernier, Jr., M.D.; David E. Bresler, Ph.D.; Thomas M. Chappell; Effie Poy Yew Chow, Ph.D.; George T. DeVries, III; William R. Fair, M.D.; Joseph J. Fins, M.D.; Veronica Gutierrez, D.C.; Wayne B. Jonas, M.D.; Charlotte R. Kerr, R.S.M., R.N., M.P.H., M.Ac.; Linnea S. Larson, LCSW; Tieraona Low Dog, M.D., A.H.G.; Dean Ornish, M.D.; Conchita M. Paz, M.D.; Joseph E. Pizzorno, Jr., N.D.; Buford L. Rolin; Julia Scott; Xiaoming Tian, M.D.; and Donald W. Warren, D.D.S. (Appendix 2)

Activities To Date

The Commission has held seven formal meetings in Washington D.C., all of which have included sessions for open public comment, and four Town Hall meetings, where hundreds of people gave testimony. In total, the Commission has heard from more than 1,000 speakers and received nearly 2,000 individual comments and recommendations from the public. In the coming months, the Commission plans to review reports from previous commissions and authoritative bodies on

the topics identified in its charge and to solicit additional written comments and suggestions from the general public by e-mail, fax, and mail.

Each of the Commission meetings have focused on one or more of the four major topics in the Presidential Executive Order, as follows:

- July 13-14, 2000: Planning Meeting
- October 5-6, 2000: Coordination of CAM Research
- December 4-5, 2000: Access and Delivery of CAM Services and Products
- February 22-23, 2001: Education, Training and Credentialing for CAM Practices
- March 26-27, 2001: Wellness, Self-Care, and Prevention and the Development and Dissemination of CAM Information to the Public
- May 14-16, 2001: Coverage and Reimbursement of CAM Services and Coordination of CAM Research
- July 2-3, 2001: Discussion of the Interim Progress Report and Draft Recommendations

At the four Town Hall meetings held in San Francisco, Seattle, New York City and Minneapolis, testimony was presented on subjects related to all four topics. Appendix 3 contains a detailed description of the subjects discussed during the Commission and Town Hall meetings. The transcripts, agenda, and other information pertaining to all Commission Meetings and Town Hall Meetings are available on the Commission's website, http://whccamp.hhs.gov. Additional information, such as Commissioner biographies and a schedule of future meetings, also is readily available at the website which is periodically updated to reflect ongoing activities. Comments, recommendations, and suggestions can be sent though the website, or to whccamp@mail.nih.gov.

II. The Commission's Progress To Date

The Commission supports the promotion of rigorous science and the appropriate use of the scientific method in research studies. The Commission recognizes the major ongoing contributions in this area by the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health. The Commission also supports making the current evidence for CAM practices and products more widely and easily available to the public and health care providers. The Commission recognizes that recommendations in the Final Report about the appropriate use of safe and effective CAM practices and products must be grounded in sound scientific and ethical principles.

Other principles that will guide the Commission in its deliberations include: an emphasis on health promotion and wellness in addition to disease prevention and the treatment of illness; a recognition that the body has a remarkable capacity for healing that can be facilitated by addressing the underlying causes of illness and suffering; an attention to all aspects of life that can impact health—physical, mental, emotional, environmental, and spiritual; an understanding that each person has unique needs that must be attended to in every therapeutic setting and encounter;

and a belief that self-care is integral to our nation's healthcare and should be taught to health professionals and the public.

The Commission also is focused on maximizing the potential benefits of CAM by considering recommendations that promote collaborations between conventional and CAM health care professionals and researchers, and by encouraging the integrated delivery of CAM along with conventional medicine, where appropriate. Furthermore, the Commission recognizes that consumers have a basic right to choose freely among qualified CAM practitioners and safe products they believe are beneficial to their health, and must be included as partners in any policy or regulatory decisions about CAM access, delivery, and research.

The Commission's recommendations will be formed by the evidence presented and gathered during its deliberations. The diverse perspectives reflected in the testimony heard from advocates, critics and other expert witnesses will be considered in the context of these principles and the potential benefits and risks of CAM use in this country. This interim report provides an overview of the issues presented to the Commission, including the need for Federal efforts to ensure access by the public to safe and efficacious CAM services and products, and for reliable and timely information.

A number of speakers noted that many CAM systems of practice place an emphasis on promoting wellness in addition to treating illness and dysfunction. There was considerable public support for the Federal government to help shape health promotion initiatives and disseminate information to the public on CAM as well as conventional approaches to wellness and disease prevention.

A. Coordination Of Complementary And Alternative Medicine Research

Americans are seeking out and using CAM practices and products. In many cases, people are using these practices and products without the scientifically-based information necessary to make informed choices about their safety and efficacy. Individuals who testified, from both the CAM and conventional medical communities, agreed that the public's health and safety calls for more rigorous scientific research and more readily available information on the results of CAM research that already exist. Underlying all research is the paramount goal of producing dependable and relevant information for practitioners and the public.

Testimony to the Commission described a growing interest in and support for CAM research, not only on the part of the CAM community and the public, but also at the Federal level, in academic health centers, in community hospitals, and in mainstream private practices. This interest has further stimulated CAM professional schools and manufacturers of CAM products to enhance their own research capacity. The importance of public input into the research agenda was discussed often during testimony.

Speakers identified several types of evidence-based medical research they believe are needed, such as studies on the basic mechanisms of action; clinical safety and efficacy; treatment

outcomes; and health services, including cost-effectiveness and health care delivery. Speakers and Commissioners agreed that to be methodologically sound, CAM-related studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. There was general agreement that the research should meet high standards of design and execution consistent with the type of information being sought; that strategies be applied that appropriately incorporate step-wise approaches to research sequence and design, as is done in many areas of conventional medical research; and that clinical research comply with human subject protections and appropriate institutional review board guidelines.

Many of those who testified agreed that CAM research might be best served by collaborations between conventional and CAM researchers and clinicians. One goal of these collaborations is to produce research results that meet the rigorous publication requirements of published and on-line peer-reviewed journals that already set standards for the conventional medical community. Testimony also emphasized the need for continued support for training conventional and CAM researchers to study CAM therapies; increased support for developing research infrastructures at accredited CAM and conventional institutions; and for developing funding initiatives to study promising nonpatentable products

Support and coordination of CAM activities by agencies of the Federal government were seen as essential to ensure the types and quality of studies needed as key elements in achieving research progress in these areas. Numerous speakers identified strong and continued support for agencies involved in CAM research and related activities and support for all other Federal agencies with research or related responsibilities. (See Appendix 4) In addition, there was considerable public support for encouraging the private sector--foundations, product manufacturers, and pharmaceutical companies--to support CAM research and collaborate with the Federal sector in strengthening research efforts.

Regulatory Activities

Effective regulations serve and protect the public by ensuring compliance with standards that are shaped by good research, and removing harmful products from the marketplace. Public testimony supported the importance of the Federal government's role in ensuring that CAM products are safe. Testimony also expressed concern that the content and purity of some CAM products, such as dietary supplements, is inconsistent and could potentially have negative health consequences. Testimony indicated that the Food and Drug Administration (FDA) has authority, through the Dietary Supplement Health and Education Act (DSHEA), to ensure product safety but FDA's resources have not been commensurate with these responsibilities. In the testimony, there was strong support to fully implement DSHEA, provide adequate funding for its full implementation, and ensure that the FDA has adequate professional staff with expertise in dietary supplements, particularly botanical products.

A number of speakers, including many from the dietary supplement industry, asked that the FDA establish regulations on Good Manufacturing Practices (GMPs) for quality control and

standardization as a minimum standard for the safety and integrity of all products. They also called upon Federal agencies and the private sector to coordinate efforts to establish and implement guidelines standardizing the composition and purity of products, and to address possible contaminants and adulterants. Researchers asked for standards that will result in a readily available supply of products with consistent composition to assure reliable research results. There was also support for the establishment of a dedicated CAM-related office and/or CAM-related core review teams to facilitate the regulatory review of CAM products.

Although the number of adverse events reported from the use of dietary supplements is relatively small, any adverse event can become a public health issue. Several speakers asked for a strengthening and expansion of the FDA's adverse event reporting (AER) system and for this information to be made widely available. This is consistent with a recent report from the Office of the Inspector General of the Department of Heath and Human Services that describes the current limitations of the AER system for all products and provides recommendations to improve it.[9]

Testimony focused on the need for manufacturers to make information on the benefits and risks of herbs and dietary supplements readily available to consumers and health care professionals through methods such as improved labeling, package inserts, and information at points-of-sale. This information should include any limitations; known interactions with drugs, foods, and other health products; and possible risks to vulnerable populations, including children, the elderly, pregnant and nursing women, and those with certain health conditions or compromised immune systems. [10]

B. Providing Reliable, Useful Information on CAM to Healthcare Professionals and the Public

The Commission heard testimony that the quality, accuracy, accessibility, and timeliness of information on CAM practices and products vary greatly, and there is a significant need for accurate, authoritative, and up-to-date information about CAM. People want to know which CAM approaches might work for them, where they can find professionals qualified to provide these services, and how CAM therapies might interact with their conventional treatments. Clinicians, likewise, need information on the safety and efficacy of various CAM approaches so that they can converse with their patients about CAM and make appropriate and authoritative recommendations and referrals.

