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Interim Report (Revisions) July 27, 2001 [1]

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RESTRICTION CODES

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NIH-117
WHCCAMP Committee Records
1100-G-8a

01 -- Interim Report 7/27/01 (revisions)
02 -- Report Interim *2001*
03 -- WHCCAMP Recommendations *2001*
04 -- WHCCAMP Report Outline *2001*
05 -- Recommendation *2001*
06 -- Report - Introduction *2001*
07 -- Report References *2000-2001*
08 -- Mary Ann Liebert *2001*
09 -- WHCCAMP Report *1999-2001*
10 -- Final Report WHCCAMP *2001-2002*
11 -- Acknowledgements *c. 2002*
12 -- Transmittal Letter *2002*

Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy
September 18, 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.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
IMMEDIATE OFFICE OF THE SECRETARY
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December 8, 2000 (11:52AM)

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[3,8] 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 NIH research Institutes and Centers, including the NCCAM, plans to fund over $220 million for CAM research and research training in Fiscal Year 2002. 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, are 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 guidelines on processing and production as approaches to ensuring the safety and integrity of all products during manufacture. 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 (FTC) 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 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 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 for 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. <u>Coordinating And Centralizing Federal CAM Efforts</u>

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

COMMISSION ROSTER

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

DEPARTMENT OF AGRICULTURE

DEPARTMENT OF DEFENSE

DEPARTMENT OF EDUCATION

DEPARTMENT OF ENERGY

DEPARTMENT OF LABOR

DEPARTMENT OF VETERANS AFFAIRS

INDEPENDENT AGENCIES

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

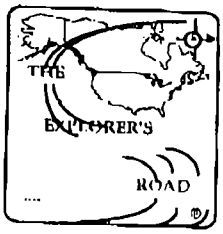
TELEFAX

Fairfax House International

The Leadership Clearinghouse for Multi-National Community Development

L'Association Européenne des réseaux d'entreprises
European-North Amerian State-of-the-Cities Report

FxHouse@compuserve.com
Fax: (703) 960-9626



To : KEN FISHER

Attention:

Number of pages including cover sheet: 1

From: RALPH WOONER, Chairman

Date: 28 September 2001

Message:

First, our condolences. Since our situation with my mother is comprable to that you had with your Dad, we know how it has been for you. But to lose somebody that close to you is always a wrench.

We can talk late Tuesday morning if you would like. I am taking my car in for a check up at 9:30, but hope to beover at Crystal's around 11 to go over logistics. We can initiate the call to either your home or office as you prefer.

Two of the most urgent matters to go over with you are: (1) the Board of Governors will meet from 6 pm to about 9:30 pm on the evening of November 12 over dinner. Any chance whether you can see if we can get a room at the Cosmos Club for that purpose? And could we reserve rooms for Governors that need them? (2) We need to work up the budget for approval by the Board. Did you lose everything in your pc crash? Do you need help working up estimated "actuals"? (3) I am trying to talk David Jones into being Treasurer next year. Don't know if I'll succeed, but if he does agree that probably means that Crystal's shop will have to do more of the bookkeeping.

Box 7212 • Alexandria, Virginia 22307 • U.S.A. • Tel: (703)960-9626

From : FAIRFAXHOUSE PHONE No. : 7039609626 Sep. 28 2001 2:39PM P01

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1259
CONNECTION TEL	93019845751
SUBADDRESS	
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RESULT	OK

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TRAVEL PRINT/REVIEW - APPROVED

09/24/01 08:20:50

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ORDER#: WYW10486 -01 ENTRY DATE: 08/28/01 FY CAN: 18338443
BID: NCCAM CLERK ID: DAK AO: MDA AO APPROV DATE: 09/24/01
UPDATE: 09/24/01

SSN: ----------
TRAVELER: BUFORD L ROLIN STATUS: REQUEST APPROVED
TITLE: WHCCAMP COMMISSIONER
MAIL ADDRESS: TRIP START: 10/03/01 04:20 PM
POST OFFICE BOX 19 END: 10/06/01 10:12 PM
ATMORE, AL 36502

DUTY STATION: BETHESDA, MD BLDG: DEM II RM: 880 TEL: 301-435-7592
CONTACT: DORIS KINGSBURY BLDG: DEM II RM: 880 TEL: 301-435-7592
RECOMMENDED BY: STEPHEN GROFT TITLE: EXECUTIVE DIRECTOR
EMPLOYEE: CIVILIAN EXEMPT FROM CREDIT CARD REGS: NO
PURPOSE: TO ATTEND WHCCAMP MEETING OCTOBER 4-6

ITINERARY: WASHINGTON/MOBILE
PRIMARY TRANSPORTATION: AIR CLASS TRAVEL: COACH
JUSTIFICATION NON-CONTRACT CARRIER: HOURS

			SPONSOR NO/RC
FARE: BLANKET GTA	CAN: 18338443 OC: 2151	EST.COST:	553.00
POV-EST. MILES:	MILEAGE RATE: .345	EST.COST:	
EXCESS TAXI (OTHER THAN TO AND FROM TERMINAL)		EST.COST:	
CAR RENTAL, IF AUTHORIZED:		EST.COST:	
OTHER TRANSP. (PARKING, TOLLS, TAXI, SUBWAY, BUS)		EST.COST:	
NIGHT'S LODGING ADVANCE, DUE DATE:		EST.COST:	.00

MIXED MODE AUTHORIZED? NO
GSA VEHICLE AUTHORIZED? NO
EXCESS BAGGAGE AUTHORIZED? NO ESTIMATED WEIGHT?

********** SUMMARY **********

	OC	EST. COST
MAXIMUM ESTIMATED PER DIEM:	2151	.00
TRANSPORTATION (EXCLUDING GTA/GTR):	2151	.00
ADDITIONAL EXPENSES:	2151	.00
	SUBTOTAL:	.00
REGISTRATION: DUE DATE:	252W	00

Groft, Stephen (NCCAM)

From: Veronicapgdc@aol.com

Sent: Monday, July 30, 2001 11:11 AM

To: Groft, Stephen (WHCCAMP)

Subject: (no subject)

Good Morning, Steve,

Here are my two final comments on the draft:

1. I am recommending for a second time that the principles that the Commission agreed upon not be run together in paragraphs. I would like to see them itemized in recognition of the importance we gave them.

