INTRODUCTION

A number of surveys taken over the past decade have documented increasing public interest in and use of complementary and alternative medicine (CAM) systems, approaches, and products in the United States (Eisenberg et al. 1993; 1998; Astin, 1998; Paramore, 1997). Depending on how CAM is defined (see Part II), CAM utilization in this country has been estimated to range anywhere from 6.5 percent (Druss and Rosenheck, 1999) to 43 percent (Eisenberg et al., 1998) of the U.S. general population.

The CAM phenomenon has been largely consumer driven and has posed major challenges for our nation's health care and research institutions as well as health insurance providers and state and federal regulatory agencies. For many years, little was known about who uses CAM, how they use it, for what conditions, and why. Additionally, there was little, if any, reliable information on the efficacy and safety of many of these systems, approaches, and products. The response to the surging interest in and use of CAM, therefore, was mainly to develop policies that restrict access to and delivery of CAM services in order to promote public safety. More recently, however, a knowledge base has begun to emerge to provide at least preliminary answers to some of these pressing questions. This has made it possible to begin to develop reasonable, proactive policies at the national level that can facilitate peoples' access to safe and effective CAM approaches and products.

Who Uses CAM, For What, and Why ?

The Demographics of CAM

What are the demographics of CAM usage in the U.S. In 1997, John Astin, Ph.D., then at the Stanford Center for Research in Disease Prevention, asked this question in a nationally representative survey of more than 1,000 randomly selected individuals. This study found people who used CAM therapies were more likely to be college educated

(50.6%), aged 35—49 (50.1%), of Caucasian descent (77%), have incomes greater than $50,000 (48.1%), and live in the western United States (50.1%) (Astin, 1998).

As mentioned, depending on how one defines CAM, there is considerable debate about the degree of CAM usage among the general population (see Part 2 for an overview of definitions and descriptions of CAM). On the other hand, there is little doubt that among certain patient populations CAM use is extremely high no matter how it is defined. A number of surveys suggest that patients with chronic and life-threatening medical conditions, such as arthritis, chronic pain, cancer, and HIV, are frequent users of CAM treatments and practitioners.

CAM and Chronic Pain

Astin's (1997) national survey found that the most common medical condition reported among the surveyed subjects was back problems at 24%. Neck problems were associated with the highest use of CAM (57% of patients). Studies of rheumatology patients have found similarly high CAM utilization rates, between 19% and 63% depending on the type and severity of the rheumatological condition (Rao et al.; 1999). Eisenberg and colleagues (1993, 1998) also have documented that people with chronic pain conditions, including arthritis and headache, and psychological problem (insomnia, depression, and anxiety) are frequent users of CAM therapies.

CAM and Cancer

A recent survey by Burstein and colleagues (1999) of 480 women with stage I or II breast cancer found that almost 40% utilized some form of CAM prior to surgery, whereas only about 30% did after surgery. Another survey of cancer patients who were enrolled in clinical trials at the National Institutes of Health, found that 63% used at least one CAM therapy, with an average use of two therapies per patient (Sparber et al, 2000). Other studies consistently have reported that from 60% to greater than 80% of cancer patients

use some form of CAM (Bennett and Lengacher, 1999; Lippert et al., 1999; Richardson et al, 2000).

CAM and HIV

Ostrow and colleagues (1997) surveyed 657 HIV-positive individuals in a Canadian clinic population and found that approximately 40% had used some form of CAM. Fairfield and colleagues (1998) surveyed 180 HIV-infected individuals and found that almost half (45.0%) of this group had visited a CAM practitioner an average of 12 times per year, compared to only 7 visits per year to their conventional physician or nurse practitioner.

What Are The Most Commonly Used CAM Approaches and Modalities?

The CAM modalities that people choose appear to closely match their health care concerns. Eisenberg et al (1998), for example, found that relaxation techniques were the most common CAM approaches and treatments for chronic pain and/or mental conditions. Other modalities, such as massage, chiropractic and acupuncture, also are used for chronic pain. Shekelle and colleagues (1995a, 1995b) found that one-third of all patients suffering from back pain choose chiropractors over physicians to treat them, and that chiropractors provided 40 percent of primary care for back pain. Moreover, these studies found that chiropractors retained a greater proportion (92 percent) of their patients for subsequent episodes of back pain care than did other providers. Similarly, Krauss and colleagues (2000) found that CAM health care approaches, practitioners, and products were chosen more often than conventional therapies and physicians by those with chronic pain (51.8% versus 33.9%) and headaches (51.4% vs 18.9%) as well as other maladies associated with these conditions, including depression (33.9% versus 25%), anxiety (42.1% versus 13.1%), and insomnia (32.3% vs 16.1%),

Among cancer patients, Burstein and colleagues (1999) found that the use of healing and psychological therapies was highest before surgery but tapered off throughout the first year. After 12 months, approximately 50% of women reported new use of both psychological and healing modalities, whereas 45% reported continued use. Sparber and colleagues (2000) found that the most frequently utilized therapies among their sample of cancer patients were spiritual, relaxation, imagery, exercise, lifestyle diet (e.g., macrobiotic, vegetarian), and nutritional supplementation. Patients unanimously believed that these CAM treatments helped to improve their quality of life through more effective coping with stress, decreasing the discomforts of treatment and illness, and giving them a sense of control. Lippert and colleagues (1999) found a similar pattern of CAM usage among men with prostate cancer, with 42% of those surveyed used vitamins, prayer or religious practices, and herbs to treat their condition. The probability of CAM use was independent of treatment modality, but only 17% to 30% reported the use of CAM to their physicians.

In the Fairfield and colleagues (1998) survey of HIV-infected individuals, more than two-thirds (67.8%) used herbs, vitamins, or dietary supplements. Eighty-one percent of those who used supplements said these remedies were "extremely" or "quite a bit" helpful. Approximately 24% reported using marijuana to treat weight loss, nausea, and vomiting in the previous year and most (87%) said marijuana said it was extremely or quite helpful. Similarly, Ostrow and colleagues (1997) found that most of the HIV-positive individuals in their study used dietary supplements (30%), followed by herbal and other medicinal therapies (22%), tactile therapies (e.g., massage) (22%), and mental relaxation techniques (20%). CAM use was independently associated with younger median age, higher income, and greater physical pain.

Ethnic Differences in CAM Usage

In addition to the severity of illness one has, individual cultural upbringing and ethnicity can influence the type of CAM people may use. For example, in a study of CAM usage among Mexican-Americans living in the Texas Rio Grand Valley, Keegan (1996)

found that 44% of respondents had used a CAM practitioner one or more times during the previous year. In contrast to other survey populations, the most commonly sought therapies, respectively, for this population were herbal medicine, spiritual healing and prayer, massage, relaxation techniques, and visits to curanderos (Mexican folk healers). Additionally, in a sample of 104 non-Mexican-American Hispanics adults with diabetes, Zaldivar and Smolowitz (1994) found that 17% of patients reported using herbs to treat their diabetes.

Similar to Hispanics, the Native American populations appear to display a different pattern of CAM usage then the general population. Kim and Kwok (1998) found, for example, in a cross-sectional interview of 300 Navajo patients at an Indian Health Service (IHS) hospital that 62% had gone to native healers and 39% visited them regularly. The factor associated with the least amount of visits was Pentecostal faith. The Navajo were more likely to rely on IHS medical therapy, either alone or with native healers, for physical conditions such as diabetes, arthritis, abdominal pain, depression, and anxiety. They sought native healers exclusively for traditional issues (family problems, blessings, "bad luck" or "sickness"). Ironically cost was the biggest barrier to seeking a native healer. Native healer costs are approximately 21% of the average Navajo income, whereas care at an IHS clinic or hospital is free.

In a study of 150 Native American patients utilizing an urban Indian Health Service clinic in Milwaukee, Wisconsin, Marbella and colleagues (1998) found that almost 40% of the patients saw a healer regularly, and of those who do not, most (86.0%) said they would consider seeing one in the future. The most frequently visited healers were herbalists, spiritual healers, and medicine men. Sweat lodge ceremonies, spiritual healing, and herbal remedies were the most common treatments. Not surprisingly, more than a third of the patients seeing healers received different advice from their physicians and healers. Among the patients seeing a healer, the rating of the healer's advice was higher than the physician's advice 61.4% of the time. Only 14.8% of the patients seeing healers tell their physician about their use.

These studies suggest that CAM treatments in ethnic populations may be rendered most frequently by traditional healers who are from the individual's native culture. They also raise some serious issues as to the rift between ethnic cultural values and access to native healers. In areas where native healers are available, Mexican-Americans and Native Americans frequent them. Income, not belief systems, prohibits interaction, however (Marbella et al., 1998). Some IHS facilities have addressed this gap by incorporating sweat lodges, or similar spaces, into their facilities and employing native healers (refs?).

Reasons People Give for Using CAM

Until recently, the prevailing view was that people who use CAM therapies were forgoing effective conventional treatments and potentially worsening their illnesses (Dwyer, 1993; Skrabenak, 1984, 1988). However, recent surveys designed to test these hypotheses have found a different picture. In the Astin (1998) survey, only 4.4% of subjects relied primarily on CAM. Astin found an association between CAM usage and cultural beliefs—specifically, a commitment to environmentalism and feminism, and an interest in spirituality and personal growth psychology. Additionally, the Astin study and others (Fliason et al, 1999; Wagner et al., 1999) have found that a holistic health philosophy, a strong internal locus of control, and transformational life experiences also are associated with CAM usage.

There also is evidence that people may use CAM because they believe it is more effective than conventional medicine or they are afraid of the stigma that they may face if treated by conventional health care professional. For example, in the Rao et al (1999) survey of rheumatology clinic patients mentioned above, the most common reasons for CAM usage were to alleviate pain and ease their rheumatic condition. Interestingly, 50% of respondents reported turning to CAM because they perceived their conventional treatment (drugs) as ineffective. When Elder and colleagues (1997) interviewed 113 patients at a family practice, the top reason to seek CAM therapies was that they believed they would work. Furthermore, in a survey of 100 patients with panic disorder or

agoraphobia, rather than seek conventional medical care, 32% preferred to self-medicate using herbs (Bandelow et al, 1995).

The Evidence Base for CAM

Surveys documenting the rise of interest in and use of CAM by consumers were a major impetus for the Federal government to begin to take a serious look at both the safety and efficacy of many CAM approaches and therapies. As a result, Congress established the Office of Alternative Medicine (OAM) at the National Institutes of Health (NIH) in the early 1992. In 1998, Congress elevated the OAM to the status of a national center for coordinating research in CAM throughout the United States. To date, this National Center for Complementary and Alternative Medicine, or NCCAM, has funded the establishment of 14 research centers to explore the safety and efficacy of a wide range of CAM therapies for a host of conditions.

Because of these and other research efforts in the U.S. and in Europe and Asia, there is preliminary but growing evidence that some CAM systems, approaches, and products are effective treatments for a number of the conditions for which people are using them. In fact, to date more research on CAM exists than is commonly recognized. For example, the library of the Cochrane Collaboration, an international effort to develop an evidence base for a wide variety of medical therapies both allopathic and CAM, lists over 4000 randomized trials for CAM therapies. Furthermore, there are a growing number of systematic reviews of this literature, many confirming that CAM approaches do have benefits for specific conditions, including:

- back pain (Van Tulder et al, 1999),
- headache (Melchart et al., 1999)
- depression (Linde and Mulrow, 2000),
- arthritis (Little and Parsons, 2001; Towheed et al, 2001),

- neurologic conditions (Soares and McGrath, 2000;Olin and Schneider, 2001), and
- heart disease (Hooper et al, 2001).

In regard to specific CAM approaches and modalities, an NIH Consensus Development Panel held in 1997 concluded that acupuncture is a plausible treatment option for treating several conditions, including nausea associated with chemotherapy and anesthesia, acute dental pain, headaches, temporomandibular joint dysfunction, fibromyalgia, and depression (NIH Consensus Statement, 1997). There also is growing scientific consensus that a variety of so-called "mind-body" techniques, such as meditation and guided imagery, are effective both in the management of painful conditions and the relief of stress and anxiety (Berman and Swyers, 1999; Broderick, 2000; NIH Technology Assessment Panel, 1996).