Internet, Radio, Television, and Print Media

The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and health care providers. The Federal Trade Commission predicts that 30 million Americans will seek health information online in 2001 and that this number is increasing dramatically.[11] There are numerous CAM-specific websites as well as a variety of general health information sites that include some CAM information. According to

public testimony, some of these sites provide accurate and current information, while many others contain inaccurate, misleading, self-serving, or outdated information.

The Commission heard that for people without access to the Internet or the skills to use the Internet, the National Library of Medicine and the public libraries, through the American Library Association, are training librarians to help people gain access to health information on the Internet. It was suggested that these efforts also could be used to help people gain access to information on CAM practices and products.

Similarly, the Commission heard testimony that television, radio, and print media coverage of CAM benefits and safety issues is often uneven, incomplete, or biased. Media representatives, health professionals, and the general public said that several Federal agencies provide important and useful resources for information on the benefits and safety of CAM. However, they said they are still hampered in their efforts to obtain objective, comprehensive information about CAM by the lack of a central, authoritative resource within the Federal government that can quickly and reliably answer questions on a variety of CAM issues.

Many people from the conventional and CAM professional communities, the public, and the media asked the Federal government to assume a greater leadership role in providing and coordinating authoritative information about CAM practices and products in an easily accessible form that ensures consistent, quality information.

Public testimony described indigenous systems of healing and the use of culturally based CAM therapies among people of different racial and ethnic groups. Community leaders called for the development and promotion of information on the appropriate use of CAM therapies that would be targeted to diverse population groups in the United States.

Public testimony suggested that the Federal government establish a public education campaign that teaches consumers how to evaluate and assess information on treatments that have not been evaluated by the FDA. It also was suggested that a public-private partnership be created to establish a voluntary code of standards for information available on the Internet and through other media, including standards for ethics and disclosure of conflicts of interest.

Advertising, Marketing, and Labeling Regulatory Activities

Advertising, marketing, and labeling are important mechanisms for disseminating information to the public about products. The Commission heard testimony that there is a significant amount of false and misleading advertising, marketing, and labeling of CAM products and practices, especially herbal and dietary supplements. Of particular concern is the marketing of products or services that may be unnecessary, harmful, or otherwise detrimental to the general public, including low-income populations, the elderly, and non-English speaking people. False and misleading advertising may lead people to seek treatments that are not only costly, but also may delay or interfere with more appropriate or effective treatments.

The Commission heard about the role of the Federal Trade Commission (FTC) in identifying false and deceptive CAM-related health claims, and their efforts to minimize the occurrence of these claims. There was public support for sufficient resources for Federal agencies such as the FTC and the Consumer Product Safety Commission to improve oversight of CAM products and services. Testimony also underscored the need for increased consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising, and the importance of involving trusted community leaders in developing successful strategies to prevent consumer exploitation.

C. Access to and Delivery of Complementary and Alternative Medicine

Access to and delivery of health care services affect health care utilization and health outcomes. Many factors influence access to and delivery and utilization of health care services. These factors may include quality of care; distribution and availability of local providers; licensing, certification, and credentialing of providers; coverage and reimbursement; characteristics of the health care delivery system; and consumer outreach, education, and satisfaction., The Commission heard testimony that, as with conventional care, these factors often are more problematic for rural, uninsured, underinsured, and diverse populations.

Consumers, health care professionals, and representatives of professional organizations and educational institutions told the Commission that Americans want to be able to choose from among conventional and CAM practices and products, and they want assurances that practitioners are qualified and products are safe. According to testimony, many Americans have neither this choice nor these assurances.

Testimony described how States regulate health care practitioners by helping to assure quality and accountability of professions and providing a process for professional conduct review and disciplinary action. Information provided to the Commission illustrates State-by-State variability in regulatory approaches to licensure and scope of practice. This information shows that chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 40, 30, and 11 states, respectively. These variations impact access to and delivery of CAM by limiting practitioners' ability to practice lawfully and obtain malpractice insurance.

While some CAM professions endorse licensure and certification to participate more fully in the health care delivery system, several witnesses testified that licensure or certification is not feasible for some categories of CAM practitioners such as Native American and other traditional healers. Some CAM practitioners consider their disciplines to be educational (Alexander Technique) or spiritual (Reiki) and have expressed concerns about licensing as health professionals. The Commission also heard from several conventional practitioners who incorporate CAM modalities in their practices and are concerned that their integrative approach does not lend itself to the licensure process. Some, but not all, of the conventional practitioners who testified recommended that scope of practice laws be broadened to allow latitude for CAM modalities to be used.

The Commission heard about several models of delivery of CAM services. These included solo CAM practitioners, freestanding CAM facilities offering multiple CAM approaches; collaborative models that support referrals, consultation, and co-management; and a variety of integrative models in which CAM practitioners work with conventional practitioners. There has been little evaluation of the effect on access, clinical outcomes, or cost-effectiveness of these models.

While many of those testifying supported integrative models of delivery, a perspective of some CAM practitioners was that the integrity, philosophy, and standards of CAM disciplines may be compromised, and the effectiveness of CAM practices may be diminished or lost, as various integrative approaches are explored. Other CAM practitioners suggested that if integration occurs, it should include entire systems of care and healing rather than only selective incorporation of CAM modalities that fit into the biomedical model. The importance of educating conventional practitioners in the philosophical and historical roots of CAM disciplines was cited as an important step in preserving the integrity of these other systems of care and healing.

Testimony indicated variation in use of CAM among people of different racial, ethnic, and cultural backgrounds, as well as geographic, economic, and condition-specific variations. However, testimony provided little information regarding factors that determine consumer choice of CAM practices and products. Obtaining this information is important in the appropriate design, development, and implementation of policies and programs.

Coverage And Reimbursement Of CAM Practices And Products

The Commission heard from a spectrum of experts on health care financing, the insurance and managed care industries, and other issues regarding coverage and reimbursement of CAM practices and products. Employers and other health plan sponsors are the major purchasers of health coverage and, in conjunction with insurance companies and managed care organizations, they determine which health benefits are covered and how the services are reimbursed for most Americans.

Testimony indicated increasing interest in and coverage of CAM services by employer-sponsored health plans in direct response to employee requests. They also are increasingly adding CAM benefits to attract and retain employees, improve health, and comply with State mandates. Various employer-sponsored health plans were described, including: limited coverage for certain CAM services (e.g. chiropractic care) as part of a basic benefit package; information-only programs (e.g. Internet-based programs related to CAM modalities); on-site services (e.g. yoga classes); a CAM benefit account (e.g. a $500 annual maximum benefit, with employee co-payments), discount programs (employees may receive CAM services and pay a discounted fee by using a pre-screened panel of CAM providers), or benefit riders (employees may opt to participate in a CAM managed care plan that offers certain services through a credentialed network of CAM providers and with utilization controls).

Federal and State governments are also major purchasers of health care. The Federal government, often through Congressional legislation, makes decisions regarding the health benefits for

Medicare, Medicaid, the military, veterans, Federal employees, and others, including funding for the State Children's Health Insurance Program. Some Federally-sponsored sites, such as military and veterans' treatment facilities, are beginning to make some CAM benefits available. States establish health plans for their employees and share responsibility with the Federal government for the Medicaid program and the State Children's Health Insurance Program. States usually enhance the Federally mandated benefits available under Medicaid and extend Medicaid coverage to the medically indigent.

Despite such programs, an overwhelming majority of Americans do not have coverage or reimbursement for CAM services or products. They must pay out-of-pocket for CAM treatment of diseases and for prevention and wellness services. Thus, access to CAM products and practices appears to be limited largely by the ability to pay. Other witnesses noted that limited access to CAM practices and products is part of the larger problem of limited access to all health care.

Representatives of the insurance and managed care industries told the Commission that they are interested in adding covered benefits provided that the services and products are safe, of consistently high quality, are no longer investigational, and that criteria exist for determining medical necessity. They also want standards of practice to guide utilization, assure quality care, and manage financial risk (in view of the potential for malpractice/medical liability suits). Another requirement they specified is that practitioners are adequately educated, trained, and qualified by licensure and/or certification.

Those health care purchasers who are interested in offering CAM services often must base their decisions on incomplete information on safety, efficacy, and cost-effectiveness. They also expressed a strong interest in research on determining whether CAM services and products would be replacements for or additions to conventional services and products. Purchasers testifying before the Commission identified a need the development of appropriate coding for CAM services, improvement of the collection of claims data, and the development of databases for managing information and conducting research on the cost-effectiveness and utilization of CAM. It was suggested that public agencies and private organizations co-sponsor conferences on the development of data on CAM services and products to address issues of coding and building claims databases, and to identify what decision-makers need regarding utilization and cost information.