2. The comment under Education and Training, paragraph 3, "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."

That sounds like a quote from the AMA! I remember numerous comments about allopathic experiences that turned out poorly. So, in all fairness acknowledging the costs, morbidilty, and mortality associated with iatrogenic events, and the malpractice experience of the medical practice, I believe a statement recognizing the need to refer reciprocally is essential.

Personally, I can tell you that in clinical practice I have made referals to dentists, naturopaths, LMPs, vascular specialists, internists, orthopedists, etc., but have never received a referral from a medical physician unless it was by way of a managed care plan necessitating a referral for chiropractic and the patient was insistent that he/she get it.

I look forward to having these two concerns considered in the very final draft. Thank you for all the endless work.

Veronica

Groft, Stephen (NCCAM)

From: EastWestQi@aol.com
Sent: Monday, July 30, 2001 5:53 PM
To: Groft, Stephen (WHCCAMP)
Cc: tierney334@yahoo.com; cmapaz@totacc.com; Bresler@aol.com; DeanOrnish@aol.com; drwarren@artelco.com; EastWestQi@aol.com; gbernier@utmb.edu; georged@ashn.com; jsgordon@mindspring.com; drpizzorno@qwest.net; jjfins@mail.med.cornell.edu; Jrsct6@cs.com; linnealarson@mac.com; Tom@toms-of-maine.com; Lowdogmd@aol.com; Veronicapgdc@aol.com; wjonas@usuhs.mil; DrFair@haelth.com; MingTian@aol.com; Axelrod, Corinne (WHCCAMP)
Subject: Re: Revised Draft Interim Progress report

Dear Steve,

The report looks generally okay taking the #2 position. I would like to see a more definitive statement about a few of the adversaries such as the physicians who testified in New York who were being called to court. This will require a look at future legislation for protection for MD's who are in practice. We should also say that we made attempts to include adversaries to express their opinions and recommendations.

I don't want to emphasize the negative... you know me....but to balance the scale of reports so that they realize that we are not just all prothesizing for CAM.
This shows also the complexity of what the Commission needs to sift through....from the very supportive to the very negative. .

I liked the emphasis on Wellness... also that it is not the Commission's opinions, but that of the people!

The report has turned out very nice...the report that I believe that we can all work from towards a good final recommendation document. Thanks to all the staff for their hard work and to all the Commissioners for their committment to excellence!! I am proud to be part of the team.

Loving Qi and hugs,
Effie

Founder and President, East West Academy of Healing Arts (EWAHA)
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email: eastwestqi@aol.com
website: eastwestqi.com

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; 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. 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 assure the types and quality of studies needed. 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 as key elements in achieving research progress in these areas. (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 ~~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

PHOTOCOPY
PRESERVATION

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~~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 Food and Drug Administration (FDA) has authority through the Dietary Supplement Health and Education Act (DSHEA) to ensure 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 the FDA has adequate professional staff with expertise in dietary supplements, particularly botanical products.

A number of speakers, including many from the herbal and dietary supplement industries, 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 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 which 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 package inserts. 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 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 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 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 is the marketing of products or services that may be unnecessary, harmful, or otherwise detrimental to 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 may also 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. ~~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 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 ~~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 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. ~~They~~ recommended that scope of practice laws be broadened to allow latitude for CAM modalities to be used. Some practitioners

Others who testified do not share this point of view ☺

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 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, 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.

Testimony provided

? factors

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 and managed care companies, 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 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 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 ~~services for the~~ treatment of diseases, and/or 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 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. 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 conferences on the development of data on CAM services and products to address issues of coding and building claims data bases, 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 level.

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, 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 herbal or nutritional supplements which may interact with medical treatments, or perioperative care associated with anesthesia or surgical procedures.[9,12,13] 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 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 limited number of currently

E. Coordinating And Centralizing Federal CAM Efforts

The Commission heard recommending

~~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 to ensure optimal 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 and 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.

~~Regardless of its final form, it will be critical to include a significant element of public input into the development of such a Federal 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 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 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. 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 or conditions. Some 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. 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~~ 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 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 4-6, 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)
Center for Medicaid and Medicare 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

Contacting WHCCAMP

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DRAFT Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy
July 26, 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 ~~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 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 ~~and change~~. CAM generally 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), some forms of 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~~ in the United States ~~population.~~

delete and?

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.[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".[7] 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.[7]

at one clinic? (seems like we've chopped out too much info - now it suggests that 69% of all patients....)

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. 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, ~~The website~~ is periodically updated to reflect ongoing activities ~~of the Commission~~. Comments, recommendations, and suggestions can be sent 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 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 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 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 final recommendations will be ~~based on these principles and~~ informed 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.

Essential Elements for Topic-Specific Chapters of the Final Report

The following are essential elements that must be included in the topic-specific chapters of the Final Report. These elements eventually may be re-organized for strategic or stylistic reasons, but each chapter must fully address one of the following 8 topics, and must include, at minimum, the following four elements.

Topics include Coordination of Research; Information Development and Dissemination; Access to and Delivery of CAM; Coverage and Reimbursement of CAM Practices and Products; Education and Training of Health Care Practitioners in CAM; Coordinating and Centralizing Federal CAM Efforts; CAM in Wellness, Self-Care, Health Promotion and Disease Prevention; and Definition of CAM, and Guiding Principles.

Element I: Topic Development

This section includes an identification of the key issues related to a topic, provides a rationale for why these issues are included in the Final Report, describes the current state-of-progress or activity on these issues in the private and public sector, and identify the obstacles and challenges impeding further progress.

Identification of the key issues will be prioritized in the Final Report so that global or critical issues are given appropriate emphasis. Description of the current state-of-progress should include a literature review where appropriate, and, while focusing on Federal efforts, should also include acknowledgment activities in the private sector.