Furthermore, spirituality, which is a commonly used approach by those with serious or life-threatening conditions and a significant component of many traditional CAM health care systems (see Part II), appears to play a role in promoting health and preventing major illness. Studies have shown, for example, that those with a high level of spiritual/religious involvement have less risk of developing conditions such as high blood pressure (Caudill et al, 1987; Cooper and Aygen, 1978; Larson et al., 1989) and depression (Idler and Kasl, 1992; Koenig et al., 1992). Several literature reviews also suggests that frequent involvement in spiritual/religious practices or activities can significantly reduce one's risk of early death or mortality (Hummer et al, 1999; Koenig et al, 1999; McCullough et al., 2000; Oman and Reed, 1998; Strawbridge et al, 1997). These finding have been largely independent of demographics, health conditions, social connections, and health practices, suggesting that spiritual/religious involvement has direct effects on health and well-being.

It must be emphasized that all of the literature reviews cited above have concluded that larger, more rigorous studies of CAM interventions are needed. This

preliminary data, however, suggest the need for comprehensive and aggressive research program in these areas.

Safety Issues with CAM Use

Despite the promising evidence for the effectiveness of CAM systems, approaches, and products for managing and treating a variety of chronic conditions, most CAM therapies that are currently being used by consumers have not been adequately studied, particularly in regard to safety (Clinical practice guidelines in complementary and alternative medicine, 1997; Ernst and Fugh-Berman A, 1999). Even among those CAM approaches and modalities where there is evidence of efficacy and safety, new safety concerns may arise when they are used in conjunction with conventional medications, which is the way most consumers use them.

For example, it was recently discovered that St. John's Wort (hypericum), an herb that has been shown effective in treating mild to moderate depression (Philipp et al, 1999), can interfere with the action of an important anti-HIV drug, indinavir (Piscitelli et al, 2000). Preliminary evidence also indicates that St. John's Wort lowers the therapeutic activity of some types of oral contraceptives (Baede-van Dijk. et al, 2000) and cyclosporin A, a drug used to prevent the rejection of transplanted organs (Ruschitzka et al, 2000). A recent literature review published in the Journal of the American Medical Association (Ang-Lee et al., 2001) found that commonly used herbal products could pose serious complications for surgery patients, including bleeding, cardiovascular instability, hypoglycemia, and increasing the strength of the anesthetics or the metabolism of many drugs used during and after surgery.

The potential adverse interaction of CAM and conventional treatments is particularly troubling to public health officials in light of findings that majority people do not tell their conventional health care providers that they are using CAM. For instance, a survey by Oldendick and colleagues (2000) found that physicians were unaware of CAM use in 57% of their patients. Only 25.8% reported their use of herbal medicine and similar

preparations. Patients were least likely to report their use of hypnosis or biofeedback (12.1%), or healing therapies (21.3%) to their physicians.

In a survey of health food store customers, Eliason and colleagues (1999) found that dietary supplement and herbal remedy users were motivated to pursue wellness and wanted to take responsibility for their health. Although they welcomed a partnership with their physician, they generally believed that their physicians were closed-minded and had little knowledge about dietary supplements. These consumers, therefore, had decided to assess the effectiveness of dietary supplements through personal study and subjective experimentation.

There have been findings of a similar lack of communication between cancer patients and their physicians regarding CAM. For example, in a survey of women with breast cancer, Adler and Fosket (1999) found that the majority of women (55—85%) use CAM therapies but did not divulge this use to their physicians due to assumed disinterest. Other reasons that the women gave for not divulging CAM use to their physicians included anticipated negative physician response, perceived physician unwillingness and inability to help, irrelevance, the disparate healing strategies between CAM and conventional medicine, and the anticipation that discussion would be too one-sided (i.e., the physician would do all the talking).

Therefore, in addition to the need for significantly greater research on the efficacy and safety of CAM, there is an urgent need for physicians and patients to become more knowledgeable about what is already known about the potential benefits and harms of CAM approaches and treatments. Such steps are not likely to proceed, however, until there is greater cooperation and collaboration between the conventional and CAM health care communities (Berman et al, 2000). Recently, there has been a major effort to increase conventional physicians' awareness and understanding of CAM through educational programs. However, there is a great deal of variability in the content of these programs (see Part II).

Overview of The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP)

To address the need for better education of consumers and health care professionals about CAM as well as issues related to research and access and delivery of CAM, the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established in March, 2000, by Executive Order 13147 of the President of the United States. The Commission's primary focus is to provide a report by March 2002, through the Secretary of Health and Human Services, to the President on legislative and administrative recommendations for assuring that public policy maximizes the potential benefits to Americans of CAM therapies.

Specifically, according, the recommendations of the Commission are to address the following:

(a) the education and training of health care practitioners in CAM

(b) coordinated research to increase knowledge about CAM products;

(c) the provision of health care professionals with reliable and useful information about complementary and alternative medicine practices and products;

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

To accomplish its mission, the Commission took testimony from the public through a series of town hall meetings. The purpose of these town hall meetings was for the Commission to listen to testimony from individuals and organizations interested in the subject of federal policy regarding CAM. Specifically, the town hall meetings were focused around four primary areas with several questions to be posed under each area:

I. Coordinated Research and Development to Increase Knowledge of Complementary and Alternative Medicine Practices and Interventions

II. Guidance for Access to, Delivery of, and Reimbursement for Complementary and Alternative Medicine Practices and Interventions

III. Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine

IV. IV. Delivery of Reliable and Useful Information on Complementary and Alternative Medicine to Health Care Professionals and the Public

In addition to the Town Hall meetings, the Commission solicited expert testimony form clinicians, researchers, educators, regulatory officials, policymakers, and consumers related to the four areas. The Commission asked these expert witnesses to provide recommendations and documentation to support the basis of their recommendations. The Commission also conducted a number of site visits to see first-hand how various medical institutions are dealing with the issues related to integrating CAM into clinical practice (see Appendix ?).

GUIDING PRINCIPLES OF THE COMMISSION

Based on its mission and responsibilities, the Commission endorsed 10 basic principles to both guide its process for making recommendations and the recommendations themselves. These Guiding Principles, include a commitment to promoting:

- **Wholeness.** Health involves all aspects of life – mind, body, spirit, relationships and environment - and quality health care must support care of the whole person in this context.

- **Evidence of Safety and Efficacy**. The Commission it committed to promoting the use of science and the appropriate scientific methods to help identify safe and effective CAM services and products and generating the evidence that will enhance the development and delivery of these services and products.

- **Health and Healing.** The body has a remarkable capacity for recovery and self-healing and a major focus of health care is to support and promote this capacity.

- **Individuality.** Every person is unique and has the right to have healthcare customized to that uniqueness, respecting their preferences and preserving their dignity.

- **Choice.** People have the right to choose freely among safe and effective therapies and qualified practitioners who are responsive to their needs and accountable for their claims and actions.

- **Prevention.** Good health care emphasizes the promotion of health in addition to the treatment of disease. There is overwhelming scientific evidence that it is significantly more humane and cost-effective to prevent illness and disease compared to treating people once they become ill.

- **Partnerships.** Good health care requires collaborative teamwork between conventional and complementary practitioners, researchers, and patients committed to the creation and delivery of optimal healing environments. Any potential benefits of CAM for the public can best be maximized through promoting collaborations between conventional and CAM healthcare professionals and researchers. These collaborations can best be encouraged by the

integrated delivery of CAM and conventional medicine, where CAM practitioners work side-by-side with conventional practitioners. Integrated delivery, however, does not mean the distillation of CAM services that are then offered by conventionally trained practitioners.

- **Education and Empowerment.** Education about prevention, healthy lifestyles, and the power of self-care and healing capacity should be made an integral part of curricula for both health care professionals and the public at all ages. Quality health care can be enhanced by promoting efforts that thoroughly and thoughtfully examine the current evidence base for CAM systems and practices and make this evidence base widely and easily available in a timely fashion. The Commission recognizes the need to enhance this evidence base by advocating for high-quality research.

- **Self Healing.** Health + Healing

- **Public Involvement.** Public and consumer views and participation must be included in all research and health care prioritizations and decisions.

Linkages with Other Health Care Reform Efforts

The 10 Guiding Principles endorsed by the Commission are remarkably consistent with the core values of the National Academy of Sciences' Institute of Medicine report on ways to improve health care in the 21st century. The IOM report, entitled *Crossing the Quality Chasm: A New Health System for the 21st Century* (see Appendix ? for an overview of this report), lists 10 rules that are intended to make the health system more responsive to patients' needs and preferences and to encourage their participation in decision-making. The IOM report's 10 rules for health care reform are:

1. Care based on continuous healing relationships. Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This rule implies that the health care system should be responsive at all times (24 hours a day, every day) and that access to care should be provided over the Internet, by telephone, and by other means in addition to face-to-face visits.

2. Customization based on patient needs and values. The system of care should be designed to meet the most common types of needs, but have the capability to respond to individual patient choices and preferences.

3. The patient as the source of control. Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decision making.

4. Shared knowledge and the free flow of information. Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.

5. Evidence-based decision making. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.

6. Safety as a system property. Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

7. The need for transparency. The health care system should make

information available to patients and their families that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice, or choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.

8. Anticipation of needs. The health system should anticipate patient needs, rather than simply reacting to events.

9. Continuous decrease in waste. The health system should not waste resources or patient time.

10. Cooperation among clinicians. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

Because of the significant overlap of its 10 Guiding Principles with the 10 rules of the IOM report, the Commission sees its mission as being closely allied to the efforts of the IOM to make our nation's health care system more patient-centered. In particular, the Commission's recommendations will focus heavily on supporting efforts to make the nation's healthcare system more centered around and tailored to consumer preferences, particularly those individuals with chronic, debilitating conditions, who are already relying quite heavily on CAM approaches and products to manage their conditions.

In addition to the IOM report, the Commission's 10 Guiding Principles have significant overlap with the U.S. Department of Health and Human Services (HHS) most 10-year health objectives for the Nation, which are embodied in the report, *Healthy People 2010: Understanding and Improving Health.* The Two overarching goals of *Healthy People 2010* are to:

- Increase quality and years of healthy life.
- Eliminate health disparities.

Healthy People 2010 also enumerates 28 specific focus areas to which these overarching goals are to be applied. Among these 28 focus areas (see side bar), are a number of areas that are also a significant focus for the Commission, as stated by its Guiding Principles. In particular, the specific patient populations that *Healthy People 2010* seeks to focus on, including people with arthritis, osteoporosis, chronic back conditions, diabetes, heart disease and stroke, and HIV, are populations, as we have seen, that typically have high rates of CAM utilization. Therefore, the Commission's efforts to improve education of patients with these conditions and the health professionals who interact with them in regard to CAM are likely to have implications for DHHS's long-term goals in these areas.

Healthy People 2010 Focus Areas

1. **Access to Quality Health Services**
2. **Arthritis, Osteoporosis, and Chronic Back Conditions**
3. **Cancer**
4. **Chronic Kidney Disease**
5. **Diabetes**
6. **Disability and Secondary Conditions**
7. **Educational and Community-Based Programs**
8. **Environmental Health**
9. **Family Planning**
10. **Food Safety**
11. **Health Communication**
12. **Heart Disease and Stroke**
13. **HIV**
14. **Immunization and Infectious Diseases**
15. **Injury and Violence Prevention**

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Two Recommendations Regarding Homeland Security and the Sequelae of the September 11th attacks

1) The Commission recommends that the utility of CAM approaches (massage, musculoskeletal manipulation and mind-body therapies in particular) in dealing with those affected by the events of September 11th be documented and that information about this work be made available to caregivers and to the public.

2) The Commission recommends that emergency medical service personnel, other "first responders", and those who work on an ongoing basis with those traumatized by terrorism or its threat be trained in the use of mind-body approaches to deal with their own stress and trauma and that of those they serve. The Commission also recommends that these personnel also be informed of the possible utility of other CAM approaches for people who have been traumatized.