Public testimony recommended that health services research and demonstration projects be funded by public, private and joint public-private sources to provide information on the efficacy, cost-effectiveness, and cost-benefits of CAM practices and products. It was also requested that the Federal government establish and adequately fund efforts to make CAM research results more available and accessible to the public and to industry, particularly employers, insurers, and policymakers at the Federal and State levels.

D. The Education and Training of Health Care Practitioners in CAM

Testimony underscored the importance of increasing the knowledge and understanding of CAM among conventional health care practitioners to enhance and protect the public's health. It was suggested that a basic or core CAM curriculum for conventional health care professionals be developed at the professional schools, in postgraduate training programs, and at continuing education programs. It also was suggested that these curricula in CAM fundamentals and principles should be developed in conjunction with CAM experts. The curricula should establish, to the extent possible, an evidence-based foundation for conventional health professionals to discuss CAM use with their patients, to make referrals to appropriately trained CAM professionals, and to develop an understanding of the interactions, either therapeutic or harmful, between conventional and CAM treatments to improve and safeguard their patients' health.

Consumer testimony revealed that many people are reluctant to disclose their CAM use to their conventional health care providers whom they believe are not knowledgeable about CAM or interested in CAM approaches to healing. This represents a potential health hazard because conventional practitioners often do not know that their patients may be taking dietary supplements or using CAM practices and products which may interact with medical treatments, [9,12,13] or perioperative care associated with anesthesia or surgical procedures.[13,14,15]

Another issue that emerged during testimony was the need to educate CAM practitioners in the basics of conventional health care so that they can recognize the limits of their clinical expertise and potential complications of their interventions, and make appropriate referrals to conventional health care providers. It was suggested that a basic curriculum for CAM students and practitioners should include information about evidence-based conventional medicine, conventional health care, and other CAM modalities and systems of heath care. The Commission learned about innovative models of cooperative and collaborative CAM training programs, which expose conventional medical and CAM students to each other's philosophies and practices. Continuing education programs exist for audiences composed of both conventional and CAM practitioners.

A number of CAM representatives reported that there is a need for access to funding and other resources for faculty, curricula, and program development as well as for student access to loan and scholarship opportunities. Testimony also suggested that training of CAM professionals should include high quality postgraduate and continuing education programs that resemble those currently available to conventional health care providers.

E. Coordinating And Centralizing Federal CAM Efforts

The Commission heard testimony recommending a centralized process at the Federal level to coordinate CAM activities to ensure optimal access to safe and effective CAM products, services and modalities. The Commission will continue to consider a range of administrative options to promote this level of coordination, including the creation of a centralized Federal office. The Office on Women's Health, or the Office on Minority Health, both established within the Office of the Secretary for Health and Human Services, may provide useful models from which the

Commission can develop an operational proposal. These Offices primarily serve to coordinate, support, and enhance ongoing and new Federal efforts relevant to their missions at all levels of the Federal sector. Thus, a centralized coordinating entity for CAM would neither preempt nor supplant those Federal efforts already in place, particularly the research activities or agenda of the NIH's National Center for Complementary and Alternative Medicine. Nor would it supplant the responsibilities of regulatory agencies, such as the Food and Drug Administration and the Federal Trade Commission.

F. CAM In Wellness, Self-Care, Health Promotion And Disease Prevention

The role of CAM in wellness, self-care, health promotion and disease prevention was a frequently emphasized topic throughout the testimony provided to the Commission, including areas where CAM may assist in achieving the Nation's health promotion and disease prevention goals. Since the publication of *Healthy People: The Surgeon General's Report on Health Promotion and Disease* in 1979, goals and objectives for the Nation's health have been defined and monitored. The most recent report, *Healthy People 2010*, includes the involvement of all of the agencies within the Public Health Service, as well as State and local health departments and a wide range of private sector health organizations. Witnesses testified that the integration of CAM in health promotion and disease prevention could have profound positive consequences for the wellness and quality of life of individuals, and may impact on the health care delivery system of the United States.

Many CAM disciplines are derived from cultural traditions and practices that are rooted in connections between the body, mind, and spirit and between individual health and the community's well being. Public testimony recommended that CAM principles and practices of health promotion be taught at all levels of the educational system, and that methods be explored to integrate CAM principles (e.g. connection of body, mind and spirit) and practices (e.g., stress reduction techniques and nutrition) into a national health and wellness initiative.

In the testimony presented to the Commission, the current health care system was described as primarily disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating diseases and conditions. Some who testified believe that the incorporation of CAM principles and practices into the current health care system would improve the emphasis on wellness, self-care, health promotion and disease prevention. Many feel that one of the most important and enduring contributions of CAM will be its emphasis on maintaining wellness and the important role of self-care.

Witnesses described programs in schools, the workplace, geriatric centers, and other institutions that are integrating CAM approaches to wellness, self-care, and prevention into their activities, and recommended that these programs be studied and expanded. It was also emphasized that conventional health professionals need to have some training in the role of CAM in wellness, self-care, and prevention, and that a multi-disciplinary team approach, with CAM and conventional

providers working together, may be a very effective way to promote health and enhance self-care and wellness.

III. Conclusion

The Commission continues to deliberate on all of the issues discussed in the Interim Progress Report and others to fully comply with the Executive Order. The Commission continues to study working models from many sources, including those from other countries. The Final Report will provide detailed recommendations regarding the four topics identified in the Executive Order: coordinating research on CAM; providing access to and delivery of CAM practices and products; developing and providing reliable information on CAM; and educating all health care practitioners in CAM. The recommendations will reflect principles that guide good health care; promote sound scientific inquiry related to CAM; maximize access and delivery of safe and efficacious health care; and promote health and prevent illness by encouraging the well-being of the whole person. As the Commission develops final recommendations and proposals for legislative and administrative actions, it will continue to solicit and consider the advice of the public.

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Appendix 1

THE WHITE HOUSE

EXECUTIVE ORDER 13147

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to establish the White House Commission on Complementary and Alternative Medicine Policy, it is hereby ordered as follows:

Section 1. Establishment. There is established in the Department of Health and Human Services (Department) the White House Commission on Complementary and Alternative Medicine Policy (Commission). The Commission shall be composed of not more than 15 members appointed by the President from knowledgeable representatives in health care practice and complementary and alternative medicine. The President shall designate a Chair from among the members of the Commission. The Secretary of Health and Human Services (Secretary) shall appoint an Executive Director for the Commission.

Sec. 2. Functions. The Commission shall provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine. The recommendations shall address the following:

(a) the education and training of health care practitioners in complementary and alternative medicine;

(b) coordinated research to increase knowledge about complementary and alternative medicine practices and products;

(c) the provision to health care professionals of reliable and useful information about complementary and alternative medicine that can be made readily accessible and understandable to the general public; and

(d) guidance for appropriate access to and delivery of complementary and alternative medicine.

Sec. 3. Administration. (a) To the extent permitted by law, the heads of executive departments and agencies shall provide the Commission, upon request, with such information and assistance as it may require for the purpose of carrying out its functions.

(b) Each member of the Commission shall receive compensation at a rate equal to the daily equivalent of the annual rate specified for Level 1V of the Executive Schedule (5 U.S.C. 5315) for each day during which the member is engaged in the performance of the duties of the Commission. While away from their homes or regular places of business in the performance of the duties of the Commission, members shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701-5707).

(c) The Department shall provide the Commission with funding and with administrative services, facilities, staff, and other support services necessary for the performance of the Commission's functions.

(d) In accordance with guidelines issued by the Administrator of General Services, the Secretary shall perform the functions of the President under the Federal Advisory Committee Act, as amended (5 U.S.C. App.), with respect to the Commission, except that of reporting to the Congress.

(e) The Commission shall terminate 2 years from the date of this order unless extended by the President prior to such date.

WILLIAM J. CLINTON

THE WHITE HOUSE,
March 7, 2000.

THE WHITE HOUSE

September 15, 2000

EXECUTIVE ORDER

AMENDMENT TO EXECUTIVE ORDER 13147, INCREASING THE MEMBERSHIP OF THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to increase the membership of the White House Commission on Complementary and Alternative Medicine Policy from not more than 15 members to up to 20 members, it is hereby ordered that the second sentence of section 1 of Executive Order 13147 of May 7, 2000, is amended by deleting "not more than 15" and inserting "up to 20" in lieu thereof.

WILLIAM J. CLINTON

THE WHITE HOUSE,
September 15, 2000.

Appendix 2

White House Commission on Complementary and Alternative Medicine Policy

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Appendix 3 Schedule of Commission Meetings and Material Subjects Reviewed

Commission Meetings

July 13-14, 2000 - Planning Meeting

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

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

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

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

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

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

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

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

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

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities
- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

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

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

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

July 2-3, 2001 – Discussion of Interim Progress Report

Town Hall Meetings

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

Topics Discussed

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems
- Dietary Supplements and Herbal Products
- Education of CAM Providers

- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

Future Meeting Dates of the Commission

- October 4-6, 2001 Bethesda, MD
- December 6-7, 2001 Washington, DC

Appendix 4

FEDERAL AGENCIES WITH HEALTH RESEARCH AND/OR RELATED ACTIVITIES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

DEPARTMENT OF AGRICULTURE

DEPARTMENT OF DEFENSE

DEPARTMENT OF EDUCATION

DEPARTMENT OF LABOR

DEPARTMENT OF VETERANS AFFAIRS

INDEPENDENT AGENCIES

Consumer Product Safety Commission
Environmental Protection Agency
Federal Trade Commission
National Science Foundation

Steve,

I have had a chance to read the DRAFT interim report. Excellent job Steve
A couple minor suggestions.