The background information included in Commissioners' briefing books, and the discussions held by Commissioners in meetings and working groups will be reflected in this section.

Element II. Topical Information Received

This section provides an overview of the testimony received from invited speakers and the public. It includes a description of the guiding questions, or conceptual framework, from which the agenda for each of the topic-specific meetings was developed. Three appendices will be referenced: 1) agenda for each meeting that lists invited speakers; 2) list of public speakers (open comment sessions and town halls); 3) alpha listing of all speakers, invited and public.

Element III. Commission Recommendations

This section provides policy recommendations for legislative and administrative action on the various topics identified by the Executive Order and Commissioners. These recommendations represent consensus among the Commissioners on the short and long-term opportunities for progress on a number of critical issues related to CAM use.

Element IV. Unresolved Issues and Conclusions

This section discusses issues where there was agreement that action was needed, but where consensus could not be reached on the exact remedy.

Working Groups – Final Report as of July 27, 2001 (6:08pm)

A. Coordination of CAM Research (Gerry)
1. Gutierrez (1)
2. Chow (1)
3. Fair (1)
4. Ornish (1)
5. Jonas (2)
6. Low Dog (2)
7. Bernier (3)

B. Information Development and Dissemination (Corinne)
1. Low Dog (1)
2. Bresler (2)
3. DeVries (3)
4. Scott (3)
5. Chappell (pending)

C. Access to and Delivery of CAM (Mi)
1. Larson (1)
2. Pizzorno (1)
3. Rolin (1)
4. DeVries (2)
5. Scott (2)
6. Paz (2)
7. Bernier (2)
8. Fins (pending)

D. Coverage and Reimbursement of CAM Practices and Products (Maureen)
1. Tian (1)
2. DeVries (1)
3. Paz (1)
4. Larson (2)
5. Ornish (3)
6. Fins (pending)

E. Education and Training of Health Care Practitioners in CAM (Joe/Gerry)
1. Bernier (1)
2. Bresler (1)
3. Warren (1)
4. Pizzorno (2)
5. Rolin (2)
6. Fins (pending)

F. Coordinating and Centralizing Federal CAM Efforts (Joe)
1. Gutierrez (2)
2. Jonas (3)
3. Kerr (3)
4. Warren
5.

G. CAM in Wellness, Self-Care, Health Promotion and Disease Prevention (Corinne)
1. Scott (1)
2. Kerr (2)
3. Tian (2)
4. Ornish (2)
5. Fair (3)

H. Definition Of CAM and Guiding Principles (Mi)
1. Chappell (1)
2. Jonas (1)
3. Kerr (1)
4. Chow (2)
5. Pizzorno (3)
6. Paz (3)

Commissioners pending:

Fair (still pending 2nd choice)
Fins (E?)
Chappell (for D,G)

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White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

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FOLDER TITLE:
Interim Report (Revisions) July 27, 2001 [1]

2011-0568-S
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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Stephen C. Groft, Pharm.D.
WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY
6701 Rockledge Drive
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Bethesda, Maryland 20817
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TO: Dr. Conchita Paz **FAX:** 505-522-9746

Total Pages including cover: ____

Comments:

I wasn't sure if your E-Mail was up & running

Steve

(If there is any problem with this facsimile, please call Doris Kingsbury at 301-435-7592)

Groft, Stephen (NCCAM)

To: Commissioners E-mail
Cc: WHCCAMP Staff
Subject: Revised Draft Interim Progress report

Attached is the revised interim progress report. Please review and send your comments for revisions, additions, or deletions to us by **Monday, July 30 at 5:00 p.m.** We will make appropriate revisions and move to the Secretary as soon as possible. A copy will be sent to you at the same time we move it forward to the Secretary.

We attempted to address the concerns and incorporate the comments provided by Commission members from the previous version. Following the survey of the Commission members, we arrived at a middle-of-the-road approach for the contents of the report. (Results: Option #1 = 2; Option #2 = 12; Option #3 = 4 with two members not reporting their votes) In doing so, we eliminated all recommendations and references to consensus having been reached by the Commission. The tone was changed to reflect opinions and recommendations received from the public at the meetings, rather than from the Commission. If you have any problems opening the file or converting to your software before opening, please call me at 301-435-6199 or at 1-866-373-1124(Toll-free)

DraftIntReptsg#22
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Working Group Activation for Preparation of the Final Report

You will receive additional information on the establishment of the working groups and the procedures that will be used to expand the issues identified in the interim report for further development in the final report. If you have not sent your choices of working groups to us yet, please do so by tomorrow, July 27. We would like to establish the working groups, contact the Commissioners, and begin to develop the necessary information to enable the Commission to have productive discussions at the October meeting.

October 4-6 Meeting Information

Please note the dates and location for the next Commission meeting - October 4-6 (until 1:00 p.m. on Saturday) at the NIH Neuroscience Building in North Bethesda (Executive Boulevard) and hotel accommodations will be at the Pooks Hill Marriott in Bethesda, MD. We ran into serious complications downtown Washington due to the IMF/World Bank meetings concurrent to our meetings. Many streets close to their meeting location which is very close to the St. Gregory Hotel will be closed presenting logistical problems for your travel. An estimated 40,000 demonstrators are expected in Washington at the same time. The meeting and hotel locations are convenient (45 minutes) to the Interstates that lead to Dulles and BWI airports and to National Airport (30 minutes in non-rush hour).

Again, thank you for your patience, understanding and consideration of the issues before us. In a year and 2 weeks we have come a long way together as a Commission. As we approached each phase of our work, starting with the planning session last July, it looked formidable and uncertain. When each meeting and Town Hall sessions were completed, the next phase looked even more daunting. So it is now, as we attempt to complete the Interim Report and prepare to address the preparation of Final Report. You have made tremendous progress in your efforts and the staff looks forward to working together in small groups as we start the last leg of this journey, but the first step to our goal of completing a useful and informative report to the public, the President, and the Congress.

Have a good weekend with your families and friends and we look forward to your comments.