Richard

Carrie Richard

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12

- Frustration/Balance
- ✓ CAM Central Next week maybe Thurs
  Section Comments
- outline of Report
- Agenda Meeting ↑ next week

Read all of the Report

Wed 28th 9:00

① Traditional Med } conf call
② Information/Congress

Speak to all Communities
Foster working Relationships
④ Report

Goal

Purpose
- Better Health Services Delivery System
- Eliminate Health Disparities
- Good Health to
- Integrate into Better Systems

REVISED EDUCATION AND TRAINING DRAFT RECOMMENDATIONS
6 November 2001

The Commission recommends that appropriate support should be made available through competitive award processes for CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

The Commission recommends that joint research, education and training programs involving CAM and conventional institutions should be supported to focus research on clinically relevant topics, improve the quality of research conducted, and link research with evidenced-based education and training.

The Commission recommends that conferences should be convened by the proposed Federal CAM Coordinating Office to assemble the leadership of professions, educational institutions, and appropriate organizations to determine the feasibility of and possible mechanisms for establishing national CAM education and training standards.

The Commission recommends that all CAM and conventional education and training programs should develop curricula and other methods to facilitate communication and foster collaboration between CAM and conventional students, practitioners, researchers, educators, institutions and organizations.

The Commission recommends that traditional healers should be educated and trained in accordance with their respective established traditions to ensure that culturally appropriate access to traditional healers and healing is maintained.

The Commission recommends that demonstration projects should be developed to determine the feasibility of expanding the role of appropriately trained CAM practitioners becoming primary care providers, so that the eligibility of CAM students to participate in existing loan and scholarship programs and CAM practitioners to participate in loan forgiveness programs can be evaluated.

The Commission recommends that a core curricula in CAM systems, modalities, therapies, approaches, fundamentals, and principles should be developed in conjunction with CAM experts and CAM institutions, based on minimal competencies, and designed with maximal latitude for easy and cost-effective implementation at conventional health professional schools, in postgraduate training programs, and in continuing education programs to increase knowledge and understanding of CAM in order to enhance and protect the public's health.

The Commission recommends that demonstration projects of joint primary care residencies for appropriately educated and trained CAM practitioners and conventional physicians should be conducted to determine the feasibility of such residencies and their impact on collaboration, clinical competency, and quality of health care.

Education and Training of Health Care Practitioners in CAM

Staff Lead: Joe Kaczmarczyk

Members: George Bernier (Facilitator), Joe Pizzorno (Facilitator), David Bresler, Joe Fins, Buford Rolin, and Donald Warren

Summary of Education and Training Issues:

- Access to funding and other resources for CAM faculty, curricula, and program development at CAM and conventional institutions
- National CAM educational and training standards
- Communication and collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations [Previously... Basic or core conventional health curriculum for CAM students and practitioners]
- "Traditional Healing" education and training
- CAM participation in scholarship and loan programs
- Basic or core CAM curriculum for conventional health care professionals at professional school, postgraduate, and continuing education levels
- Postgraduate education for CAM practitioners resembling that of conventional health care providers.

INTRODUCTION

UNDER CONSTRUCTION.... But will include the number of organizations contacted and the number from which information was received.

Issue 1. Access to funding and other resources for CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

Background: Access to funding and other resources for CAM faculty, curricula, and program development is needed at both CAM and conventional institutions. Theoretically, at CAM institutions, this could result in better CAM education and training, better trained CAM practitioners, and better quality of CAM services. Likewise, at conventional institutions, this could result in better conventional education and training, better trained conventional providers, and better patient satisfaction. While CAM faculty, curricula, and program development can be regarded as a continuum, faculty development is perhaps one of the most appropriate points at which to begin for both CAM and conventional institutions, so that there can be adequately trained faculty for curricular and program development. However, limited funding currently appears to be directed toward only a small number of curricula and program development projects at largely conventional institutions.

The type of faculty development needed should be expected to be different for CAM and conventional institutions and vary from institution to institution. For conventional faculty, faculty development can include experiencing CAM systems, modalities, and therapies; learning how to collaborate with CAM practitioners and educators; and learning how and what to teach about CAM, including how to collaborate with CAM practitioners. For CAM faculty, faculty development can include how to teach using evidence-based, problem-based, and competency-based approaches and other pedagogic techniques appropriate for their students and how to collaborate with conventional providers and educators.

CAM programs at conventional institutions can encompass a variety of activities, including CAM or integrative medicine/health clinics or centers, integrative medicine/health residencies and fellowships, and CAM research programs. CAM or integrative medicine/health clinics or centers can be the site for CAM or integrative medicine/health clinical rotations, residency and fellowship training, and clinical research and research training, particularly health services research. Juxtaposing CAM education, training, and research can focus CAM research on clinically relevant topics, improve the quality of the research conducted especially by CAM practitioners, and link CAM

research with evidence-based education and training. This juxtaposition is essential for acceptance of CAM by evidenced-based conventional health care.

Because CAM institutions are more heterogeneous than conventional institutions, the program needs of CAM institutions can be significantly more variable than those of conventional institutions. Although CAM institution ought to be able to pursue support of their unique program needs, some CAM institutions could be more successful by partnering with conventional institutions to form joint activities and programs such as Bastyr University and University of Washington or National College of Naturopathic Medicine and University of Oregon Health Science Center. Recent funding trends validate this assertion.

The majority of support from NCCAM has been given to conventional institutions. During FY2000, the only CAM institutions to be awarded research grants by NCCAM were Bastyr University, Maharishi University of Management, and Palmer College of Chiropractic. In FY 2001, four institutional training grants (T32) were awarded to Harvard Medical School, Minneapolis Medical Research Foundation, University of Pennsylvania School of Medicine, and University of Virginia all of which focus primarily on conducting CAM research. In response to Public Law 105-277 which mandated the Director of NCCAM to "study the integration of alternative treatment, diagnostic and preventive systems, modalities, and disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States," NCCAM established the CAM Education Project Grant (PAR-00-027). Between FY2000 and FY2001, 10 CAM Education Project Grants awards were made by NCCAM to accelerate development, refinement and expansion of innovative new educational approaches to incorporate CAM into the medical, dental, nursing, and allied health professional school curriculum, into residency training programs, and into continuing education courses. The most recent recipients of the CAM Education Project Grants (R25) were Maine Medical Center, Georgetown University School of Medicine, Tufts University School of Medicine, University of Michigan School of Medicine, and University of Washington School of Medicine/Bastyr University.

Health Resources and Services Administration (HRSA), Bureau of Health Professions (BHPr) has provided very limited support of CAM training and education programs. The BHPr Division of Nursing has funded three graduate programs that include content on complementary and alternative therapies and the Chiropractic Demonstration Project Grants Program that supports research projects in which chiropractors and physicians collaborate to identify and provide effective treatment for spinal and low-back conditions. Currently, chiropractic research is the only BHPr CAM activity that is legislatively authorized. All of the BHPr education and training programs are established legislatively through Titles VII and VIII of the Public Health Service Act. These programs are directed toward specific health disciplines delineated in legislation and allow very little, if any, latitude in allocation of funds.

Since both NCCAM and HRSA BHPr examples illustrate how legislation drives funding of CAM education and training, ultimately it may be necessary to pass new legislation or amend current legislation to support CAM education and training. Before recommending or embarking on any legislative initiatives, it is necessary to identify effective CAM education and training strategies and programs. This can be accomplished through a series of demonstration projects for CAM faculty, curricula, and program development at accredited CAM and conventional institutions and subsequent compilation, publication, and on-line availability of the various models and their evaluation data. Since faculty, curricula, and program development at either a CAM or conventional institution can benefit from collaboration between CAM and conventional institutions and provide an economy of scale, collaboration should be an essential element of these demonstration projects. Wherever possible, joint CAM and conventional institution demonstration projects should be undertaken to take full advantage of the economy of scale by creating one program rather than two programs and by sharing faculty, expertise, facilities, and resources.

Funding sources for CAM education and training other than NCCAM and HRSA BHPr should be identified and possible funding from other NIH institutes, Centers for Disease

Control and Prevention, Agency for Health Care Quality and Research, Department of Education, foundations, and other public and private sources should be explored. In addition, collaboration between funding sources and organizations such as the American Association of Medical Colleges, American Association Colleges of Osteopathic Medicine, American Dental Education Association, American Association of Colleges of Nursing, Association of Schools of Allied Health Professions, Association of Schools of Public Health and comparable CAM organizations should be established to identify programs, faculty, resources, and opportunities to improve CAM education and training. Identification of funding sources, collaboration between funding sources and organizations, development of selection criteria for competitive award processes for CAM faculty, curricula, and program development at accredited CAM and conventional institutions could be achieved through Federally-sponsored workshops and conferences facilitated by the proposed Federal CAM Coordinating Office.

Challenges: The challenges include availability of funding in an era of diminishing resources and increased competition for all available resources, conventional health professions organizational and institutional resistance, equitable identification and prioritization of recipients for funding, and ultimately the need for Federal legislation and appropriations.

Draft Recommendations:

1. The Commission recommends that appropriate support should be made available through competitive award processes for CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

2. The Commission recommends that joint research, educational and training programs involving CAM and conventional institutions should be supported to focus research on clinically relevant topics, improve the quality of research conducted, and link research with evidenced-based education and training.

Issue 2. National CAM Educational and Training Standards.

Background: Despite the large number of practices, therapies, modalities, disciplines, and professions involved in the exceedingly complex mosaic of CAM, the House of Lords Select Committee on Science and Technology (Sixth Report: Complementary and Alternative Medicine, 21 November 2000, Chapter 6: Professional Training and Education) stated: "We recommend that CAM training courses should become more standardised and be accredited and validated by the appropriate professional bodies. All those who deliver CAM treatments, whether conventional health professionals or CAM professionals, should have received training in that discipline independently accredited by the appropriate regulatory body." They went on to say, " This would protect the public who use CAM and would improve the transparency of the organisations and make understanding what practitioners' qualifications mean easier. It is clear to us that the quality and degree of standardisation of training within each therapy are closely linked to how successful each individual therapy has been in overcoming internal divisions and coming together under the auspices of a single body that agrees core objectives for education and regulation."

The ideal situation of national CAM education and training standards described above by the House of Lords Select Committee on Science and Technology may not be attainable in the United States because of a number of reasons or factors. For example, in the United States, there are 50 States each with jurisdiction and varying educational requirements for licensure ~~for a multiplicity of~~ each of the professions. In an attempt to provide some uniform guidance, the Federation of State Medical Boards' Special Committee for the Study of Unconventional Health Care Practices ~~[CAM]~~ has begun to develop draft model guidelines for the use of CAM which address education but focus on the scientific basis of treatment methods without delineating any specific education and training requirements. Simultaneously, nascent efforts by physician organizations to standardize CAM education and training for allopathic and osteopathic physicians have emerged. For example, the American Board of Holistic Medicine has administered a board certification examination covering 13 areas of holistic medicine, including exercise

medicine, nutritional medicine, environmental medicine, biomolecular medicine, behavioral medicine, spiritual medicine, energy medicine, social medicine, manual medicine, homeopathic medicine, botanical medicine, ethnomedicine including acupuncture, and conventional medicine. For physicians practicing medical acupuncture which is distinctively different from traditional Chinese acupuncture and should not confused or equated with traditional Chinese acupuncture, the American Board of Medical Acupuncture has administered a board certification examination in medical acupuncture.

Although chiropractic and traditional Chinese acupuncture have evolved perhaps the closest toward establishing national education and training standards, chiropractic and traditional Chinese acupuncture have not achieved national education and training standards and still are plagued by the internal divisions alluded to by the House of Lords Select Committee on Science and Technology. Because of their progress toward national education and training standards, chiropractic and traditional Chinese acupuncture are appropriate candidates for conferences convened by the proposed Federal CAM Coordinating Office to assemble the leadership of their respective professions, educational institutions, and appropriate organizations to determine the feasibility of and possible mechanisms for establishing national CAM education and training standards for chiropractic and traditional Chinese acupuncture.