1. In the second paragraph it should be interest and "use" (not just "in the use" CAM).
2. Under "National Surveys" the word "appreciatetive" is a good one although Ernst has shown that patients are actually more satisfied with visits to CAM practitioners than conventional practitioners.
3. I would split up the sentences on the prinicples. It all runs together as written. Didn't we have 10?
4. In the the paragraph that starts "Speakers before the Commission identified various types of CAM research programs..... there should be an "and" not "of" between cost-effectiveness and heath services research.
5. I have a list (can't locate right now) of government reports to connect too. Will send for the final report.
6. I would emphasize "health promotion" as a word in the wellness section by adding it a in a few places where you list, "self-care, wellness, and prevention, etc.".
7. I am collecting some of he generic writings we did while at the OAM that address CAM issues to be used as deemed appropriate and with modifications for the final report. They have never been published but represent hours of word smithing. Some of them might be useful for you and Jim.

Good job and good luck. Hope you get some time off after this is turned in.

Wayne

Groft, Stephen (NCCAM)

From: EastWestQi@aol.com
Sent: Wednesday, July 18, 2001 3:35 AM
To: Groft, Stephen (NCCAM)
Subject: Interim Report comments....

Dear Steve,

I would agree with Dean Ornish's note with the addition of these:

1. A statement that there are numerous definitions for CAM and give NCCAM's operational definition and a couple of others as an example.
3. There is a need to define "evidence-based".
4. The only real consensus from the people who testified and the commissioners is for the establishment of a center: To act as a clearinghouse and to continue work and also to further carry out the recommendations of WHCCAMP. Recommendations will be forthcoming with the final report. Definitely a statement that denotes the tremendous diversity of opinions, practices which are put under the whole umbrella of CAM in light of over a thousand testimonies that has been heard. And give a brief page on the range of organizations and institutions and individuals who testified to assure them that this process involved have been a very diversified groups.

There are so many unresolved issues.

I think the staff have been a wonderful ongoing supportive group. Thanks.

Loving Qi,
Effie

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DRAFT Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy

July 25, 2001

(NOT FOR RELEASE TO PUBLIC)

I. Introduction

Executive Order 13147 on March 7, 2000, to develop legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public established the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP).

The President and Congress created the Commission in response to the public's interest in the use of complementary and alternative medicine (CAM) modalities and approaches and in a variety of self-care practices. The Commission was charged with submitting a final report to the President and Congress by March 7, 2002.

This Interim Progress Report provides a brief overview of CAM as well as the Commission and its activities. It also discusses the Commission's progress to date in reaching consensus and developing recommendations around the four major topic areas outlined in the President's Executive Order. Individuals and organizations are encouraged to provide written comments on this Interim Progress Report for further consideration by the Commission through its website or by letter to the Commission staff.

The Commission's Charge

The President's Executive Order (see Appendix 1) charged the Commission to consider four broad topics related to CAM:

- Coordinated research to increase knowledge about CAM practices and products;
- The provision to health care professionals of reliable and useful information about CAM that can be made readily accessible and understandable to the general public;
- Guidance for appropriate access to and delivery of CAM; and
- The education and training of health care practitioners in CAM.

The Commission's role is to recommend policies that ensure the public's health and safety when accessing CAM practices and products and to practitioners who offer them. It is also the Commission's responsibility to recommend strategies to increase the availability of authoritative information about the safety and efficacy of all CAM practices, techniques, practitioners, and products.

A. Overview of CAM

Complementary and alternative medicine (CAM) refers to the modalities, practices, techniques, and systems of healing that are used together with ("complementary to") or instead of ("alternative to") conventional medicine. Among the modalities that are most often associated with the term CAM are chiropractic, acupuncture, massage therapy, mind-body techniques (e.g., biofeedback, guided imagery, yoga, and meditation), nutritional therapy, dietary supplements, and herbal products, as well as homeopathy, naturopathic medicine, various forms of energy healing, and the indigenous healing systems of the multiethnic groups of the United States population.

Over the past decade, several nationwide surveys have documented a substantial and growing usage of CAM practices by the American public.[1-4] These surveys have found that most CAM users seek out conventional medical treatment first, and then turn to CAM practitioners and practices. Most people appear to use CAM in conjunction with, not as a replacement for, conventional medical therapy.[1] The use by the general population of CAM modalities, practices, and products reported in the published literature varies from 6.5 percent to 42 percent depending on the population studied and the criteria used to define "CAM". Other studies have documented even higher use of CAM therapies among people with chronic and life-threatening conditions.[5-7] For example, a recent study indicated that 69 percent of patients included CAM approaches as part of their cancer care.6

B. An Overview Of The Commission: Its Membership and Activities To Date

Commission Membership

The Commission includes twenty members representing a diverse range of expertise in medical, scientific research, and CAM fields. The Commissioners include the Chair, James S. Gordon, M.D.; George M. Bernier, Jr., M.D.; David E. Bresler, Ph.D.; Thomas M. Chappell; Effie Poy Yew Chow, Ph.D.; George T. DeVries, III; William R. Fair, M.D.; Joseph J. Fins, M.D.; Veronica Gutierrez, D.C.; Wayne B. Jonas, M.D.; Charlotte R. Kerr, R.S.M., R.N., M.P.H., M.Ac.; Linnea S. Larson, LCSW; Tieraona Low Dog, M.D., A.H.G.; Dean Ornish, M.D.; Joseph E. Pizzorno, Jr., N.D.; Conchita M. Paz, M.D.; Buford L. Rolin; Julia Scott; Xiaoming Tian, M.D.; and Donald W. Warren, D.D.S. (Appendix 2)

Activities To Date

To date, the Commission has held seven formal meetings in Washington D.C., all of which have included sessions for open public comment. In addition, the Commission held four Town Hall meetings, where hundreds of people gave testimony. In total, the Commission has heard from more than 1,000 speakers and received nearly 2, 000 individual comments and recommendations from the public. The Commission plans to review reports from previous commissions and authoritative bodies on the topics identified in its charge. The Commission also continues to solicit additional written comments and suggestions from the general public by e-mail, fax, and mail.

Each of the Commission meetings have focused on one or more of the four major topics in the Presidential Executive Order, as follows:

- July 13-14, 2000: Planning Meeting
- October 5-6, 2000: Coordination of CAM Research;
- December 4-5, 2000: Access and Delivery of CAM Services and Products;
- February 22-23, 2001: Education, Training and Credentialing for CAM Practices;
- March 26-27, 2001: Wellness, Self-Care, and Prevention and the Development and Dissemination of CAM Information to the Public; and
- May 14-16, 2001: Coverage and Reimbursement of CAM Services and Coordination of CAM Research.
- July 2-3, 2001: Discussion of the Interim Progress Report and Draft Recommendations.

At the four Town Hall meetings--held in San Francisco, Seattle, New York City and Minneapolis-- testimony was presented on subjects related to all four topic areas. Appendix 3 contains a detailed description of the subjects discussed during the Commission and Town Hall meetings. In addition, the transcripts, agenda, and other information pertaining to all Commission Meetings and Town Halls are available on the Commission's website, http://whccamp.hhs.gov. Additional information, such as Commissioner biographies and a schedule of future meetings, also is readily available at the website. Periodic visits to the website are the best mechanisms to view ongoing activities of the Commission. Comments, recommendations, and suggestions can be sent to the Executive Director though the website, or to whccamp@mail.nih.gov.

II. The Commission's Progress To Date

In developing policy recommendations to ensure the public's health and safety, the Commission recognizes that recommendations about the appropriate use of safe and effective CAM practices and products must be grounded in sound scientific and ethical principles. The Commission, supports the promotion of rigorous science and the appropriate use of the scientific method in research studies. The Commission recognizes and commends the major ongoing contributions in this area by the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health. The Commission also supports making the current evidence for

CAM practices and products more widely and easily available to the public and health care providers.

Other principles that will guide the Commission in its deliberations include: an emphasis on health promotion and wellness in addition to disease prevention and the treatment of illness; a recognition that the body has a remarkable capacity for healing that can be facilitated by addressing the underlying causes of illness and suffering; an attention to all aspects of life that can impact health—physical, mental, emotional, and spiritual; an understanding that each person has unique needs that must be attended to in every therapeutic setting and encounter; and a belief that education in self-care to promote wellness is integral to all health care and should be taught to health professionals and the public.

The Commission also is focused on maximizing the potential benefits of CAM by considering recommendations that promote collaborations between conventional and CAM health care professionals and researchers and encourage the integrated delivery of CAM along with conventional medicine, where appropriate. Furthermore, the Commission recognizes that consumers have a basic right to choose freely among CAM practitioners and products they believe are beneficial to their health and must be included as partners in any policy or regulatory decisions about CAM access, delivery, and research.