Jim Gordon Steve Groft

DRAFT Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy
July 26, 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 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 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 and change. CAM generally 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), some forms of 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 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.[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 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. 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. The website is periodically updated to reflect ongoing activities of the Commission. Comments, recommendations, and suggestions can be sent 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 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 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 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 final recommendations will be based on these principles and 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 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 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; 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. 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 assure the types and quality of studies needed. 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 as key elements in achieving research progress in these areas. (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 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 Food and Drug Administration (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 the 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 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 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 which 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 package inserts. 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 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 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 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 is the marketing of products or services that may be unnecessary, harmful, or otherwise detrimental to 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 may also 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. 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 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 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 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. They 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, 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 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, 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 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 and managed care companies, 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 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 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 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 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. 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 CAM services and products to address issues of coding and building claims data bases, 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.

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, 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 herbal or nutritional supplements 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 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 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.

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 to ensure optimal 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. Nor would it 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 significant element of public input into the development of such a Federal 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 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 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. 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 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. 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 4-6, 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)
Center for Medicaid and Medicare 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

Contacting WHCCAMP

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Bethesda, MD 20892-5467
Phone: 301-435-7592 or 1-866-373-1124
Fax: 301-480-1691
e-mail:WHCCAMP@mail.nih.gov
WEBSITE: http://whccamp.hhs.gov

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1: AANA J 2000 Jun;68(3):217-20 Related Articles, Books, LinkOut

Hemorrhage after the preoperative use of complementary and alternative medicines.

Norred CL, Finlayson CA.

School of Nursing, University of Colorado Health Sciences Center, Denver, Colo., USA.

The preoperative use of certain complementary and alternative medicines may predispose surgical patients to an acquired coagulation disorder resulting in excessive bleeding. Many herbs and dietary supplements inhibit platelet adhesion and aggregation or contain coumarins. We report the case of a patient undergoing breast surgery at the University of Colorado Health Sciences Center Denver, Colo, who had extensive postoperative bleeding requiring surgical re-exploration. Preoperatively the patient consumed vitamin E and several herbs with potential to alter the hemostatic process combined with the drugs quinine sulfate and sertraline hydrochloride. These combinations of alternative and conventional drugs may have contributed to inhibition of coagulation.

PMID: 11132009 [PubMed - indexed for MEDLINE]

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1: Am Surg 2001 Jan;67(1):33-5 Related Articles, Books, LinkOut

Gingko biloba: a case report of herbal medicine and bleeding postoperatively from a laparoscopic cholecystectomy.

Fessenden JM, Wittenborn W, Clarke L.

Department of Surgery, Mercy Hospital of Philadelphia, Pennsylvania 19143, USA.

An increasing variety of alternative health care products (defined as "over-the-counter," nonprescribed herbal medicines) are taken by patients for a plethora of reasons. Unfortunately these self-prescribed remedies are seldom considered by the patient to be medications and as a result it has been noted that 70 per cent of patients do not reveal herbal use to their allopathic practitioners or hospital personnel. The rapid growth of this herbal self-therapy has important implications for the practice of surgery. A case of post-laparoscopic cholecystectomy bleeding in a patient taking Gingko biloba is reported. This preparation has been reported to cause spontaneous bleeding and may interact with anticoagulants and antiplatelet agents. Other herbal medicines have also been associated with potential increased bleeding including garlic, feverfew, ginger, and ginseng. It is vital for surgeons to be apprised of all substances ingested by patients, to be cognizant of their potential adverse effects and drug interactions, and to be familiar with their therapeutic modality, all of which will help to optimize therapeutic approaches and improve patient outcome.

PMID: 11206893 [PubMed - indexed for MEDLINE]

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Herbal supplements: considerations in dental practice.

Cohan RP, Jacobsen PL.

University of the Pacific School of Dentistry, USA. rcohan@sf.uop.edu

Over-the-counter natural herb products constitute a rapidly growing market in the United States. As with conventional medications, the health care provider needs to be aware of these products' effects, side effects, advantageous synergies, and possible or probable adverse drug reactions. This paper will present 20 of the most frequently used herbs in the United States and discuss appropriate precautions and herb-drug interactions of possible concern in clinical dental practice.

PMID: 11324121 [PubMed - indexed for MEDLINE]

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Use of complementary and alternative medicines by surgical patients.

Norred CL, Zamudio S, Palmer SK.

School of Nursing, University of Colorado Health Sciences Center, Denver, USA.

This study examined the frequency of surgical patient use of complementary and alternative medicines prior to surgery. After conducting a literature review on the known effects of alternative medicines, we evaluated their potential interactions with anesthetics. At the University of Colorado Health Sciences Center, Denver, Colo, we surveyed 500 elective surgical outpatients about alternative medicines taken during the 2 weeks prior to surgery. Of the 500 patients surveyed, 51% preoperatively took herbs, vitamins, dietary supplements, or homeopathic medicines (range, 1-22 per patient). Substances from 2 or more categories of alternative medicines (herbs, vitamins, dietary supplements, or homeopathic medicines) were consumed by 24% of patients. Twenty-four percent of surveyed patients consumed 50 different herbs, 41% took 9 types of vitamins, 44% took 31 types of dietary supplements, and 1% of patients took the homeopathic arnica. Classification by potential adverse effects revealed that 27% of surgical patients consumed alternative medicines that may inhibit coagulation, affect blood pressure (12%), cause sedation (9%), have cardiac effects (5%), or alter electrolytes (4%). Greater communication, knowledge, and scientific research are needed to safely integrate complementary and alternative medicines in the future management of the surgical patient.

PMID: 10876447 [PubMed - indexed for MEDLINE]

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Preoperative considerations with herbal medicines.

Murphy JM.

Children's Hospital, Boston, USA.

More patients are using herbal remedies. Even though herbs are natural products, they often act like medications and may interact with or potentiate other medications. During a preoperative evaluation, nurses should ask patients about their use of herbal remedies. Certain herbs are dangerous and should never be taken, and others must be avoided before elective surgery. Today's perioperative health care professionals must become familiar with basic information about herbs to carry out thorough assessments. At times, caregivers may need to educate and counsel consumers about benefits and harmful aspects of herbal preparations.