Because many conventional health professions are required to obtain continuing education for licensure renewal, board certification, or professional organization membership, it is likely that continuing education requirements may evolve for CAM practitioners. In general, opportunities for continuing education for CAM practitioners is limited at this time. While new discipline-specific continuing education programs could be created, a more cost-effective approach would be to develop and offer combined or joint continuing education which could include different types of CAM practitioners and conventional health care providers, all of whom could receive their respective continuing education credit. The House of Lords recognized the importance and relative non-availability of continuing education for CAM practitioners and recommended that "CAM

therapies... should identify continuing professional development in practice as a core requirement for their member" (House of Lords Select Committee on Science and Technology, Sixth Report: Complementary and Alternative Medicine, 21 November 2000, Chapter 6: Professional Training and Education).

Challenges: The challenges include similarity to education and training requirements for licensure and perceived encroachment on States' rights, degree of complexity owing to numerous disciplines or professions involved with a given modality, multiple contentious issues, funding requirements, and wide-spread resistance.

For continuing education, the challenges include professional and organizational resistance; funding; achieving consensus on curricula, and availability of appropriate faculty.

Draft Recommendation:

3. The Commission recommends that conferences should be convened by the proposed Federal CAM Coordinating Office to assemble the leadership of professions, educational institutions, and appropriate organizations to determine the feasibility of and possible mechanisms for establishing national CAM education and training standards.

Issue 3. Communication and collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations.

Background: After acknowledging a deficiency in CAM training for allopathic students, Caspi et al. (Arch Intern Med 2000;160:3193-3195) asserted that there "should be a perfectly symmetrical process, ie, that the depth and breadth of the training of CAM practitioners should be such that they would be able to speak the biomedical language." These authors also expressed concern about lack of exposure of CAM students "to allopathy and its related sciences."

Central to these complex inextricably linked issues is communication through a common language of biomedicine which currently is as foreign to CAM environments as much of CAM terminology is to conventional environments. Because of its importance, commonality of language should be the initial focus of improving communication between the CAM and conventional health care and should begin in CAM education and training programs. Minimal fluency in biomedical language should be the foremost competency in a core curriculum for CAM education and training programs built on a foundation of knowledge about the components and function of the conventional health care system, including public health. This foundation should be augmented by an evidenced-based approach and provide training to attain minimal competency in interpreting CAM and conventional literature and critiquing CAM research, particularly clinical trials. This core curriculum also should include competencies such as recognition of limits of one's clinical expertise, potential complications of CAM interventions, and indications for appropriate referral to conventional health care provider. Additional competencies should include achieving a basic knowledge of other CAM systems, modalities, practices, and approaches and how and when to refer to those CAM practitioners.

The elements of the core curriculum for CAM education and training and best pedagogic methods of incorporating them into existing curricula could be determined by a series of demonstration projects conducted at a number of representative CAM education and training programs supported, for example, by NCCAM, HRSA Bureau of Health Professions, Department of Education, foundations, or innovative partnerships. Similarly, these curricular elements and pedagogic methods could be ascertained through conferences facilitated by the proposed Federal CAM Coordinating Office. Since these two approaches are not mutually exclusive, both demonstration projects and conferences could be undertaken, if adequate funding were available, and the results, models, and recommendations complied and made available on the internet.

Other methods to facilitate communication and collaboration between CAM and conventional environments also could begin with students. For example, CAM and

conventional students could take classes together or participate in joint clinical rotations. CAM and conventional institutions could share or exchange faculty which would be cost-effective for both institutions. Even if the institutions were geographically separated, faculty sharing could occur through distant learning technology. Likewise, faculty who engage in research and full-time researchers could be shared between CAM and conventional institutions to teach each other about conducting CAM research or participate in joint CAM research projects. At conventional institutions, CAM organizations could be the point of contact for locating CAM practitioners to participate in teaching CAM survey and elective courses and providing practical examples and information on bilateral communication and collaboration between CAM practitioners and conventional health care providers. In addition, CAM organizations could be the point of contact for locating CAM practitioners to participate in CAM research projects conducted at conventional institutions. At the organizational level, joint conferences could be held between CAM and conventional organizations representing students, practitioners, researchers, educators, or institutions.

Challenges: The challenges include professional, organizational, and institutional resistance; funding; providing adequate incentives to adopt these curricula; numerous logistical design, development, and implementation issues; achieving consensus of curricula; availability of adequately trained faculty and faculty development; and ability to make any addition to very full curricula.

Draft Recommendations:

4. The Commission recommends that all CAM and conventional education and training programs should develop curricula and other methods to facilitate communication and foster collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations.

Issue 4. Traditional Healing Education and Training.

Background: INSERT DEFINITION OF TRADITIONAL HEALER/MEDICINE. Since traditional healing falls under the rubric of CAM, traditional healing needs to be included in a discussion of CAM education and training. However, because of its close ties to specific cultures such as American Indians, Native Hawaiians, and Alaskan Natives, some rather unique education and training issues arise. For example, what education and training are necessary to be designated a "traditional healer?" To whom should traditional healing be taught? Should traditional healing be taught only to members of the culture of origin? How should traditional healing be taught? These questions have relevance to the Indian Health Service and Health Resources and Services Administration's Bureau of Primary Health Care. The Association of American Indian Physicians, Dine [Navajo] Medicine Association Inc., Papa Ola Lokahi and Native Hawaiian healer Kawaikapuokalani Hewett, and Alaskan Natives answered these questions definitively by ~~unanimously~~ affirming continued application and practice of their traditions for designation, selection, and education and training of traditional healers.

Recognized Native Americans/American Indian tribes are sovereign nations and free to practice their traditions for education and training of traditional healers on tribal lands. Consequently, the integrity of those traditions is relatively preserved on or near reservations. In urban settings, particularly those remote form tribal lands and influence, those rich traditions are vulnerable to exploitation as part of CAM (Rhoades ER and Rhoades DA. 2000. Traditional Indian and Modern Western Medicine. In: American Indian Health, ed . Rhoades EA. Baltimore: MD, Johns Hopkins University Press). Such urban exploitation could be averted ~~in theo~~ry by: (1) limiting the education and training of traditional healers to members of the culture of origin and requiring documentation of that training; (2) mounting a public health ~~type of heal~~th education campaign to educate consumers of traditional healing about potential exploitation and suggestions to prevent it; and (3) allowing or perhaps recruiting "qualified" traditional healers with the culturally appropriate education and training to practice at Federally funded community health centers and outpatient and inpatient facilities. In practice, only the third possible method of prevention has been shown to be feasible. The experience of the Indian Health

Service, Seattle Indian Health Board, and Native Hawaiian programs including those of Papa Ola Lokahi, Waianae Coast Comprehensive Community Health Center, and Waimanalo Community Health Center with traditional healers in a conventional health care setting, could serve as the basis for innovative demonstration projects by the HRSA Bureau of Primary Health Care and other Federal Agencies by linking bona fide education and training of Native Americans/American Indians, Native Hawaiians, and Alaskan Natives traditional healers with urban Federally funded health care facilities.

Challenges: The challenges include the definition of "traditional healing" and "traditional healer," funding, cultural sensitivity, questionable authority in this area, and wide-spread resistance.

Draft Recommendation:

5. The Commission recommends that Traditional healers should be educated and trained in accordance with respective established traditions to ensure that culturally appropriate access to traditional healers ~~an~~ and healing is maintained.

Issue 5. CAM Participation in Scholarship and Loan Programs.

Background: CAM students, CAM institutions, and CAM professional organizations have shown and expressed considerable interest in participation in scholarship and loan programs. This implies participation in Federal programs such as the National Health Service Corps (NHSC) scholarship and loan forgiveness programs. Participation in NHSC scholarship and loan forgiveness programs is defined in authorizing legislation (PHS Act, Title III, Section 301) which is interpreted narrowly by NHSC. ~~In other words,~~ Unless a health profession is specifically named in authorizing legislation, members of that health profession cannot participate in NHSC programs.

NHSC, ~~which recently was relocated within HRSA by transferring it from~~ the Bureau of ~~Primary Health Care (BPHC) to~~ the Bureau of Health Professions (BHPr), meets

approximately 12-15% of its need through exclusive participation of conventional health care providers. There is no CAM participation in NHSC programs at this time. NHSC has indicated a preference for loan forgiveness programs, because it is considerably easier for NHSC to match a fully trained provider through loan a forgiveness program than it is through a scholarship program.

There are two CAM populations who could be affected by Federal scholarship and loan program policy changes: CAM students and fully trained CAM practitioners. CAM students would be impacted more directly by scholarship and loan program changes, whereas fully trained CAM practitioners would be affected more by loan forgiveness programs. Any policy changes would have to be legislatively mandated. However, before considering any Federal scholarship and loan program policy or legislative changes, a number of fundamental, critical aspects of potential CAM participation in these programs need to be broached. Since these types of programs have a service component for medically underserved populations, program participants should be able to provide the necessary health care services which generally are described as or included as a component of primary care. Although a precise suitable definition of primary care is elusive, Public Health Service Act Section 330 Part D subsection (b) (1) which delineates required primary care services of health centers provides examples of representative clinical competencies. These include health services related to family medicine, internal medicine, pediatrics, obstetrics, or gynecology that are furnished by physicians and where appropriate, physicians assistants, nurse practitioners, and nurse midwives; diagnostic laboratory and radiologic services; preventive health services (including prenatal and perinatal services, screening for breast and cervical cancer, well-child services, immunizations against vaccine-preventable diseases, screenings for elevated blood lead levels, communicable diseases and cholesterol, pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care, voluntary family planning services, and preventive dental services); emergency medical services; and pharmaceutical services.

Moreover, because of the medical needs of the populations and challenges of the service sites, all providers should be able to provide primary care. If a choice between a CAM practitioner and a conventional provider were necessary, the choice would have to be substitutive not additive. In other words, a CAM practitioner would have to be able to provide the same level of primary care as a conventional provider in addition to CAM rather than provide only CAM. There also would have to be a demonstrated community need or demand for the type of CAM service or services the CAM practitioner could provide. In addition, the type of CAM practitioner or practitioners as well as the type and duration of post-graduate training appropriate for participation in these program should be ascertained.

The multiplicity and complexity of these considerations should be addressed by demonstration projects to determine the feasibility of expanding the role of appropriately trained CAM practitioners to become primary care providers in these programs. After determining the feasibility, type or types of appropriate practitioners, education and training requirements, and minimal clinical competencies, the financial impact of CAM practitioner participation should be estimated by the Congressional Budget Office. Then, a retrograde implementation plan could be considered, starting with loan forgiveness for fully trained appropriate CAM practitioners and subsequently adding scholarship and loan programs for appropriate CAM students. Since there are guidelines for determining the number of a given type of conventional health care practitioner for a defined population size or geographic area but none for CAM practitioners, these guidelines would need to be developed.

Currently, there is a Senate--but not an accompanying House—draft NHSC reauthorization bill which includes chiropractors in a three-year demonstration. However, neither NHSC nor BHPr has conducted any type of financial analysis of the proposed three-year chiropractic demonstration. Meanwhile, the most recent NHSC data indicate decreasing ability to meet identified need, meeting only 10% of the identified need in terms of conventional providers. NHSC expects to award only 300 new

scholarships in FY2002, while approximately 800 providers leave medically underserved areas per year.

Challenges: The challenges include preference for conventional health care providers to fill the largely unmet need, requirement for legislative and appropriations changes, identification of specific CAM disciplines and practitioners, and difficulty in administering CAM–inclusive programs particularly in the absence of population and geographic guidelines for CAM practitioners and financial impact data.

Draft Recommendation:

6. The Commission recommends that demonstration projects should be developed to determine the feasibility of expanding the role of appropriately trained CAM practitioners becoming primary care providers, so that the eligibility of CAM students to participate in existing loan and scholarship programs and CAM practitioners in loan forgiveness programs can be evaluated.