The Commission's recommendations based on these principles and formed by the evidence presented and gathered during its deliberations, will be included in the Final Report. The diverse perspectives reflected in the testimony heard, from both advocates and critics, will be considered in the context of these principles and the potential benefits and risks of CAM use in this country. This interim report provides an overview of the issues presented to the Commission including the need for Federal efforts to ensure access by the public to safe and efficacious CAM services and products, and reliable and timely information.

A number of speakers noted that many CAM systems of practice place an emphasis on promoting wellness in addition to treating illness and dysfunction. There was considerable public support for the Federal government to take a significant role in helping to shape health promotion initiatives and disseminate information to the public on CAM as well as conventional approaches to wellness and disease prevention.

A. Coordination Of Complementary And Alternative Medicine Research

Americans are seeking out and using complementary and alternative medicine (CAM) products and practices. In many cases, decisions to use these products and practices are being made without the scientifically based information necessary to make informed choices about safety and efficacy. Many who testified, from both the CAM and conventional medical communities, agreed that the public's health and safety calls for more rigorous scientific research and more readily available information on the results of CAM research that already exist. Underlying all research

is the paramount goal of producing dependable and relevant information for practitioners and the public.

Testimony to the Commission described a growing interest in and support for CAM research, not only on the part of the CAM community and the public, but also at the Federal level, in academic health centers, in community hospitals, and in mainstream private practices. This interest has further stimulated CAM professional schools and manufacturers of CAM products to enhance their own research capacity. The importance of public input into the research process was discussed often during testimony.

Speakers identified the types of evidence-based medical research they believe are needed, such as studies on the basic mechanisms of action; clinical safety and efficacy; treatment outcomes; and health services, including cost effectiveness and health care delivery. Speakers and Commissioners agreed that to be methodologically sound, CAM-related studies must have a clear question; a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. There was general agreement that the research should meet high standards of design and execution consistent with the type of information being sought; that strategies be applied that appropriately incorporate step-wise approaches to research sequence and design, as is done in many areas of conventional medical research; and that clinical research comply with human subject protections and appropriate institutional review board guidelines.

Many of those who testified agreed that CAM research might be best served by collaborations between conventional and CAM researchers and clinicians, and improved understanding of CAM by institutional review boards. They emphasized the need for continued support for training conventional and CAM researchers to study CAM therapies; increased support for developing research infrastructures at accredited CAM and conventional institutions; and developing funding initiatives for studying promising nonpatentable products. One goal of these collaborations is to produce research results that meet the rigorous publication requirements of published and on-line peer-reviewed journals that already set standards for the conventional medical community.

Support and coordination of CAM activities by agencies of the Federal government were seen as essential to assure the types and quality of studies needed. Speakers identified as key to research progress strong and continued support for agencies involved in CAM research and related activities, and support for all other Federal agencies with research-related responsibilities. (See Appendix 4) In addition, there was considerable public support for encouraging the private sector--foundations, product manufacturers, and pharmaceutical companies--to support CAM research and collaborate with the Federal sector in strengthening research efforts.

Regulatory Activities

Effective regulations serve and protect the public by ensuring compliance with standards shaped by good research, and removing harmful products from the marketplace. Public testimony

supported the importance of the Federal government's role in ensuring that CAM products are safe. Testimony also expressed concern that the content and purity of some CAM products, such as herbs and dietary supplements, is inconsistent.

The Commission heard testimony that some products do not contain the ingredients or the amount of ingredients listed on the label, resulting in consumers receiving more, less, or something other than what they understand the label to indicate. All of these could potentially have negative health consequences. Testimony made clear that the FDA has authority through the Dietary Supplement Health and Education Act (DSHEA) to insure product safety, but that its resources have not been commensurate with these responsibilities. In the testimony, there was strong support to fully implement DSHEA, provide adequate funding for its full implementation, and assure that FDA has adequate professional staff with expertise in dietary supplements, particularly botanical products.

A number of speakers, including many from the herb and dietary supplement industries, asked the FDA to establish regulations on Good Manufacturing Practices (GMPs) for quality control and standardization as a minimum standard for the safety and integrity of all products. They also called upon Federal agencies and the private sector to coordinate efforts to establish and implement guidelines standardizing the composition and purity of products, and to address possible contaminants and adulterants. Researchers also asked for standards that will result in a readily available supply of products with consistent composition to assure reliable research results. There was also support for the establishment of a dedicated CAM-related office and/or CAM-related core review teams to facilitate the regulatory review of CAM products.

Although the occurrence of adverse events from the use of dietary supplements is considered to be quite small, any adverse event can become a public health issue. Several speakers asked for a strengthening and expansion of the FDA's adverse event reporting (AER) system and for this information to be made widely available. This is consistent with a recent report from the Office of the Inspector General of the Department of Heath and Human Services that describes the current limitations of the AER system for all products and provides recommendations to improve it.

Testimony called upon manufacturers to make information readily available to consumers and health care professionals on the benefits and risks of herbs and dietary supplements through methods such as package inserts. This should include any limitations; known interactions with drugs, foods, and other health products; and possible risks to vulnerable populations, including children, the elderly, pregnant and nursing women, and those with certain health conditions or compromised immune systems.

B. Providing Reliable, Useful Information on CAM to Healthcare Professionals and the Public

The Commission heard testimony that the quality, accuracy, accessibility, and timeliness of information on CAM practices and products vary greatly, and there is a significant need for accurate, authoritative, and up-to-date information about CAM. People want to know which CAM approaches might work for them, where they can find professionals qualified to provide these services, and how CAM therapies might interact with their conventional treatments. Clinicians, likewise, are interested in assessing the various approaches and learning enough about them so that they can converse with their patients about CAM and make appropriate and authoritative recommendations and referrals.

Internet, Radio, Television, and Print Media

The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and health care providers. The Federal Trade Commission predicts that 30 million Americans will seek health information online in 2001 and that this number is increasing dramatically.9 There are numerous CAM-specific web sites as well as a variety of general health information sites that include some CAM information. According to public testimony, some of these sites provide accurate and current information, while many others contain inaccurate, misleading, self-serving, or outdated information.

The Commission heard that for people without access to the Internet or the skills to use the Internet, the National Library of Medicine and the public libraries, through the American Library Association, are training librarians to help people gain access to health information on the Internet. It was suggested that these efforts also could be used to focus on CAM practices and products.

Similarly, the Commission heard testimony that television, radio, and print media coverage of CAM benefits and safety issues is often uneven, incomplete, or biased. Media representatives, health professionals, and the general public said that several Federal agencies provide important and useful resources for information on CAM. However, they said they are still hampered in their efforts to obtain objective, comprehensive information about CAM by the lack of a central, authoritative resource within the Federal government from which questions on a variety of CAM issues can be answered quickly and reliably.

Many people from the conventional and CAM professional communities and the general public as well as the media asked the Federal government to assume a greater leadership role in providing and coordinating authoritative information about CAM practices and products in an easily accessible form that ensures consistency and quality of the information.

Public testimony also focused on the use of CAM therapies and particularly indigenous systems of healing among people of different racial, ethnic, or cultural groups. Community leaders have called for the development and promotion of CAM information that is targeted to diverse population groups in the United States.

Public testimony suggested that the Federal government establish a public education campaign that teaches consumers how to evaluate and assess information on treatments that have not been evaluated by the FDA. It was also suggested that a public-private partnership be created to establish a voluntary code of standards for information available on the Internet and through other media, including standards for ethics and disclosure of conflicts of interest; and that the Federal Government extend privacy protections for health information on the Internet to users of CAM-related sites.

Advertising, Marketing, and Labeling Regulatory Activities

Advertising, marketing, and labeling are important mechanisms for disseminating information to the public about products. The Commission heard testimony that there is a significant amount of false and misleading advertising, marketing, and labeling of CAM products and practices, especially herbal and dietary supplements. Of particular concern are low-income populations, the elderly, and non-English speaking people to whom products or services are marketed that may be unnecessary, harmful, or otherwise detrimental. False and misleading advertising may lead people to seek treatments that are not only costly, but may also delay or interfere with more appropriate or effective treatments.

The Commission heard about the role of the Federal Trade Commission in identifying false and deceptive CAM-related health claims, and their efforts to minimize the occurrence of these claims. There was public support for sufficient resources for Federal agencies such as the FTC and the Consumer Product Safety Commission to improve oversight of advertising of CAM products and services. Testimony also underscored the need for increased consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising, and the importance of involving trusted community leaders in developing successful strategies to prevent consumer exploitation.

C. Access to and Delivery of Complementary and Alternative Medicine

Access to and delivery of health care services affect health care utilization and health outcomes. Many factors influence access to and delivery and utilization of health care. These factors may include quality of care; distribution and availability of local providers; licensing, certification, and credentialing of providers; coverage and reimbursement; characteristics of the health care delivery system; and consumer outreach, education, and satisfaction. Testimony provided to the Commission suggests that access to and delivery of CAM practices and products face many of the same issues as conventional care, but also face some issues that are unique to CAM. As with conventional care, these issues often are magnified for rural, uninsured, underinsured, and diverse populations.