PMID: 9932176 [PubMed - indexed for MEDLINE]

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1: J Perianesth Nurs 2001 Feb;16(1):19-26 Related Articles, Books

Preoperative assessment: Safety considerations for patients taking herbal products.

Flanagan K.

Katy Flanagan, RNC, CAPA, is the Coordinator for the ASPAN Preoperative Assessment Specialty Practice Group and the Medical-Surgical Patient Coordinator at Grady Memorial Hospital, Delaware, OH.

The increased use of herbal therapy and other dietary supplements in the past decade has increased the risk of complications for patients undergoing surgery. The use of herbal products is projected to rise in the United States. Therefore, it is important for the perianesthesia nurse to be aware of the herbal products that patients are taking and the possible anesthesia and/or surgical complications related to herbal products. Current resources are reviewed in this article to increase awareness for the perianesthesia nurse. Recommendations for establishing local protocols are given, and patient education on the use of herbal products is also considered. Copyright 2001 by American Society of Anesthesia Nurses.

PMID: 11266639 [PubMed - in process]

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Herbal medicines: current trends in anesthesiology practice--a hospital survey.

Kaye AD, Clarke RC, Sabar R, Vig S, Dhawan KP, Hofbauer R, Kaye AM.

Department of Anesthesiology, Texas Tech University, Lubbock, TX 79430, USA.

STUDY OBJECTIVES: To develop a simple survey to determine the patient population actively utilizing dietary supplements and/or herbs, during the preoperative period. DESIGN: Prospective study, with survey instrument. SETTING: University medical center. PATIENTS: 1,017 patients presenting for preanesthetic evaluation prior to outpatient surgery. INTERVENTIONS: After undergoing preanesthetic evaluation, patients were asked to complete a survey listing which of the nine most popular nutraceuticals currently available on the market they were using. MEASUREMENTS AND MAIN RESULTS: A total of 1017 surveys were submitted over a period of five months, with 32% being poorly completed and thus discarded. Of the remaining 755 valid surveys, 482 patients used at least one nutraceutical agent. 90% of these patients were using vitamins, 43% garlic extracts, 32% Gingko Biloba, 30% St. John's Wort, 18% Ma Huang, 12% Ecchinaceae, 10% Aloe, 8% Cascare, 3% licorice. CONCLUSION: A significant population of patients scheduled for an elective surgical procedure are self-administering nutraceutical agents. Some of these agents have the potential to cause serious drug interactions and hemodynamic instability during surgery. Hence, it may be important to identify patients self-administering these medications, during the preoperative period.

PMID: 11090733 [PubMed - indexed for MEDLINE]

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DRAFT Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy
July 26, 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 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 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 and change. CAM generally 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), some forms of 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 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.[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 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. 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. The website is periodically updated to reflect ongoing activities of the Commission. Comments, recommendations, and suggestions can be sent 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 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 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 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 final recommendations will be based on these principles and 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 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 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; 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. 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 assure the types and quality of studies needed. 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 as key elements in achieving research progress in these areas. (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 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 Food and Drug Administration (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 the 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 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 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 which 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 package inserts. 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 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 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 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 is the marketing of products or services that may be unnecessary, harmful, or otherwise detrimental to 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 may also 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. 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 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 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 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. They 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, 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 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, 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 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 and managed care companies, 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 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 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 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 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. 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 CAM services and products to address issues of coding and building claims data bases, 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.

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, 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 herbal or nutritional supplements 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 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 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.

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 to ensure optimal 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. Nor would it 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 significant element of public input into the development of such a Federal 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 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 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. 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 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. 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 4-6, 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)
Center for Medicaid and Medicare 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

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e-mail:WHCCAMP@mail.nih.gov
WEBSITE: http://whccamp.hhs.gov

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Active Living magazine
Atlanta Parent
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EP (Exceptional Parent)
inMotion
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PALAESTRA
Paraplegia News
Sports 'N Spokes
Teaching Exceptional Children
Today's Caregiver
We Media

SUPPORTING ORGANIZATIONS

American Association on Mental Retardation
Amputee Coalition of America
Children's Association for Maximum Potential
Council for Exceptional Children
Down Syndrome Association of Atlanta
Families of S.M.A.
Family Voices
Muscular Dystrophy Family Foundation
National Family Caregivers Association
National Multiple Sclerosis Society
National Parent Network on Disabilities
National Perinatal Association
Paralyzed Veterans of America
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Special Olympics
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The ARC of the United States
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U.S. Disabled Athletes Fund

EDUCATIONAL SPONSORS

American Academy for Cerebral Palsy & Developmental Medicine (AACPDM)
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Child Neurology Society
Dystonia Medical Research Foundation
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EP Foundation for Education
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Marcus Institute
National Institutes of Health
United Cerebral Palsy Foundation for Education & Research
WE MOVE

Produced by: H.A. Bruno, LLC, 210 Rte 4 East
Paramus, NJ 07652 ● 877-923-3976

SOLUTIONS WITHIN OUR REACH

Date: September 28-30
Location: Georgia International Convention Center
College Park, Georgia – Adjacent to Hartsfield Airport

Over 250 exhibitors and more than 40 leading organizations to help you understand what products and services are available for you and people with a special need.

This Ticket enables you to a FREE admission to the Exhibit floor and up to $35 off your conference attendance fee.

The WCD is for physicians, OTs, PTs, related healthcare professionals, general and special education teachers, therapists, psychologists, adapted physical education teachers, social workers, caregivers, families, and of course, people with disabilities, as well as anyone involved in the disability community.

Check the conference program, produced by the EP Foundation for Education to see which sessions you would like to attend. CME accreditation is available. CEU accreditation is pending for educators, social workers, OTs, PTs, recreation therapists and speech/language pathologists. Certificates of attendance will also be available to other disciplines and parents. Look over our growing family of exhibitors and mark those you want to meet when you come to the WCD.

Register with the enclosed registration form by faxing it to 201-226-1236 or mail to: WCD, 210 Route 4 East, Suite 303, Paramus, NJ 07652. You may also register on the Internet: www.wcdexpo.com. First click on "Attendee Info" and then the "Registration" button. Enter the source code: "GP" to receive special discounts until September 14th.