Issue 6. Core CAM curriculum for conventional health care professionals at professional school, postgraduate, and continuing education levels.

Background:

UNDER CONSTRUCTION

Challenges: The challenges include professional, organizational, and institutional resistance; funding; providing adequate incentives to adopt these curricula; numerous logistical design, development, and implementation issues; achieving consensus of curricula; availability of adequately trained faculty and faculty development; and limited ability to make any addition to very full curricula.

Draft Recommendations:

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7. The Commission recommends that a core curricula in CAM systems, modalities, therapies, approaches, fundamentals, and principles should be developed in conjunction with CAM experts and CAM institutions, based on minimal competencies, and designed with maximal latitude for easy and cost-effective implementation at conventional health professional schools, in postgraduate training programs, and in continuing education programs to increase knowledge and understanding of CAM in order to enhance and protect the public's health.

Issue 7. Postgraduate education for CAM practitioners resembling that of conventional health care providers.

Background: Development of postgraduate education for CAM practitioners resembling and, in certain cases comparable to, that of conventional health care providers may be necessary to enhance the competency of some CAM practitioners and quality of CAM provided. Postgraduate training has relevance to physicians such as naturopathic and ayurvedic physicians, particularly as these types of physicians seek licensure. At this time, only one state, Utah, requires the completion of a one-year postgraduate program that is certified by CNME for licensure of naturopathic physicians. Naturopathic postgraduate education has been in existence since 1979 and consists of approximately twenty, one-year programs with an emphasis on naturopathic family practice type of primary care. Although naturopathic postgraduate education appears to be evolving slowly, its evolution is limited by the number of one-year "residencies" and lack of funding.

Existing naturopathic postgraduate training programs could be expanded in scope and extended in duration for comparability with allopathic and osteopathic primary care residencies. Although current naturopathic programs could be expanded or new programs established, joint training with existing allopathic or osteopathic residencies may be more feasible. However, before establishing joint primary care postgraduate training programs on a large scale, the feasibility of this approach should be ascertained

through demonstration projects sponsored by Federal Agencies and Departments such as NIH, NCCAM, HRSA Bureau of Health Professions, HRSA Bureau of Primary Health Care, DOD and VA. Those primary care residencies affiliated with community health centers supported by HRSA Bureau of Primary Health Care should be given special consideration for development of joint training, because of the unique opportunities they represent for combining education in ethnically, racially, and culturally diverse learning environments with service to medically underserved populations who otherwise might not have access to CAM. These joint primary care postgraduate training program demonstration projects should be awarded on a competitive basis and funded with monies that are distinct from the current graduate medical education (GME) funding streams. In addition, these demonstration projects should have longitudinal evaluative components to assess the feasibility of this type of program, type of CAM and conventional providers who should participate, collaboration between CAM and conventional providers, competency-based educational effectiveness, impact on health care quality, and financial analyses including comparisons with existing allopathic and osteopathic residencies for estimating financial impact on future GME funding.

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Challenges: The challenges for establishing joint primary care postgraduate training program demonstration projects include professional and institutional resistance; funding; availability of a sufficient number of training sites, patients, and faculty; and attaining consensus on the content of the training.

Draft Recommendation:

8. The Commission recommends that demonstration projects of joint primary care residencies for appropriately educated and trained CAM practitioners and conventional physicians should be conducted to determine the feasibility of such residencies and their impact on collaboration, clinical competency, and quality of health care.

REVISED EDUCATION AND TRAINING DRAFT RECOMMENDATIONS

6 November 2001

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5. The Commission recommends that traditional healers should be educated and trained in accordance with their respective established traditions to ensure that culturally appropriate access to traditional healers and healing is maintained.

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existing loan and scholarship programs and CAM practitioners to participate in loan forgiveness programs can be evaluated.

7. The Commission recommends that a core curricula in CAM systems, modalities, therapies, approaches, fundamentals, and principles should be developed in conjunction with CAM experts and CAM institutions, based on minimal competencies, and designed with maximal latitude for easy and cost-effective implementation at conventional health professional schools, in postgraduate training programs, and in continuing education programs to increase knowledge and understanding of CAM in order to enhance and protect the public's health.

8. The Commission recommends that demonstration projects of joint primary care residencies for appropriately educated and trained CAM practitioners and conventional physicians should be conducted to determine the feasibility of such residencies and their impact on collaboration, clinical competency, and quality of health care.

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November 9, 2001

Hello Jim:

We hope you are doing well. David Swankin sent us this editorial by George Barrett from the latest Journal of Medical Licensure and Discipline (the official journal of the Federation of State Medical Boards). Finally, organized medicine is paying attention!

In response -- and while they seem to be paying attention -- we are considering sending in an article that that we wrote in 1999 that summarizes the Pew Commission regulatory recommendations. We had originally sent the article to Health Affairs and Inquiry but it was rejected. It might be time to bring the issues and recommendations back into national conversation.

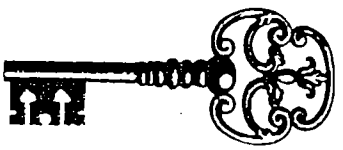
On a personal note, Catherine is busy with her new daughter Katusch and back to work full-time at the Center. Len finally completed his Dr.P.H. and is doing a post-doc at the Institute for Health Policy Studies.

Best regards,

Len & Catherine

enclosure

IMMEDIATE PAST PRESIDENT'S MESSAGE



George C. Barrett, MD.

Immediate Past President,

Federation of State

Medical Boards.

THE PUBLIC AND PROFESSION: BEGINNINGS

The 1998 Pew Health Professions Commission report, "Strengthening Consumer Protection: Priorities for Health Care Workforce Regulation," is on the shelf but it contains recommendations that should be implemented. Some of the recommendations reflect efforts of the Federation of State Medical Boards (FSMB) to strengthen protection of the public by state boards, e.g., provision of "resources necessary to adequately staff and equip . . . boards to meet their responsibilities"; portability of licenses; accountability and provision of "practice-relevant information to the public in a clear and comprehensible manner." Prior to the report the FSMB and National Board of Medical Examiners (NBME) were developing a program of Post Licensure Assessment known as PLAS. The program was implemented in mid-2000 and serves as a resource to medical boards, hospitals, practitioners, managed care organizations, and individual physicians when competence is questioned. It does not address the issue of requiring "demonstration of competence throughout their careers." But it is a beginning.

The report notes that health professional licensure "plays a critical role in consumer protection. Licensur is a state privilege bestowed upon a profession that enables it to self-regulate through educational standard setting and peer discipline. For most of this century, state regulation of health care occupations and professions has established minimum standards for safe practice. The ostensible goal of professional regulation – to establish standards that protect consumers from incompetent practitioners – is eclipsed by the tacit goal of protecting the professions' economic perogatives." References and our own experience make this difficult to refute.

At the interim meeting of the American Medical Association in December 2000 a report of the Board of Trustees (BOT) to the House of Delegates (HOD) recommended (wisely) a review of the AMA's policy on the National Practitioners Data Bank (NPDB). Recognizing the inevitability of profiling initiatives and Internet access to physician information, the Board of Trustees (BOT) recommended consideration of state-based and private initiatives possibly in lieu of maintaining the NPDB. In addition, the report noted the FSMB's efforts toward the All Licensed Physicians project and the work of the Special Committee on Physician Profiling. The House of Delegates (HOD) did not adopt the Board's recommendations as presented; however, I believe the BOT's report represents a giant leap forward in thinking and an acceptance of the reality that the profession can no longer hold to a position that defends the denial of information to the public. The HOD did endorse the concept that state boards can best implement publication of practice-relevant information. Not stated, but absolutely necessary, is the development of educational footnotes that clarify the significance of negative data in relation to competence, ethical behavior, and professional misconduct. Patients do have the ability to accurately judge performance information about their physician when it is appropriately and honestly presented. Our responsibility is not to obfuscate and hide behind the self-interested claim "they won't understand." Rather, it is our duty to make the information understandable. Another beginning.

A project that can be extrapolated to a paradigm for lifelong learning and assessment of competence has resulted from The Institute of Medicine's (IOM) report, "To Err is Human – Building a Safer Health System." The report forcefully calls to our attention some of the problems in our health care

delivery system. Most of these are systemic in origin, however, there are errors related to substandard health care delivered by incompetent physicians. In response to this problem the Citizen Advocacy C r (CAC) has contracted with the Health Resources and Services Administration to develop pilot projects involving hospitals and boards of medicine and nursing. The thrust of the pilot project is to develop cooperative relationships between hospitals and regulators involving sharing of information when a practitioner is identified as delivering substandard care. Hospitals at times identify but fail to report physicians whose problems do not rise to the level of suspension or restriction, instead suggesting they would benefit from additional education, training, or proctoring. This has created an environment that fails to protect the public. Under the CAC program, hospitals would agree to inform licensing boards of every intervention to upgrade skills and knowledge, and boards would agree to inform hospitals when a physician with a problem is brought to the attention of the board. Similar to the physicians' health programs, confidentiality would be maintained as long as the physician complies with terms of the intervention plans. Failure to comply results in loss of anonymity and possible discipline. Administrators in Medicine, an organization of medical board executives, is to be commended for assisting in identifying medical boards willing to participate in developing this program. The non-punitive program can provide a market for focused educational opportunities as well as assessment programs. In turn, this will create the infrastructure for ongoing assessment and education. Furthermore, it makes CAC and licensing boards proactive in decreasing errors in medicine.

To the extent possible our profession needs to look critically at itself.

IT IS ANOTHER BEGINNING

I am under no illusion that the recommendations of the Pew Commission are simple to implement or without flaw. But make no mistake they do reflect current attitudes and trends in public expectations. To the extent possible our profession needs to look critically at itself. When financial considerations enter into the determination of physicians' scope of practice, when privacy or fear of legal action is c lered more important than reporting substandard care to an appropriate regulatory board, when the cost of assessing a physician is more important than protecting patients, when a hospital credentials a poorly trained physician to perform the latest high-tech procedure, we are being less than professional.

Nevertheless, the legislative changes required pose a significant barrier to the implementation of needed changes. However, with the AMA beginning to support accountability, the FSMB and NBME beginning focused assessment, the CAC beginning a program that has the potential to provide early intervention for marginal physicians, and effective CME requirements and programs being developed, a collective approach led by the profession could significantly reduce the legislative barriers to all the issues raised by the Pew Commission report. Further, a more collective approach could assure less resistance to changes needed and avoid duplication of effort and resources. We must all understand that being present at the beginning is not enough. It's working for and accomplishing the task that counts. An audacious idea? Of course! But so was Jefferson's concept of an educated populace. When educated, the people can be trusted. To the extent it is committed to openness, sound evaluation and strong regulation in the public interest, the medical profession will retain the people's confidence.

To the extent it is committed to openness, sound evaluation and strong regulation in the public interest, the medical profession will retain the people's confidence.

Axelrod, Corinne (NCCAM)

From: Sparber, Andrew (CC/NURS)
Sent: Thursday, November 15, 2001 8:12 AM
To: Axelrod, Corinne (NCCAM)
Subject: RE: deadline

Steve - FYI
I gave this to Jenny
- C

Corinne-

Hi- my main recommendation (not really) is to develop acupuncture needles that have a coating of topical lidocaine on the tip- There are some points (near my umbilicus) which HURT-add to that, Karla is needling me again!

Well- for the real stuff- I have just two comments: Having read the prior draft of all recommendations I am drawn to the prevention/wellness in the school. In the 2nd draft you sent me it speaks about the Internet. Is it to be included- to help kids learn to use the internet at school to access information about their health and CAM therapies?

The other one is in the Herbal section: May be good to include recommendations about what I have been working on here about Biomedical research and patients use of herbals. I will forward you a copy on NIH Catalyst when it comes out which myself and my colleague have written. A more in-depth article is being expanded on now which includes some really nice Legal comments. Also that FDA and IRBs require investigators to include assessment of patient use of herbals/supplements (other CAMs?)in protocol development/possible drug-herb interactions.Since it is now policy here to ask/assess patients it is beginning to have a rippling effect with some groups of investigators building in language into their protocols.