Consumers, health care professionals, and representative of professional organizations and educational institutions told the Commission that Americans want to be able to choose from among conventional and CAM practices and products, and they want assurances that practitioners

are qualified and products are safe. According to testimony, many Americans do not have either this choice or these assurances.

Testimony described how States regulate health care practitioners by helping to assure quality and accountability of professions and providing a process for professional conduct review and disciplinary action. Information provided to the Commission illustrates state-by-state variability in regulatory approaches to licensure and scope of practice. This information shows that chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 41, 30, and 11 states, respectively. These variations impact access to and delivery of CAM by limiting practitioners' ability to practice lawfully and obtain malpractice insurance.

While some CAM professions endorse licensure and certification to participate more fully in the health care delivery system, several witnesses testified that licensure or certification is not feasible for some categories of CAM practitioners such as Native American and other traditional healers who do not have accredited educational facilities and who function under local community standards. Some CAM practitioners consider their disciplines to be educational (Alexander teachers) or spiritual (Reiki) and have expressed mixed feelings about licensing as health professionals. The Commission also heard from several conventional practitioners who incorporate CAM modalities in their practices and are concerned that their integrative approach does not lend itself to the licensure process. They recommended that scope of practice laws be broadened to allow latitude for different CAM modalities to be used.

The Commission heard about several models of delivery of CAM services. These included solo CAM practitioners, freestanding CAM facilities offering multiple CAM approaches; collaborative models that support referrals, consultation, and co-management; and a variety of integrative models in which CAM practitioners work with conventional practitioners. There has been little evaluation of the effect on access, clinical outcomes, or cost-effectiveness of these models.

While many of those testifying supported integrative models of delivery, some CAM practitioners expressed concern that the integrity, philosophy, and standards of CAM disciplines may be compromised and the effectiveness of CAM practices may be diminished and possibly lost, as various integrative approaches are explored. Some CAM practitioners testified that when integration occurs, it also should include entire systems of care and healing rather than only selective incorporation of CAM modalities that fit into the biomedical model. In addition, the importance of educating conventional practitioners in the philosophical and historical roots of CAM disciplines was cited as an important step in preserving the integrity of these other systems of care and healing.

Testimony indicated variation in use of CAM among people of different racial, ethnic, and cultural backgrounds, as well as geographic, economic, and condition-specific variations. However, little information is known regarding factors that determine consumer choice of CAM

practices and products. This information was described as important in the appropriate design, development, and implementation of policies and programs.

Coverage And Reimbursement Of CAM Practices And Products

The Commission heard from a spectrum of experts on healthcare financing, the insurance and managed care industries, and other issues regarding coverage and reimbursement of CAM practices and products. Employers and other health plan sponsors are the major purchasers of health plans and, in conjunction with insurance and managed care companies, they determine what health benefits are covered and how the services are reimbursed for most Americans.

Testimony indicated increasing interest in and coverage of CAM services by employer-sponsored health plans in response to employee requests, as well as to attract and retain employees, improve health, and comply with state mandates. Various employer-sponsored health plans were described, including: limited coverage for certain CAM services (e.g. chiropractic care) as part of a basic benefit package; information-only programs; on-site services (e.g. yoga class); a CAM benefit account (e.g. a $500 annual maximum benefit, with employee co-payments), discount programs (employees may receive CAM services and pay a discounted fee by using a pre-screened panel of CAM providers), or benefit riders (employees may opt to participate in a CAM managed care plan that offers certain services through a credentialed network of CAM providers and with utilization controls).

Federal and State governments are also major purchasers of health care. The Federal government, often through Congressional process, makes decisions regarding the health benefits for Medicare, Medicaid (although this authority is shared with States), the military, veterans, Federal employees, and others. Some Federally sponsored health plans, such as military and veterans' treatment facilities, are beginning to make some CAM benefits available. States establish health plans for their employees and may enhance the benefits available under Medicaid and for the medically indigent.

Still, an overwhelming majority of Americans do not have coverage or reimbursement for CAM services or products. They must pay out of pocket for CAM services for the treatment of diseases, prevention, and wellness services. Thus, access to CAM products and practices is largely limited by the ability to pay.

Representatives of the insurance and managed care industries told the Commission that they are interested in adding covered benefits provided that the services and products are safe, of consistently high quality, are no longer investigational, and that there are criteria to determine medical necessity. They also want standards of practice to guide utilization, assure quality care, and manage financial risk (in view of the potential for malpractice/ medical liability suits).

Another requirement they specified is that practitioners are adequately educated, trained, and qualified by licensure and/or certification.

Health care purchasers interested in offering CAM services often must base their decisions on incomplete information on safety, efficacy, and cost effectiveness. Purchasers testifying before the Commission identified a need for efforts to develop appropriate coding for CAM services, improve the collection of claims data, and develop data bases for managing information and conducting research on the cost-effectiveness and utilization of CAM. They also expressed an interest in supporting research to determine whether CAM services and products would be replacements for or "additions" to conventional services and products. It was suggested that public agencies and private organizations co-sponsor a conference on the development of data on the delivery of CAM services and products, including utilization, cost effectiveness, claims data, and coding.

Public testimony also recommended that health services research and demonstration projects be funded by public, private and joint public-private sources to provide information on the efficacy, cost-effectiveness, and cost-benefits of CAM practices and products. It was also requested that the Federal government establish and adequately fund efforts to make CAM research results available and accessible to the public and to industry, particularly employers, insurers, and policymakers.

D. The Education and Training of Health Care Practitioners in CAM

Testimony underscored the importance of increasing the knowledge and understanding of CAM among conventional health care practitioners to enhance and protect the public's health. It was suggested that a basic or core CAM curriculum for conventional health care professionals be developed at the professional school, postgraduate, and continuing education levels. It also was suggested that these curricula in CAM fundamentals and principles should be developed in conjunction with CAM experts. The curricula should establish, to the extent possible, an evidence-based foundation for conventional health professionals to discuss CAM use with their patients, to make referrals to appropriately trained CAM professionals, and to develop an understanding of the interactions, both therapeutic and harmful, between conventional and CAM treatments to improve and safeguard their patients' health.

Consumer testimony revealed that many people are reluctant to disclose their CAM use to their conventional health care providers who they believe are neither knowledgeable about CAM nor interested in CAM approaches to healing. This represents a potential health hazard because conventional practitioners often do not know that their patients may be taking herbal or nutritional supplements, for example, which may interact with medical treatments, [9,10] or perioperative care associated with anesthesia or surgical procedures.[11,12]

Another issue that emerged during testimony was the need to educate CAM practitioners in the basics of conventional health care so that they can recognize the limits of their clinical expertise

and make appropriate referrals to conventional health care providers. It was suggested that a basic curriculum for CAM students and practitioners should include information on evidence-based medicine, conventional health care, and other CAM modalities and systems of heath care. A number of CAM representatives reported that there is a need for access to funding and other resources for faculty, curricula, and program development as well as for student access to loan and scholarship opportunities. Testimony also suggested that training of CAM professionals should include postgraduate and continuing education programs that resemble those currently available to conventional health care providers.

The Commission learned about several innovative models of cooperative and collaborative CAM training programs in medical and other conventional health professional schools, which expose conventional and CAM students to each other's philosophies and practices. Continuing education programs exist for audiences composed of both conventional and CAM practitioners.

E. Coordinating And Centralizing Federal CAM Efforts

Based on testimony received and documents reviewed, the Commission has come to appreciate the need for a centralized process at the Federal level to coordinate CAM activities such that maximal access to safe and efficacious CAM products, services and modalities is ensured. The Commission will continue to consider a range of administrative options to promote this level of coordination, including the creation of a centralized Federal office. The Office of Women's Health, or the Office of Minority Health, both established within the Office of the Secretary for Health and Human Services, may provide useful models from which the Commission can develop an operational proposal. These Offices primarily serve to coordinate, support, and enhance ongoing and new Federal efforts relevant to their missions at all levels of the Federal sector. Thus, a centralized coordinating entity for CAM would neither preempt nor supplant those Federal efforts already in place, particularly the research activities or agenda of the NIH's National Center for Complementary and Alternative Medicine, or supplant the responsibilities of regulatory agencies, such as the Food Drug Administration and the Federal Trade Commission.

Regardless of its final form, it will be critical to include a strong element of public input in such a Federally constituted coordinating entity.

F. CAM In Wellness, Self-Care, Health Promotion And Disease Prevention

The role of CAM in wellness, self-care, health promotion and disease prevention was a topic emphasized throughout the testimony provided to the Commission, including areas where CAM may assist in achieving the Nation's health promotion and disease prevention goals. Since the publication of *Healthy People: The Surgeon General's Report on Health Promotion and Disease* in 1979, goals and objectives for the Nation's health have been defined and monitored. The most recent report, *Healthy People 2010*, includes the involvement of all of the agencies within the Public Health Service, as well as State and local health departments and a wide range of private sector health organizations. Witnesses testified that the integration of CAM in health promotion

and disease prevention can have profound consequences on the wellness and quality of life of individuals, and may impact on the health care delivery system of the United States.