SPECIAL EVENTS

MEET RONALD McDONALD
September 29, 12:00pm - 2:00pm; September 30, 12:00pm - 3:00pm

ADAPTED SPORTS: A NATIONAL MODEL WORKSHOP
September 28, 6:30pm – 9:30pm

Organized by PALAESTRA, and sponsored by AAALF and Flaghouse, participants will be introduced to a model for providing sports training and competition for those with a variety of physical disabilities, as well as those with visual impairment and blindness. This unique program was developed by the American Association of Adapted Sports Programs. Workshop participants will be exposed to a variety of fundamental skills by actively participating in various adapted sports. Learn how to develop the program, as well as, how to establish the financial base needed to implement and keep a program viable in your community.

CAREER FAIR

Career opportunities in all types of fields need to be filled by many of the leading companies in the Greater Atlanta metro area as well as the southeastern region of the United States. Many of these employers will be at the WCD promoting their job vacancies. Openings in management, computers, administration, sales, marketing, schools, hospitals and other medical facilities for those with disabilities, as well as special education teachers, OTs, PTs and allied healthcare personnel.

SPORTS & RECREATION ACTIVITY CENTER

One of last year's popular features – this unique interactive program will showcase the country's top athletes with disabilities performing a wide variety of sports which may include basketball, rugby, tennis, fencing, and track and field. Besides participating in sports demonstrations, the athletes will also be available for photos and autographs during the event, organized by the U.S. Disabled Athletes Fund (USDAF), with contributions by Special Olympics and PALAESTRA and sponsored by McDonald's Corporation. Fan participation will be welcome.

Exhibit Hall Hours

Friday, September 28	11:00 am – 6:00 pm
Saturday, September 29	11:00 am – 6:00 pm
Sunday, September 30	10:00 am – 3:00 pm

Conference Hours

Friday, September 28	1:00 pm – 6:00 pm
Saturday, September 29	8:00 am – 5:00 pm
Sunday, September 30	8:00 am – 2:00 pm

EXHIBITOR LIST

AAUAP ● ABILITY magazine ● AbilityForum.com ● Active Living magazine ● Advanced Respiratory ● Allergan ● ALVA-Parrot ● American Academy for Cerebral Palsy & Developmental Medicine ● American Academy of Pediatrics ● American Association for Active Lifestyles & Fitness (AAALF) ● American Association on Mental Retardation ● Amputee Coalition of America ● Angelman Syndrome Foundation ● Annandale Village ● AP4 – Genuine Virgin Aloe International ● Athena Diagnostics ● Atlanta Parent magazine ● Aurora Ministries ● Baggo, Inc. ● Barrier Free Lifts, Inc. ● Bellsouth-TCCD ● Best Bath Systems ● BnH Corp. ● Brain Actuated Technologies ● Canine Companions for Independence ● Care Trak Inc. ● Carts Blanche Inc. ● Centers for Disease Control & Prevention ● Challenge Publications ● Chattanooga Group Inc. ● Chattanooga Rehabilitation Cluster of the Chamber of Commerce ● Child Neurology Society ● Children's Association for Maximum Potential ● Children's Hospital ● Cloister Creek ● Coca-Cola Company, The ● Communications Access Network ● Continental Press ● Council for Exceptional Children ● Crotched Mountain ● Daimler Chrysler Motors Corp. ● DBH Attachments Inc. ● Dept. of Defense Dependents Schools ● Department of Veterans Affairs ● Disabled Dealer of the Southeast magazine ● Dorling Kindersley ● Down Syndrome Association of Atlanta ● Duraline Medical Products, Inc. ● Dystonia Medical Research Foundation ● E-Car (Poltron) ● Electronic Keyboards ● EP (Exceptional Parent) magazine ● EP Foundation for Education ● Families of S.M.A. ● Family Voices ● FDA National Bed Safety Work Group ● Flaghouse ● Ford Motor Company ● Freedom Concepts ● General Motors Corp ● Governor's Council on Developmental Disabilities ● Gregory Center For Exceptional Children & Family ● Guldmann Inc. ● Handicapped Driver Service ● Health Care Financing Administration ● Hoveround Corp. ● iCan, Inc. ● inMotion magazine ● InterAct Plus ● Irwin Siegel Agency, Inc. ● JayJo Books, LLC ● Kaplan Co. ● Kaye Products ● KayJae Manufacturing Co., Inc. ● Kennedy Krieger Institute ● Keybowl, Inc. ● Kidability ● Kinetech Inc. ● La Salud Hispana magazine ● Law Office Of Joseph Romano ● Leader Dogs for the Blind ● Levo ● Light Force Therapy ● Magitek.Com, LLC ● Marcus Institute ● McDonald's Corporation ● Med Covers, Inc. ● Melmark Inc. ● Metropolitan Life Insurance Co. ● Microsoft ● Mobility Designs ● Mobility Engineering Corp. ● Muscular Dystrophy Family Foundation ● MyMedMart.inc ● National Family Caregiver Association ● National Institutes of Health ● National Multiple Sclerosis Society ● National Parent Network on Disabilities ● National Perinatal Association ● Nestle Clinical Nutrition ● NeuroControl ● New Mobility magazine ● NewHope Generation ● Nikken ● No Boundaries ● Nokia ● NOMC EuroPeds ● Ocean Hyperbaric Center ● Oxy-Health Corp. ● PALAESTRA magazine ● Paralyzed Veterans of America ● Paraplegia News magazine ● Parent to Parent of Georgia ● Pathways Development Group, Inc. ● PediaPals ● Pride Mobility Products Corp. ● Prince Products ● PVA Publications ● Q'Straint ● R.D. Equipment Inc. ● Rifton Equipment ● Rusch, Inc. ● Safeco Insurance Companies ● Sage Products, Inc. ● Shire US Inc. ● Sigma Tau Pharmaceuticals ● Social Security Administration ● Southeast Disability & Business Technical Assistance Center ● Southpaw Enterprises Inc. ● Special Olympics ● Sportime Abilitations ● Sports 'N Spokes magazine ● Stages Learning Materials ● StarMed Staffing Group ● SunTrust Bank ● SureHands Lift & Care Systems ● TASH ● Teaching Exceptional Children magazine ● The ARC of the United States ● The Associated Blind Inc. ● The Center for Discovery ● The Disability Resource ● The Liberty Motor Co., Inc. ● The Linktree ● Theradapt Products Inc. ● Tishcon Corp. ● Today's Caregiver magazine ● UCP ● U.S. Department of Justice ● U.S. Disabled Athletes Fund ● Vail Products Inc. ● Verizon Wireless ● Vision For Life ● We Media magazine ● WE MOVE ● Wheelchair Gateways, Inc. (Exhibitors at press time)