Well there you are- but really- if you can come up with painless points it would be great! :)

Andrew

-----Original Message-----
From: Axelrod, Corinne (NCCAM)
Sent: Thursday, November 08, 2001 2:50 PM
To: Sparber, Andrew (CC/NURS)
Subject: RE: deadline

Ok - here it is. This is just the Info section but Steve thought this is what you'd be most interested in. Looking forward to your comments. Thanks,

<< File: Info08Nov01.wpd >>
<< File: Info08Nov01.rtf >>

CDR Corinne Axelrod, M.P.H., L.Ac.
Senior Program Analyst
White House Commission on Complementary and Alternative Medicine Policy
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axelrodc@mail.nih.gov
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-----Original Message-----
From: Sparber, Andrew (CC/NURS)
Sent: Thursday, November 08, 2001 7:48 AM
To: Axelrod, Corinne (NCCAM)
Subject: RE: deadline

Oh- that would be nice- I will PROMISE not to share it with anyone.

thanks

11/14/01
2:15 p.m.

COORDINATION OF RESEARCH DRAFT: 11/1

Introduction

To be developed. Brief review of the growth of CAM research, its value and its promise for future research/directions. Refer to activities reflective of NCCAM and other agencies-- possibly move some general text on NCCAM, other IC's and agencies to this section as well as examples of programs at CAM and conventional institutions and private and nonprofit organizations. *Include updated information on Federal agency CAM research and related activities.* Make *reference to the Commissioners interest in addressing the paucity of private investment in research on herbal products, which are increasingly being advertised and sold by pharmaceutical and other manufacturing companies. Also make reference to the concept that in conventional medical practice all treatments used are not necessarily based on conclusive evidence (citation/Tieraona). Educated assumptions or judgment calls are made in conventional medical practice based on an accepted ~~expanding~~ knowledge base established in the research literature. Assumptions in CAM are not viewed in a similar light because of the lack of a sufficient evidence base on which to form such assumptions. As the research literature in CAM expands, judgment calls predicated on the underlying body of evidence-based knowledge will become more acceptable.*

Dialogue, Partnerships, and Public Input

The Commission recognizes that scientific and health services research is essential to establishing the safety, efficacy, and cost-effectiveness of CAM practices and products and for establishing the appropriate use of CAM within the health care system. The Commission also recognizes the importance of research to discover the basic mechanisms of action underlying these practices and products, and the crucial role of research training and infrastructure to produce grant applications of sufficient quality to compete

successfully for research support.

It is the view of some CAM professionals that the requirements for CAM research are higher than for conventional research. On the other hand, representatives of the conventional medical research community have expressed the belief that CAM research often is not held to as high a standard as conventional research. Therefore, the Commission wishes to state its position that both CAM and conventional medical research, research training, publication of research results in scientific and medical journals, presentations at research conferences, and review of products and devices meet the same high standards of quality and rigor.

The Commission views partnerships and cooperation as being at the very heart of the challenge to increase the quality CAM research and the acceptance of research applications that may be outside the mainstream. The building of working relationships among professionals from both conventional medical and CAM disciplines is essential to progress in studying CAM practices and products. The absence of these relationships impedes progress in building knowledge about CAM.

During testimony, the Commission heard often about the public's interest in CAM and the value of integrating conventional and CAM approaches. In a random household telephone survey, of 831 respondents who saw a medical doctor and used CAM therapies in the previous year, 79 percent perceived the combination to be superior to either one alone. Of 411 respondents who saw both a medical doctor and a CAM provider, 70 percent saw the medical doctor before or concurrent with their visit to a CAM provider.*(citation–AIM)*. The growing influence of the public on the health care system and considerable public interest in why people are turning to CAM is becoming increasingly evident, pointing to the need to ensure public participation in shaping the

CAM research agenda.

Requirements and opportunities for public participation currently exist, such as the NIH Director's Council of Public Representatives and the long standing representation of public members on Institute and Center advisory councils, boards, and committees, FDA advisory committees, *and public representation on institutional review boards. Public members of Federal research and research-related advisory committees and the agencies they advise would most likely gain from programs designed to train public representatives on how to provide their input most effectively with regard to bench-to bedside biomedical research and health services research agendas and budget policy, and information dissemination activities.*

It is in response to the public's use of CAM practices and products that an emerging dialogue between CAM and conventional medicine and a growing willingness to experiment with integration appears to be taking place slowly. *(AIM citation)* These gradual changes are painting an exciting and hopeful picture. One of the major challenges facing both CAM and conventional medicine is to foster this emerging dialogue and, by doing so, increase the much needed mutual respect and better understanding of one another's expertise, concerns, and contributions that will help protect the public while expanding opportunities to improve health care.

To be most effective, CAM and conventional researchers, clinicians, and practitioners, and the leadership of CAM and conventional research centers, programs, accredited institutions, and professional organizations need to participate in the dialogue and form meaningful working relationships. Federal and state research and health agencies, the private and nonprofit sectors and the public *are also integral to this cooperative environment that gives the scientific and health care community an opportunity to raise*

the quality of CAM research and the research infrastructure. The regulation of CAM research, the publication of CAM research results, and the review and approval of CAM practices and products also depend on increased interaction. Therefore, ***knowledgeable and experienced*** *(or "trained and properly qualified") CAM and conventional medical professionals need to be represented, as appropriate, on research, journal, and regulatory advisory and/or review committees, as well as in discussions on CAM-related research policy issues.*

Multidisciplinary workshops and conferences are excellent instruments for enhancing communication among various disciplines and the public, private, and nonprofit sectors on joint program, policy, and research questions. They also offer the opportunity to build on the expertise of a broad variety of disciplines and interests to find innovative methodologic approaches to solving difficult research questions in focused CAM areas. Conferences such as NCCAM's "Exploring Opportunities for Collaboration with Industry," the Josiah Macy, Jr. Foundation's "Conference on Education of Health Professionals in Complementary/Alternative Medicine," the conference on "Building Bridges: the Link between Allopathic and Alternative Medicine in Clinical Practice and Research" sponsored by Johns Hopkins University School of Medicine and School of Hygiene and Public Health and the Traditional Acupuncture Institute; and the symposia and conferences on "Complementary, Alternative and Integrative Medical Research" sponsored by the Harvard Medical School, Division of Research and Education in Complementary and Integrative Medical Therapies are just a few of the many excellent examples of interdisciplinary activities that make important contributions to progress in CAM research. ***(Add interdisciplinary meetings sponsored by CAM organizations, e.g. chiropractic or naturopathy)***

Federal conference support mechanisms, such as NIH or SAMHSA conference grants, are

available. In addition, the idea was put forth during testimony that interested nonprofit organizations might pool resources to support, independently or collaboratively with the public and/or private sectors, interdisciplinary conferences on CAM research, as well as to support CAM research, research infrastructure and training, and information dissemination..

Draft Recommendations

1. The Commission recommends strengthening the emerging dialogue between conventional medicine and CAM by continuing to develop ways to enhance communication, cooperation, and collaboration among conventional and CAM research and clinical professionals, research centers and accredited institutions, professional organizations, and Federal and state research and health agencies, the private and nonprofit sectors, and the general public.

2. The Commission recommends that standards of quality for all aspects of research and related activities be the same for CAM as for conventional medicine.

3. The Commission recommends that research, journal, and regulatory advisory and review committees in both the public and private sectors include, as needed, trained and qualified CAM and conventional professionals, and recommends adapting as appropriate, any regulations that might impede such representation.

4. The Commission recommends independent or collaborative support by the public, private, and nonprofit sectors to organize multidisciplinary conferences on CAM research to increase opportunities for CAM and conventional medical practitioners, clinicians, researchers and others to exchange ideas on approaches to

studying and supporting CAM research.

5. The Commission encourages the creation of novel funding partnerships or consortia within the nonprofit sector and the private sector to augment, collaboratively with Federal agencies or separately, support for CAM research, research infrastructure and training, research conferences, and information dissemination.

6. The Commission recommends supporting research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM itself and in comparison with conventional medicine, and parallel this research with the public impact on the emerging integrated healthcare system.

7. *The Commission recommends that Federal agencies supporting biomedical and health services research develop training programs for public representatives to help them provide their input in the most effective way with respect to biomedical and health services research agendas and budget policy, and information dissemination.* ~~*(Combine with #6?)*~~

Research Support

The Commission believes that research provides the accurate information needed to increase the public's knowledge about CAM, and for educating and training CAM and conventional health care professionals, regulating the quality and use of CAM products and devices, and improving access to safe and effective practices and products and coverage for them. The point was made and reiterated during testimony, that clinical, basic, and health services research are all essential and any of these types of research

absent the others is insufficient for achieving safe and effective CAM use within an improved health care system. *(citation--Eisenberg 5/01)*

Multiple research approaches that are pertinent and relevant to the question being asked all contribute in valuable ways to developing evidence of safety and efficacy, improving our understanding of CAM in the evolving health care system, and formulating accurate information for practitioners and the public. Among these approaches are randomized controlled clinical trials, non-randomized studies, empirical observation, case studies, evaluations of practice-based data, epidemiologic and surveillance studies, behavioral and quality-of-life studies, cost-effectiveness studies, population and utilization studies, studies on health care delivery, and health care demonstration projects on various aspects of CAM.

The Commission considers the funding of research on frequently purchased or promising CAM products, including suitable use with other CAM and non-CAM products and the development of analytical methods for producing better quality products, to be of paramount importance. Meeting this need requires both substantial public research support and increased incentives to stimulate more private sector support for this research. Incentives for consideration might include low interest loans, tax incentives, market exclusivity, and resolution of intellectual property issues. Public Health Service research support mechanisms, such as the Small Business Innovative Research program, the Small Business Technology Transfer Research program, and the Cooperative Research and Development Agreement are effective support mechanisms for private industry, along with Federal agency assistance with protocol development.

Many people who testified noted the emphasis CAM places on wellness separate from disease and expressed admiration for the attention many CAM practitioners give to self

care, life-style, quality of life, the recognition that mind, body, and spirituality play a combined role in health, disease, and healing, and the importance of the patient-practitioner interaction. *Combining the best of CAM with conventional medical care may help reunite the art and science of medicine.* The Commission believes that CAM practices that build on lifestyle, self care and self healing merit further research and increased public and private investment. CAM may contribute in important ways to the management of certain chronic diseases and disorders ~~*and rehabilitation*~~.

Beyond safety and efficacy, CAM research may offer exciting areas for scientific inquiry and the Commission recognizes the potential of CAM research to contribute to emerging areas of scientific study beyond isolated treatments for conditions or diseases. Therefore, in addition to the primary task of examining CAM practices and products which, if found to be safe and effective, may be identified as *collaborative or integrative with (suggest original: complementary or alternative to*)* conventional care for a condition, disorder, or disease, CAM may also contribute innovative and novel ideas to emerging areas of scientific study that might help to expand our understanding of health, disease, and healing.

**[people collaborate not practices and products and C/A is integrative]*

The CAM research spectrum is broad. It includes areas that are almost indistinguishable from conventional medicine except for application, such as exercise/diet/lifestyle therapies, herbal/nutritional supplements, behavioral/mind-body methods; pain management; and the effects of culture on health and treatment. It includes areas that receive less attention but are or are becoming areas of interest to conventional science, such as increasing our understanding of complete biological systems and how they interact, the placebo effect, *the ability of the body to heal itself,* spirituality, consciousness, and electromagnetic fields. The spectrum includes areas that challenge

biological/scientific concepts and assumptions depending on the context in which they are presented, such as homeopathy, energy medicine, bioelectromagnetic therapy, biofields, and distance healing. Answers to some of the questions posed by these approaches may be found in the study of Ayurvedic Medicine, Traditional Chinese Medicine, Tibetan Medicine, Native American Medicine, African Medicine, Naturopathy, *Chiropractic*, and other systems of healing that involve a complexity of elements. Applying rigorous scientific methods to the exploration of these areas may require merging whole system concepts with modern reductionist expertise and the input of CAM practitioners working with experts in a wide variety of fields, including but not limited to physics, epidemiology, cell and molecular biology, genetics, immunology, physiology, chemistry, neurobiology, psychology, sociology, and engineering.