Many CAM disciplines are derived from cultural traditions and practices that are rooted in connections between the body, mind, and spirit and between individual health and the community's well being. In testimony presented to the Commission, it was recommended that CAM principles and practices of health promotion be taught at all levels of the educational system, and that ways to integrate CAM principles (e.g. connection of body, mind and spirit) and practices (e.g., stress reduction techniques and nutrition) into a national health and wellness initiative should be explored.

In the testimony presented to the Commission, the current health care system was described as primarily disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating disease. Experts believe that the incorporation of CAM principles and practices into the current health care system would improve the emphasis on wellness, self-care, health promotion and disease prevention. Indeed, many feel that one of the most important and enduring contributions of CAM will be its emphasis on maintaining wellness and the important role of self-care.

Witnesses described programs in schools, the workplace, geriatric centers, and other institutions that are integrating CAM approaches to wellness, self-care, and prevention into their activities, and recommended that these programs be studied and expanded. It was also emphasized that conventional health professionals need to have some training in the role of CAM in wellness, self-care, and prevention, and that a multi-disciplinary team approach, with CAM and conventional providers working together, can be a very effective way to promote health and enhance self-care and wellness.

III. Conclusion

The Commission continues to deliberate on all of the issues discussed in this Interim Report and others in order to fully comply with the Executive Order. The Commission continues to study working models from many sources, including those from other countries. The Final Report will provide a contextual overview of complementary and alternative medicine so that recommendations provided enforce principles that guide good health care, including empowering consumers through choice and reliable, accurate information; maximizing access and delivery of safe and efficacious health care; and promoting health and preventing illness by encouraging the well-being of the whole person. As the Commission develops final recommendations and proposals for legislative and administrative actions, it will continue to solicit and consider the advice of the public.

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Appendix 1 Executive Order 13147

Appendix 2 Commission Membership Roster

Appendix 3 Schedule of Commission Meetings and Material Subjects Reviewed

Commission Meetings

July 13-14, 2000 - Planning Meeting

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

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

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

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

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

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

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

Practices

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

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

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities
- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

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

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

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

July 2-3, 2001 – Discussion of Interim Progress Report

Town Hall Meetings

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

Topics Discussed

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems

- Dietary Supplements and Herbal Products
- Education of CAM Providers
- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

Future Meeting Dates of the Commission

- October 4-5, 2001 Washington, D.C.
- December 6-7, 2001 Washington, D.C.

Appendix 4

FEDERAL AGENCIES WITH CAM RESEARCH AND/OR RESEARCH-RELATED RESPONSIBILITIES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

DEPARTMENT OF DEFENSE

DEPARTMENT OF VETERANS AFFAIRS

INDEPENDENT AGENCIES

Federal Trade Commission
Consumer Products and Safety Commission
National Science Foundation

Contacting WHCCAMP

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WEBSITE: http://whccamp.hhs.gov

Email to All Commissioners, staff

Subject: Urgent Request for Consideration of Draft Interim Progress Report

Thank you for taking the time to review the Commission's Draft Interim Progress Report and for sending your comments to us and the other Commissioners. We have reviewed all of the comments we've received up to this time and shared them with the staff. Steve has also spoken with a number of you by phone. As can be expected, we have a diversity of opinions on how to proceed, with no clear consensus. ~~Now, we need your guidance.~~

The majority of ~~those who~~ you responded ~~were~~ quite favorably to the general structure and content of the ~~Draft Interim~~ Report and ~~the Commission Recommendations and~~ offered specific suggestions on how to improve it ~~about wording including omission and addition of specific thoughts~~. Several Commissioners ~~were, however,~~ expressed concern~~ed~~, however, that the Commission recommendations in the most recent draft went too far too fast. There were two major concerns here. 1) Though we did arrive at a consensus on the recommendations in the July 2-3rd meeting, we, in fact, needed more discussion and specificity before we put Recommendations forward as Commission Recommendations and/or that we would be better served by waiting until the Final Report to make our recommendations.

2) There were two areas – Access and Delivery and the Creation of a Coordinating Center – which we did not, because of our discussion on "guiding principles", have a chance to review as a whole Commission in the meeting. Therefore recommendations should not be presented in these areas. Also, there were a number of conflicting comments on the discussion of the major issues.

Because we believe ~~feel~~ it is essential ~~very important~~ for the Commission to move ahead with consensus, we're now asking each of you to consider three ~~(3)~~ possible alternatives that ~~all of us, or at least as many of us as possible~~ we can all agree on, for the Interim Report. They're listed below, ~~together~~ along with the advantages and disadvantages ~~pros and cons for~~ of each. We want you to consider them and let us know what you think. Steve will be calling each of you between now and close of business Friday, July 20th, to discuss them with you. We are hoping to submit the final Interim Report to Secretary Thompson by the middle of next week.

1) **The "Basic Facts" Version with no recommendations or discussion of issues identified by the public. A less is better approach.**

Advantages: No controversy, ease in preparation, ease of clearance.
Disadvantages: No information will be provided to the public, Congress and the Administration for action. This approach will raise significant questions about what the Commission has been doing with the public's money for the last 12 months. There will be ~~no~~ basis on which to have discussions with Congress or the Administration about the Commission's work, possible legislation, or Administrative change. This will significantly inhibit the engagement of the public in debate about any of the issues before

a very limited

the Commission. Stakeholders will be extremely troubled by lack of information and take it for lack of commitment. This does not represent the position of the vast majority of Commissioners.

2) **"Middle-of-the-Road" approach. Identification and discussion of the issues as raised by the public in each of the areas we've covered as we've presented in the Draft, taking your comments into account.** This would focus on what we've heard from the public, but the Commission itself would make no recommendations at this time, deferring them to the Final Report.

Advantages: little controversy and criticism of report; ease of clearance; suggests direction of Commission's thoughts; will generate public discussion on the issues; will provide a sense of the Commission's work and its scope to the public; will offer a platform to begin discussions of possible legislation and administrative recommendations; would offer the public an opportunity to provide input; will shield the Commission from potential criticism at this time; will leave to the Final Report the force of our recommendations. This represents a position which may be the easiest for Commissioners who are unsure about many recommendations to concur with.

Disadvantages: May slow the Commission's momentum: without firm Commission positions or recommendations, efforts at formulating legislation or advancing administrative changes will move more slowly; does not provide our supporters in Congress with specific proposals on which to build legislation in this session of Congress; will likely cause confusion and consternation in stakeholders who have been actively engaged in the Commission process, and will raise questions about the Commission's commitment. This position may be particularly distressing to those present at July 2-3 meeting or the many to whom reports of that meeting are circulating. Why they will wonder if we reached consensus about recommendations, are we now withdrawing them?

3) **"Modified Version of the July 12th Draft" recently circulated on which Commissioners have made comments.** The modifications would include making it clear that recommendations about Access and Delivery and the Central Office were not being made, because of lack of full Commission discussion, until the Final Report.

Advantages: Makes the Commission's work and its considered thought on matters presented clear to Congress, the Administration and the stakeholders; provides a clear basis for legislative and administrative recommendations now and for moving the process ahead in this session of Congress; adheres to public actions in July 2-3rd meeting; fulfills our commitment to Congress; will gain significant public attention. Represents the position we publicly agreed on at the July 2-3 meeting.

Disadvantages: May indeed be a premature representation of the Commission's collective positions; general recommendations will be made before specific implementation has been worked out; may put the Commission in high profile and exposed position; may provoke criticism from those who are opposed to

when

recommendations; may focus too much attention on the Interim as opposed to the Final Report at a time where we're not prepared to discuss in detail the recommendations; Clearance process may be more difficult; may move too quickly for several Commissioners. This position represents the views of a few Commission members

We encourage you to tell us within the next day and a half how you feel about these options and talk with Steve about them. After these discussions, Steve and Jim Gordon, together with the staff and Jim Swyers, will complete the re-draft of the report and send it out to you again.

Steve can be reached on 1-866-373-1124 (Toll Free) or 301-435-6199 (Direct Line).

Steve Groft and Jim Gordon

Email to All Commissioners, staff

Subject: Urgent Request for Consideration of Draft Interim Progress Report

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↑ Delete. Position of Commissioners Not known!

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Steve Groft and Jim Gordon

Provide

Axelrod, Corinne (NCCAM)

From: Groft, Stephen (NCCAM)
Sent: Wednesday, July 18, 2001 4:41 PM
To: 'jsgordon@mindspring.com'; Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); Jim Swyers; Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Urgent Request for Consideration of Draft Interim Progress Report - Draft and Awaiting Commenst for revision

Jim,

Here is a draft note to the Commissioners Please revise as appropriate.

Thanks.

Steve

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1.) **Basic Facts** ~~version with~~ No recommendations or discussion of issues identified by the public. A less is better approach.