2001

GUEST PASS

WORLD CONGRESS & EXPOSITION ON DISABILITIES

WCD

ADMIT ONE
RATES VALID THROUGH SEPTEMBER 14TH ONLY!
FREE EXHIBITS
DISCOUNTED CONFERENCES
September 28-30
Georgia International Convention Center, Atlanta
GUEST PASS

COMPLIMENTS OF:

CONFERENCE PROGRAM

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EP Foundation for Education, Inc.

ADAPTED PHYSICAL ACTIVITY SPONSOR

PALAESTRA

ADAPTED PHYSICAL ACTIVITY SUPPORTER

AAALF

FRIDAY SEPTEMBER 28

- Accessibility Today, Accessibility Tomorrow
- Assessment: Successful Inclusion in PE
- Advances in Prenatal Healthcare
- Getting Media Coverage for Disability Programs
- ADD/ADHD
- Children with Autism/PDD in PE
- Role of the Government in Research on MR and DD
- Management of Dystonia
- Ability Awareness Activities and Cooperation
- Ticket to Work Programs
- Aquatics: Assessment, Equip and Rehab Exercise
- Community Trusts
- Using Biomechanics for Inclusion in PE
- Ethics for the Direct Support Professionals
- Adapted PE Program for Students with Autism
- Geriatrics and the MR/DD Population
- Reading to Enhance Perceptual Motor Skills
- Research in Rare Diseases
- Theme the Day Away
- Assistive Technology and Augmentative Communication
- Ai Chi Balance in the Pool
- Genetic Disorders and Counseling
- True Inclusion for High School Students
- Teaching Empathy to MD Residents
- Community-based Transition Sites for APA
- The Exceptional Family Member Program
- Sensorimotor Activities for Classroom Education
- Creating Movement in a Variety of Settings
- Adapted PE: Teach Culturally Diverse Individuals
- Wheelchair Tai Chi
- Child's Play the Aqua Therapy Way
- Alzheimer's: Art Forms for Positive Feelings
- Transition: What Should Be Happening
- Gross Motor Activities for Preschoolers
- Inclusion is MORE than Keeping Score

SATURDAY SEPTEMBER 29

- Project DOCC
- Come Ride With Us
- Knowing Your Legal Rights
- Peer Partner PE
- The Medical Home
- Adapted Equipment in PE, Recreation, etc.
- Language - PreVerbal and Early Verbal
- "More" Modifications for Students
- Life Needs and Estate Planning
- Stroke in Sickle Cell Disease
- Modified Rhythmic and Dance Activities
- The Medical Home
- Pediatric AquaHab
- Language - Developing Conversational Skills
- Teaching Sport Skills to Children
- Humor as a Tool in Medical Treatment
- Other Neurologic Problems in Sickle Cell Disease
- IEP: Extracurricular and After-School Activities
- A Communicative Approach Used for Autism
- Benefits of Vigorous Physical Activity
- Mitochondrial and Metabolic Disorders
- Effect of Neurologic Problems on Lives & Livelihoods
- Low Budgets Don't Have to Be a Barrier
- Seizures and Seizure Management
- Disability Sport in General PE Curriculum
- Autism
- Treating Rheumatological Disorders in the Water
- Services & Resources for People with Sickle Cell Disease
- Self-Determination
- A Gross Motor Center in My Classroom!
- IDEA '97 and IEPs
- Safe and Appropriate Physical Activity
- Perinatal Care
- Parents: Best Advocates for Physical Activity
- Calculator Plus: Fun and Functional Math
- We're People First
- Parents Ponder Inclusion
- Progressive Orthopedic Aquatics
- Motor Development and the Brain
- Stroke Prevention
- Who Does What in the Public School Setting
- Technology to Supplement Teaching APE
- Cooperative Games for All
- Start Your Own Parkinson's Aquatic Class
- Brain Based Learning and Your APE Program!
- Para-Professionals in the General PE Setting
- Providing Ideal Treatment for Everyone
- Socialization and Physical Activity
- Individual Differences Ability Stations
- Autism/Sensory Processing Through Aquatics
- Physically Active Lifestyle in Older Adulthood
- Addressing PE Transition Needs Early
- More Theme the Day Away
- Working with Children with ADD

SUNDAY SEPTEMBER 30

- Learning Disabilities
- Sponges, Splashes, & Sprinkles
- Management of Spasticity
- Revising the APE National Standards & Exam
- Newborn Screening: Hearing Detection
- The Adaptive Adventure Sports Coalition
- Life Needs and Estate Planning
- Adapting Activity for Older Adults
- End Stage Renal Disease
- Activity-based Intervention for Preschoolers
- Newborn Screening: Ethical Issues
- Achieving the Ultra-Stretch
- Ob/Gyn for Women with MR/DD: A Nursing Perspective
- Adapted Aquatics Future
- Secondary Unified PE & Recreation
- Oral Healthcare for People with Disabilities
- The Fitness Clinic
- Personal Perspectives on Disabilities
- Assessment in APA
- Behavioral Aspects of Neurodevelopment Diagnosis
- Early Childhood/Elementary Children in PE
- Using the Internet for Medical Information
- Medicine Ball Cardio-Strength Training
- IDEA, Section 504, and ADA in PE
- The Halliwick Method: Water Freedom
- Motor and Academic Achievement for Toddlers
- Integrated Recess
- Resistance Training
- Movement Activities for the SpEd Classroom Setting

[redacted]

Incomplete or improperly completed forms will not be processed. Use one form per person; photocopy if necessary. This form may only be used in advance of the show and is not valid for on-site registration. Advance registration and payment must be received by September 14, 2001. After that day, only on-site registration is available. **All registrations are non-refundable.** The World Congress & Exposition on Disabilities reserves the right to use photographs taken of you at the show for promotional purposes. **Registration also available at www.wcdexpo.com.**

1. PRINT ALL INFORMATION AS YOU WISH IT TO APPEAR ON YOUR BADGE. PRINT OR TYPE CLEARLY.
Information that is not printed clearly will not be processed.