The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial is recognized as the gold standard for examining clinical questions. However, because of the complexity and uniqueness of many CAM questions, it may be necessary to adapt clinical trial methodology, in a flexible and step-wise fashion, to the unique characteristics of CAM questions *and systems of care*, while complying with human subject protections and institutional review board guidelines. Questions of standardization/non-standardization, individualization/generalization, blinding, randomization, the placebo effect, and compound mixtures, need to be resolved within the context of the study design.

The adaptation of methodology and design, the Commission notes, is also required in conventional clinical research. Science has always followed its quests for knowledge by developing new ways to answer difficult questions and the Commissioners believe that

pluralism in research design allows scientists to develop innovative methods to examine complex CAM questions. The NIH Specialized Center Awards, such as the Specialized Center of Research (SCOR) or the Special Program of Research Excellence (SPORE), are examples of programs that promote interdisciplinary exchange in order to address difficult research questions. The James A. Shannon Director's Award, is a limited grant mechanism for developing, testing, and defining research techniques and the feasibility of innovative, creative, research approaches.

The Commission recognizes the need to allow physicians and other health professionals who believe they have promising data on non-approved CAM treatments ~~or approaches~~ to move successfully from promising data to clinical investigation of the treatment, while meeting their ethical and professional responsibilities toward their patients and thus their right to practice. The Commission agrees that the practitioner must be knowledgeable about the development and collection of objective and valid observational data and record keeping; the investigation of the treatment ~~or approach~~ must be part of a well designed study meeting rigorous scientific standards; and human subject protections and IRB guidelines must be in place and followed. Research support can be obtained from reputable, high quality public, private, or nonprofit institutions or organizations.

To help implement the process, the Commission would like to see NIH Institutes and Centers and other Federal agencies, as appropriate, develop programs to evaluate adequately developed practice-based data for potential research support, communicate the availability of such initiatives in a proactive manner to CAM and conventionally-trained practitioners and, if the project receives funding, include the practitioner and CAM-trained researchers as part of the research team. The programs may also offer training in data collection and the scientific method, as well as ethical guidelines and human subject

protection. NCCAM communicates its interest in reviewing such preliminary data as does OCCAM/NCI through its best case series program.

(Move some of this text to Introduction) The Commission commends NCCAM for its excellent leadership and contributions to CAM research and research methodology, research training, infrastructure development, and supports increasing the Center's crucial activities in these areas, including its information dissemination responsibilities. The Commission also recognizes the important work of the ODS/OD/NIH and the collaborations between NCCAM and ODS and with other NIH/ICs. The Commissioners encourage the NIH/ICs to continue their good work supporting CAM research collaboratively or separately, and want to note especially the work of both NCI's OCCAM and the NLM. In addition, the Commission encourages collaboration between NCCAM and other Federal agencies with research and health responsibilities, such as AHRQ, CDC, HRSA, and FDA. The Commission believes that all Federal agencies need to be more proactive in evaluating aspects of CAM, if relevant to their missions, and in developing programs to ensure that CAM is properly integrated into the evolving health care system.

Need to get accurate, up-to-date budget information on current NCCAM and other NIH CAM research funding, historical NCCAM research application success rate/NIH success rate, ***and categories of emphasis/types of CAM research being funded.*** *(Discuss strategic question as to whether specific issues regarding agency budgets, new money vs reallocated money should be featured, treated as a subtext, remain silent, or simply recommend increasing funding for all CAM research)*

Draft Recommendations

8. The Commission recommends that all Federal agencies with research or related health care responsibilities increase CAM activities relevant to their biomedical or health services missions in a more proactive manner to ensure that CAM is properly integrated into the health care system.. (~~NIH ICs and other agencies, e.g., strategic planning, CDC, AHRQ (example: OAM NCCAM)~~)

9. The Commission recommends *that state professional boards develop processes that will* allow practitioners who have developed scientifically acceptable preliminary data to move successfully to clinical investigation of a non-approved treatment *or approach* while maintaining their ethical and professional responsibilities toward their patients and the public.

10. The Commission recommends that NIH Institutes and Centers and other Federal agencies, as appropriate, develop programs to evaluate practice-based data for potential research support, communicate the availability of such initiatives in a proactive manner to CAM and conventionally-trained practitioners who believe they have promising data on non-approved treatments *and approaches*, and provide training in data collection, protocol development, and ethical guidelines and human subject protection.

11. The Commission recommends continuing adequate public funding for research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars.

12. The Commission recommends that the Federal government provide incentives to stimulate private sector investment in research on CAM products and NDA

development, and on *developing* analytical methods for producing better quality CAM products.

13. The Commission recommends that the Federal and private sectors provide support for workshops to discuss research needs for regulatory review and approval of CAM products and devices.

14. The Commission recommends Federal, private, and nonprofit support for innovative and sometimes controversial CAM research in emerging areas of scientific study that could expand our understanding of health and disease, and recommends ~~that NCCAM and the National Institute of General Medical Sciences~~ support basic ~~science~~ on core CAM questions described in many CAM systems, such as ***bioenergy and consciousness*** ~~***to be expanded and in the text)***~~

15. The Commission recommends that NCCAM conduct a review assisted by the National Science Foundation, the Institute of Medicine, *the World Health Organization, or another Federal or non-Federal* body on methods to study in a credible manner, emerging areas of scientific investigation associated with CAM.

Research Training and Infrastructure

The Commission fully appreciates the crucial role that a strong research infrastructure plays in the conduct of quality CAM research and the training of skilled researchers. Sustained, adequate funding is essential to building and maintaining long-term research capacity for training clinical investigators, health services researchers, and those who study the underlying mechanisms of CAM products, practices and concepts. A

government-wide effort involving NIH, NSF, DOD, the VA and others would strengthen the funding and strategic planning to develop or enhance CAM research sites and training programs.

The same rigorous training is a requirement for both CAM and conventional medical researchers and needs to be available to both. Conventional researchers need a knowledge of CAM concepts and approaches and both CAM and conventional investigators need rigorous training in the fundamental elements of quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process and methodology, an understanding of the constitution of a research team, unbiased data collection, all aspects of protocol/study design, IRB and other regulatory requirements, and the grant application, submission, and review processes. CAM research training should teach multiple outcome measures, including social and biopsychological measures of health, and offer experience working as part of a multdisciplinary research team. *The opportunity to gain solid training in the conduct of quality research should continue to attract both conventional medical and CAM students interested in the study of CAM questions.*

Research sites supported publicly, privately, or by foundations need to be strategically located and structured to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Each site depends on a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. The Commission would like to see CAM research sites developed at public, private and accredited CAM institutions with CAM-trained professionals serving on faculty and/or as consultants, and experienced researchers serving as mentors. Cooperation between CAM and conventional

medical researchers or institutions and joint research grant applications can contribute to successful research funding.

Research centers offer excellent opportunities to exchange experiences on how best to educate researchers in CAM practices and how to introduce CAM practitioners to the research culture. (*Examples: center grants supported by NCCAM, NCI, NICHD, and others; NCRR/GCRCs, and university/hospital examples) Along with continued strong support for pre- and post-doctoral CAM research training, it was noted during testimony that CAM research trainees need experienced mentors and incentives may have to be developed to attract them. Strong support of career development awards that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards to provide the time required to mentor new CAM investigators are of considerable importance.*

[Move some text to the Introduction] The Commission recognizes the work of NCCAM and (*other organizations)* in developing a core of CAM and conventional medical researchers investigating CAM questions, who receive the same rigorous research training in basic, clinical, or health services research. The Commission also notes the Institute's support of career development awards that enable investigators focusing on CAM to develop into independent investigators and mid-career awards to provide the time required to mentor new CAM investigators and would like to see strong support for career development in CAM research.

<u>Draft Recommendations</u>

16. The Commission recommends providing increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional medical and CAM sites to expand the core of researchers knowledgeable about CAM, who have received rigorous research training in basic, clinical, and health services research.

17. The Commission recommends strong support for enhanced research training by all Federal health agencies with research training programs and responsibilities that encompass CAM-related questions.

18. The Commission recommends utilizing existing resources, such as NCCAM centers and the National Center for Research Resources' General Clinical Research Centers to increase opportunities to conduct clinical research and training on CAM and examine the integration of CAM into the clinical setting.

19. The Commission recommends continued strong support for career development awards that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards to provide the time required to mentor new CAM investigators.

CAM Research Results: Systematic Reviews and Evaluations

The Commission agrees that publication of CAM research results in recognized, rigorously peer-reviewed research journals is needed to provide reliable information about CAM to researchers, practitioners, and ultimately the public. *Decisions on regulating use and reimbursement for CAM therapies should be based on published evidence of safety and effectiveness and cost-effectiveness analyses instead of depending on traditional use,*

anecdotal reports, consumer interest, and market demand (may be moved later. The quality of the research and the standards of review that the research must meet to gain journal publication affect how readers determine the reliability and usefulness of the information. To ensure a fair and accurate review, both CAM and conventional medical expertise should be represented on journal review boards when reviewing CAM research submissions.

In addition, the Commission recognizes the value of examining currently available research information from the published literature, and recognizes the value of the Cochrane Collection's systematic reviews, the evidence-based reports developed by the Agency for Healthcare Research and Quality, and the databases of the National Library of Medicine; e.g., PubMed and MedlinePlus. The Commission was pleased to hear during testimony representatives of these organizations describe their CAM-related activities and especially their efforts to cooperate.

The Commission supports strengthening the process for making *concise,* reviews of the research literature *written for and* available to *scientists*, practitioners, community health centers, and policy makers, and to offer clear and understandable, summaries of reviews to the public through NLM's MedlinePlus and other information services. Examples of efforts that the Commission believes could effectively be applied to CAM are the Department of Health and Human Services' "Report of the U.S. Preventive Task Force Guide to Clinical Preventive Services, which is a complete assessment of the literature on preventive medicine, and the more recent British Medical Journal publication, "Clinical Evidence" that regularly updates information on clinical evidence.

(Mention NCCAM/*AHRQ/ and check on U of MD/Cochrane).*

Draft Recommendations

20. The Commission recommends that public and private resources support, conduct, and update systematic reviews of current evidence in the research literature on the safety (including contraindications) and efficacy of CAM practices and products. These reviews should be written in understandable English and other languages, and should be easily obtained from multiple publicly available information services, including the National Library of Medicine's MedlinePlus database, which is accessible directly and through public libraries.

21. The Commission recommends that the Agency for Healthcare Research and Quality expand its Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

22. The Commission recommends that a summary report of current clinical evidence on CAM be produced and updated at appropriate intervals.

(Chang) November 9, 2001 (9:11AM)

Draft Discussion Document for December 5-6, 2001 Meeting
TOPIC: Access and Delivery of CAM
Facilitators: Joseph Fins, Linnea Larson
Staff Lead: Michele Chang

Introduction:

Access to health care has been described as a multi-dimensional concept that balances factors such as manpower, financing, transportation, freedom of choice, public education, quality, and allocation of technology. [The World Health Medical Association, Inc. Statement on Access to Health Care, Vienna, Austria, September 1988.] These factors contribute to the quantity and quality of care received by a population, and determine the nature and extent of access to care.

In the United States, the use of complementary and alternative medicine (CAM) has increased steadily since the 1950's. [Annals of Internal Medicine, volume 134, #4, August 21, 2001] Although visits to CAM practitioners have grown from 400 million to more than 600 million visits per year, and the amount spent on these practices in 1997 rose from $14 billion to $27 billion, most of these were outside of the mainstream health care system and paid for out-of-pocket. [Eisenberg, Davis, Ettner et al. Trends in alternative medicine use in the United States 1990-1997: results of a follow-up national survey. JAMA 1998;280:1569-1575] Access to CAM products and practices remains largely inaccessible to those dependent on insurance reimbursements, or whom are uninsured.