Advantages: No Controversy; Ease of Preparation; Ease of Clearance;
Disadvantages: No information to the public, Congress, and the Administration for Action; Question Activities of the Commission in last 12+ months; No sense of direction of the Commission; No Message to Float Trial Concepts or Issues

2.) **Middle-of-the-Road** ~~approach~~ Brief identification and discussion of the issues. No recommendations from the Commission ~~as such~~. Previous recommendations would be provided as "suggestions" from public testimony.

Advantages: Little Controversy and criticism of report; Ease of Clearance; Suggests direction of Commission's thoughts; Generate Comments from Public on the issues; Can take sense of the Commission to the public
Disadvantages: No Firm positions or recommendations

3.) **Fully Expanded Version**: Highlight the Recommendations and include an extensive discussion of the issues and presentation of the Consensus of the Commission as presesented in most recent draft of July 12.

Advantages: High Degree of Controversy; Active discussion of issues and recommendations by the public;
Disadvantages: Limited approval or acceptance of recommendations by Commission;More Difficult Clearance Process; High Resistance Factor; Possible Adverse Action on Commission's activities

After receiving your suggestions and deciding which approach to take, we will recast the Draft Report as directed and send to you one more time for your review. I will also attempt to call you to discuss rationale for course of action. I can be recahed on 1-866-373-1124 (Toll Free)or 301-435-6199(Direct Line).

I will send more information on Activation of Working Groups for preparation of Draft Final Report for October Meeting, timelines, goals, and process for developing and reviewing the significant issues, recommendations and the Final Report

I do need to hear from you to obtain the sense of the Commission and the next steps to take for the Draft Interim progress report ~~Recommended~~ Please email or call me ASAP so we can get a sense of the direction the Commission want to take. ~~and~~ Thank you for your attention & patience! ~~Action~~

deadline

Steve - do you want to mention that staff recommends #2? And that we are preparing it (in case that is the phone calls?) 1

19 July 2001 Steve,

Kaczmarczyk, Joseph (NCCAM) Here are my Comments. Joe

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Is this an advantage or disadvantage ?

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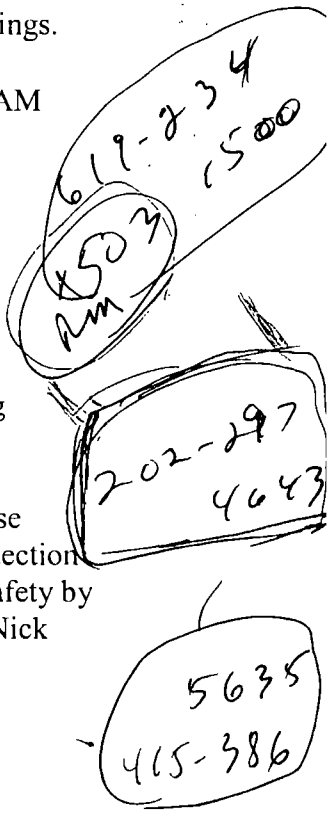
Core Values of the Commission:

The Commission is committed to:

1. Improving the health of Americans by ensuring the availability of safe and efficacious CAM services and products.
2. Science and the appropriate use of the scientific process as a method for identifying and developing safe and efficacious CAM services and products.
3. The concept that individuals should have freedom of choice among practitioners, with accountability. All human beings have the right to feel cared for and have access to their practitioner of choice.
4. The concept that the body has a remarkable capacity for healing that can be facilitated by addressing underlying causes of illness and suffering.
5. The emphasis on the care of the whole person (mind, body, and spirit). Health is more than just the absence of disease.
6. The concept that CAM is consumer-driven health care movement—both on a personal and policy level (research and delivery)
7. The concept that many areas of CAM do have scientific validity but they need stronger evidence.
8. The concept that each person is unique and has to be addressed as so.
9. To promoting CAM education at all levels and for all ages
10. Focusing on the facilitation of integration/collaboration activities between CAM and conventional medicine practitioners and researchers, wherever appropriate.

Coordinated CAM Research

- Research is urgently needed because consumers are already using these things.
- There should be more research that should cover the entire spectrum of CAM research from basic sciences to health services research.
- Money should be made available not to just NCCAM but to other Federal agencies involved in health care research and delivery.
- Research should meet high standards
- Funding should be made available both to academic medical centers doing research on CAM as well as free-standing research centers
- Encourage partnerships between CAM and conventional researchers. Those people who are going to be doing the research need some umbrella of protection both for the researchers and the subjects of the research. Need to ensure safety by involvement of people with deep knowledge of the patients' conditions. Nick



Gonzalez is one example of such a collaboration. Field studies may be an integral part of this. Ethical standards would need to be developed.

Regulation of CAM

- DSHEA needs to be fully implemented. Any additional funding needs to be clearly directed at implementing DSHEA. Look at IOG report and find more information on European and other international models.

- There needs to be a greater focus on the reporting of adverse events and interactions. These issues are not just confined to CAM approaches, however. Any discussion should recognize this.

- There needs to be involvement of CAM experts in all issues of development and adverse events reporting.

- There needs to be an effort to find a middle ground between DSHEA and NDA's. We are not sure yet what this middle ground would look like.

- We do not have consensus on entity to conduct research on botanicals. It is too early to recommend whether it should be within or outside of FDA.

- There needs to be a great deal more information made available and many ways of providing this information. How the information will be provided, we are not yet sure.

Education and Training

- A good recommendation:
  1. Is clear and jargon-free
  2. Is achievable
  3. Is non-global (non overly general)
  4. Is in a form that can be operationalized
  5. Can be evaluated
  6. Honors various traditions of the system of healing as well as emerging approaches
  7. Based on experience that can be extrapolated

- All conventional health care professionals need to know more about the field of CAM, including definitional issues and historical approaches. Modalities often are defined as conventional or CAM based solely on how they were introduced into the marketplace (e.g., glucosamine). They also need to know the level of evidence for each kind of approach.

- There needs to be much greater knowledge about the traditional systems of healing that are available in the local community.

- All CAM professionals need to have some knowledge of conventional medicine. CAM and conventional practitioners need to know their limitations so they known when they can refer patients to the appropriate practitioner.

- Demonstration projects in these areas and what we are already doing in these areas.

- All those who are in accredited schools who are learning in the health profession, whether CAM or conventional, should have access to federally backed student loans. There are still unresolved issues in the area of loan forgiveness. There is also some disagreement about licensed versus unlicensed.

- A simple increment would be to removing restrictive language from federal legislation.

- Consensus around cross-training. The goal is to give CAM and conventional practitioners exposure to each other's methods of practice so that they can communicate and refer to one another. This is not a mandate but more of a fostering of cross fertilization of ideas.

Credentialing and Licensing

- A good recommendation:

    1. Protects consumer safety
    2. Protects freedom of choice
    3. Ensures accountability of practitioners;
    4. accounts for existing laws and licensing entities;
    5. accounts for WHCCAMP scope of authority.
    6. Takes into account request for guidance from National Governor's association

- The Commission was generally in favor of licensing because in many instances it assures accountability and giving increased access. However, it was recognized that there are many unintended consequences of licensure, including:

    1. A clear feelings on the part of traditional healers that any attempt to license CAM professions will work against them.

    2. The narrow definition that comes with licensure will prevent others from being able to practice their trade.

- Although Commissioners could see the wisdom in recommending such things as national mandatory standards of care, there was substantial uneasiness for

endorsing any specific recommendations at this time. Commissioners were not willing to go any further than general recommendations that are in the draft of the interim report.

- There was consensus that a distinction be made between encouraging versus mandating licensure.

- There also was consensus against repealing freedom of choice measures.

Information Dissemination and Advertising

- There is a need for a central Federal entity that can provide a variety of types of information on CAM. This entity, office, or clearinghouse will deal with all of the issues related to information as time goes on.

- There was general support for a public-private venture to develop national standards for the dissemination of information to which Internet sites could voluntarily subscribe.

- A significant need exists for dissemination of information above and beyond the Internet or a centralized website. There needs to be an additional focus to use local libraries, public service announcements, as well as other entities in the community to disseminate CAM information to hard-to-reach populations. The staff could help identify ways that information has been provided to the public in other health contexts.

- There was strong consensus for supporting the FTC in its efforts to substantiate claims made by Internet sites and in other media. This is not just limited to CAM, however. FTC needs significantly more resources if it is to adequately handle these responsibilities.

- There is a need for more collaboration between state and federal agencies to provide information about CAM practitioner licensing and credentialing as well as to better report potential adverse events.

Process for Finishing the Interim Report:

WHCCAMP staff et al. will incorporate comments/concerns from Commission over the next five or six days.

Staff will send the revised draft to the Commissioners and give them 72 hours to review.

WHCCAMP staff will incorporate final comments and submit to Secretary of HHS on July 16th, 2001.

Process Leading Up to the October Meeting:

WHCCAMP staff will work with discreet committees of Commissioners to develop individual sections of the report (other than the first three overview sections). Michelle is going to send out lists of the committees for people to look at and either continue on the same committee or to ask to be assigned to another committee.

As much of the report that has been developed by mid-September will be sent to the full Commission for review by the October meeting. Every effort will be made to pull together

October meeting will be expanded to three days (October 4-6) to allow for more discussion of the draft full report.