FIRST NAME _____

LAST NAME _____

TITLE _____

COMPANY _____

ADDRESS 1 _____

ADDRESS 2 _____

CITY _____

STATE/PROVINCE _____ ZIP _____

COUNTRY _____ TELEPHONE _____

FAX _____ E-MAIL _____

2. REGISTRATION FEES FOR EXPOSITION AND CONFERENCE
(All conference registrations include 3 day admissions to the exhibits)

	By Sept. 14 Regular Rates	Guest Pass Rates
Exhibits Only (All Three Days)	$ 5.00	Free
General Admission One Day Conference (select one) ❑ Friday ❑ Saturday ❑ Sunday	$ 40.00	$ 35.00
Three Days General Admission Conferences	$ 80.00	$ 70.00
Three Days General Admission Conferences (Student)*	$ 50.00	$ 45.00
CEU Accredited One Day Conference ❑ Friday ❑ Saturday ❑ Sunday	$ 90.00	$ 80.00
CEU Accredited Three Day Conferences	$175.00	$160.00
CME Accredited One Day Conference ❑ Friday ❑ Saturday ❑ Sunday	$190.00	$170.00
CME Accredited Three Day Conferences	$375.00	$340.00
Adapted Sports: A National Model	$ 15.00	$ 10.00
TOTAL		$ _____

CME accreditation is available. Details available on our website www.wcdexpo.com.
CEU accreditation for Educators, Occupational Therapists, Physical Therapists, Nurses, Recreational Therapists, Social Workers and Speech/Language Pathologists are pending. Call 877-923-3976 ext. 852 for updates on credit hours.

3. METHOD OF PAYMENT
❑ Check or money order enclosed (payable in U.S. funds to: World Congress & Exposition on Disabilities)
❑ MasterCard ❑ VISA ❑ American Express
(PLEASE INCLUDE CREDIT CARD NUMBER EXPIRATION DATE AND SIGNATURE WITH CHARGE ORDERS)

CARD HOLDERS NAME _____
(as shown on credit card)

CARD NO _____

EXPIRE DATE _____

SIGNATURE _____

TOTAL AMOUNT ENCLOSED/AMOUNT TO CHARGE $ _____

*Student Registration - by fax or mail only. Must include copy of student ID

1. Relationship to an individual with a disability or special healthcare need.
1. ❑ I am a person with a disability 2. ❑ Parent or Family Member
3. ❑ Other caregiver 4. ❑ Not applicable

2. In what professional capacity are you visiting the WCD?
(please select one)
HEALTHCARE PROFESSIONAL
1. ❑ Physician (specialty: _____)
2. ❑ Physician Assistant 3. ❑ RN
4. ❑ Nurse Practitioner 5. ❑ Physical Therapist
6. ❑ Occupational Therapist 7. ❑ Psychologist
8. ❑ Facility Administrator/Director 9. ❑ Social Worker
10. ❑ Rehabilitation Therapist/Consultant/ Counselor
11. ❑ Speech/Language Pathologist/Audiologist
12. ❑ Recreation Therapist
13. ❑ Other _____

EDUCATOR
14. ❑ Special Education Teacher 15. ❑ Technology Coordinator
16. ❑ Administrator/Director 17. ❑ Assistive Technology Educator
18. ❑ General Education Teacher 19. ❑ Physical Education Teacher
20. ❑ Adapted Physical Education Specialist
21. ❑ Other _____

OTHER
22. ❑ Direct Support Professionals 23. ❑ Association/Society Member
24. ❑ Student 25. ❑ Advocate
26. ❑ Home Medical Equip. Supplier 27. ❑ Government Employee
28. ❑ Purchasing (specify business _____)
29. ❑ Other _____

3. How did you learn about the World Congress & Exposition on Disabilities?
1. ❑ Exceptional Parent Magazine 2. ❑ Internet
3. ❑ TV 4. ❑ Radio
5. ❑ Direct Mail 6. ❑ Newspaper
7. ❑ Friend/Relative 8. ❑ Educational Professional
9. ❑ Healthcare Professional
10. ❑ Association/Professional Society
11. ❑ Other Magazine _____
12. ❑ Other _____

4. For Conference Registrants Only:
Please rank your top four program interests 1,2,3,4 respectively.

1. _____ Adapted Physical Activity 2. _____ Assistive Technology
3. _____ Communication 4. _____ Legislation
5. _____ Medical/Health 6. _____ Para-Medical
7. _____ Parenting 8. _____ Product Availability
9. _____ Professional Services 10. _____ Special Education

MAIL COMPLETED FORM WITH PAYMENT TO:
World Congress & Exposition on Disabilities, 210 Route 4 East, Suite 403, Paramus, NJ 07652 USA, Attn: Registration Department
Credit card orders only may be faxed to 201-226-1236.

Please advise at the time of pre-registering if you have a disability that may require special accommodations. (please specify) _____

Source Code GP

Activities
- Transmittal letter
- Cover

① ITAS
② Jun 2 Log
③ Cancel meeting

8:00 Jim Gordon
5225 Ct. Ave, N.W. 414
(Van Ness North)
202-966-7338
202-537-6838
Craig Heggie 202-225-3508

12:00 Jim Albertine
Dr John Blanke
University Club
1135 16th St, N.W
Farragut North

1:30 H&K/MD

3:00 Michael Oksenberg
301-404-7890