The rise in CAM use is most often characterized as a "consumer-based movement," reflecting broader concerns by the American public to re-examine and revitalize how health care currently is delivered and received. Many of the reasons influencing consumers' decisions to try unconventional approaches are the same as those stimulating change in the current health care system. Foremost among these include pressures to reduce the costs of health care, which are expected to reach the $2.1 trillion mark by 2007. Mind-body therapies used to control pain and stress have been estimated to eliminate 37 percent of doctor visits, potentially saving the country some $54 billion a year [Health Education Alliance for Life and Longevity, Eureka, CA–Johns Hopkins Newsletter, 10/22/01].

Secondly, chronic conditions are now the leading cause of illness, disability, and death in the United States, affecting nearly half of the U.S. population and accounting for the majority of health care expenditures [IOM Crossing the Quality Chasm]. The IOM's 2001 report, *Crossing the Quality Chasm*, reported than more than 40 percent of those who suffer from chronic conditions have more than one such condition, arguing strongly for more coordinated care overall. Many of the holistic philosophies and traditions often emphasized in CAM approaches focus on a prevention (rather than treatment) orientation, which tends to promote self-healing and rely on more healthy lifestyle and self-care changes, beginning early in life. As consumers have become more interested in and more knowledgeable about health maintenance and promotion, the use of CAM approaches such as relaxation

therapies, acupuncture and herbal medicine, all of which share an emphasis on spiritual health and mind-body links, also have increased significantly .

A third influence is the accessibility of health information through the Internet and other communication technologies. While the impact and opportunity presented by the rapid evolution of health information technology is addressed elsewhere in this report, it is important to acknowledge its influence on consumer demand for CAM products and services. As of 1997, 35 percent of US households owned a computer, approximately 25 million Americans used the Internet weekly, and some websites provide information on more than three hundred different diseases [Junnarker S. Doctors Face Newly Knowledgeable Patients as Consumers Learn on the Net. *The New York Times.* Cybertimes, Nov. 19, 1997]. A growing number of patients are equipping themselves with more, often quite detailed, information, not only about conventional treatments to their ailments, but about more unorthodox approaches as well. The ready availability of consumer information about such topics, whether accurate or not, and the ability to experience diverse cultures around the world have had a significant impact on the accelerated consumer movement toward CAM.

Fourth, patients are increasingly more interested in being active participants in their health care decisions. This participation includes evaluating information about treatment options, accessing products and practices that enable them to explore those options, and engaging in activities that may help them remain healthy through all stages of life. [Kelner, Wellman, ed. Complementary and alternative medicine:challenge and change. Reading, England: Gordon and Breach (cited from Essentials of CAM by Jonas and Levin)]. Consumers' expectations are expanding the definition of health care from beyond treatment of illness to include prevention and wellness. As consumers become more empowered users of health care, whether to address chronic health conditions, or in an effort to increase overall wellness, their expectations for high quality, affordable, effective and safe health care from a range of providers and competent practitioners, both CAM and allopathic, also will increase.

A fifth factor influencing changes in the current health care system, but perhaps less acknowledged as part of the consumer movement toward CAM, is the growing disparity of health indicators among U.S. populations. Research has found that income disparity between the rich and poor is the most powerful predictor of a nation's health as measured by life expectancy [Wilkinson, R. National Mortality Rates: The Impact of Inequality? *AJPH,* 82(8):1082-1084, 1992.] CAM services are primarily delivered through non-reimburseable mechanisms, paid for out-of-pocket by the majority of its users.

In 2000, the Kaiser Commission on Medicaid and the Uninsured [Immigrants' Access to Health Care After Welfare Reform: Findings from Focus Groups in Four Cities, November 2000] reported that the most common barrier to care cited by immigrants was cost, followed by language. A supplement to the 2001 Surgeon General's Report on Mental

- CAM
- more time w CAM practitioners

Illness [DHHS. (2001). *Mental Health: Culture, Race, and Ethnicity – A Supplement to Mental Health: A Report of the Surgeon General.* Rockville, MD: DHHS, SAMHSA.] also underscored the barriers for adequate health services experienced by racial and ethnic minorities collectively. The report cited a constellation of barriers, many of which operate for all Americans: cost, fragmentation of services, and lack of availability of services. Adequate and appropriate access and delivery of CAM is possibly most limited among those who can least afford to pay out-of-pocket. The cost of maintaining public health centers (county hospitals, public health centers) continues to increase. CAM proponents argue that many of the patients waiting hours for treatment are suffering from problems that might be appropriately treated by CAM practitioners (acupuncture, homeopathy, bodywork). Many of the indigent and homeless that comprise the patient population at publicly run health centers, clinics and hospitals also present a diverse range of health challenges, including current or former alcohol and drug addiction problems. The use of appropriate CAM approaches by Federally funded programs [CSAT, SAMHS programs–need cite] has been shown to play a significant and cost-effective role in the recovery of these patients.

Both the Kaiser Commission and Surgeon General's report identified significant additional barriers to health care for racial and ethnic minorities: mistrust and fear of treatment, racism and discrimination, and differences in language and communication. The findings of these reports underscored, in particular, the importance of communication between consumers and providers as essential for all aspects of health care. It is possible that the communication gap between health care providers and the community may be facilitated by traditional healers, many of whom are trusted and valued by the community, but operate outside standard regulatory systems. Until bridges can be forged between traditional healers within the community and health professionals outside the community, collaborative and integrative healing systems are less likely to succeed, the potential added value of community-based traditional services remain unknown, and reimbursement or support for them will continue to be largely unavailable.

The consumer movement toward increased CAM use is only one of the forces through which health care is changing. Access to CAM will be subject to the same demands placed on access to conventional health care: more efficient and effective use of available resources. To accomplish resource management goals will require, at least, identifying clearly intended outcomes for care, using evidenced-based best practices to achieve measurable goals, and improving overall systems of care delivery.

The Commissioners believe that CAM practitioners and the health care institutions delivering such care also should be properly regulated and accountable to the public. This chapter addresses the regulatory issues attendant to the delivery of CAM services and oversight of the broad spectrum of institutions through which CAM services are delivered; lays out the challenges in delivering CAM product services; provides an overview of current CAM service delivery models, and provides recommendations regarding each of these four major issues.

Issue 1: The Effects of Regulation on Access

Ideally, health care access would define an ability to choose from both conventional and CAM practices and products, with assurances that all practitioners are qualified and products are safe. Currently, 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. However, there is much variability State-by-State in regulatory approaches to licensure and scope of practice. For example, 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.

Most practitioners, whether CAM or conventional, will practice where they have the legal authority to do so. For naturopaths and practitioners of oriental medicine, the most influential factor in distribution appears to be licensure; these clinicians are concentrated in Northeastern and Western States, where the greatest professional opportunities exist. Similar observations have been made about specialty providers and nurse practitioners or physician assistants, whose number per capita in each State correlates with the professional prerogatives granted to them. [ES Sekscenski et al. "State Practice Environments and the Supply of Physician Assistants, Nurse Practitioners, and Certified Nurse-Midwives," *NJM* 331(1994): 1226-1271.] The variability of regulation between States for any given CAM practice, the role of regulatory bodies, and the ambivalence of CAM practitioners towards regulation all contribute to the lack of definition and clarity on this issue.

In general, States that have fewer CAM providers also appear to have the lowest numbers of physicians and physician assistants per capita, as well. A better understanding of CAM utilization in such areas is needed to determine what can be done to improve access to CAM within the proper context of other public health and medical needs. Additionally, more information is needed on what constitutes "appropriate access" to CAM to better facilitate the mobility of qualified CAM practitioners within the health care system, and in collaboration with current services.

Early studies of licensure sponsored by the U.S. Department of Labor focused on licensure's impact on workforce availability, and the cost and quality of services. [MH Cohen. *Complementary and Alternative Medicine: Legal Boundaries and Regulatory Perspectives* (Baltimore, MD: 1998) 97]. The principle findings challenged the wisdom that occupational regulation results in higher service quality and benefits consumers beyond the increased cost that licensure causes. These reports recommended that regulation should evaluate carefully the need for new licensed occupations, assure the continuing competence of licensees and greater equity in the discipline of licensed practitioners, improve public representation on licensing boards, remove artificial barriers to interstate mobility, and remove the control of

educational functions from boards.

In 1990, the Federal Trade Commission (FTC) reported that occupational licensing had the capacity to "protect the public's health and safety by increasing the quality of professionals' services through mandatory entry requirements, such as education."[Cox and Foster, 1990, cited in Dec 1995 Pew Health Regulation Report, pg vi] The report also found that many occupational licensing restrictions often did not accomplish these goals, but rather had the effect of increasing prices and imposing costs on the consumers. Despite this, the FTC concluded that the "costs of licensing did not always exceed the benefits to consumers," and recommended that such cost-to-benefits ratios should figure into the consideration of any licensing proposal.

In 1989, The Pew Charitable Trusts established the Pew Health Professions Commission to review and respond to the challenges of the changing health care system. Recognizing that health care workforce reform would necessitate regulatory reform, the Pew Commission assembled the Taskforce on Health Care Workforce Regulation to identify and explore how regulation protects the public's health and to propose new approaches to health care workforce regulation to better serve the public's interest. [Considering the Future of Health Care Workforce Regulation: Responses from the Field, pg 4]

In 1995, the Taskforce published 10 recommendations for regulatory reform and offered policy options for State considerations under each recommendation as a way of stimulating debate and discussion. The 10 recommendations made by the Taskforce are as follows:

PEW Taskforce Commission Recommendations for Regulation of the Health Care Workforce

~~Recommendation~~ 1	States should use standardized and understandable language for health professions regulation and its functions to clearly describe them for consumers, provider organizations, businesses, and the professions.
Recommendation 2	States should standardize entry-to-practice requirements and limit them to competence assessments for health professions to facilitate the physical and professional mobility of the health professions.

Recommendation 3	States should base practice acts on demonstrated initial and continuing competence. This process must allow and expect different professions to share overlapping scopes of practice. States should explore pathways to allow all professionals to provide services to the full extent of their current knowledge, training, experience and skills.
Recommendation 4	States should redesign health professional boards and their functions to reflect the interdisciplinary and public accountability demands of the changing health care delivery system.
Recommendation 5	Boards should educate consumers to assist them in obtaining the information necessary to make decision about practitioners and to improve the boards's public accountability.
Recommendation 6	Boards should cooperate with other public and private organizations in collecting data on regulated health professions to support effective workforce planning.
Recommendation 7	States should require each board to develop, implement and evaluate continuing competency requirements to assure the continuing competence of regulated health care professionals.
Recommendation 8	States should maintain a fair, cost-effective and uniform disciplinary process to exclude incompetent practitioners to protect and promote the public's health.
Recommendation 9	States should develop evaluation tools that assess the objectives, successes and shortcomings of their regulatory systems and bodies to best protect and promote the public's health.
Recommendation 10	States should understand the links, overlaps and conflicts between their health care workforce regulatory systems and other systems which affect the education, regulation and practice of health care practitioners and work to develop partnerships to streamline regulatory structures and processes.

While the Pew Commission focused primarily on the conventional health care workforce, many of the recommendations made are ~~relevant~~ equally appropriate when considering regulation of CAM practices and products. The

(A1)

Improve accountable

recommendations made by the Commission stimulated significant response from the health care community and subsequently fostered a high level of regulatory activity and policy discussions that were captured in an 1998 follow up report by the Commission. [Strengthening Consumer Protection, Oct 1998, appendix B]

Who Regulates?

The power to protect citizens' health, safety, and welfare authorizes States to decide who may practice medicine, and to establish licensing boards that admit or exclude persons from practice. The U.S. Supreme Court has affirmed the constitutional right of State licensing boards to require a specific educational credential for health professionals. Therefore, occupational regulation is a "State's right." However, the Federal government has contributed to the shape of health professional regulation through its reimbursement and other policies in Medicare and Medicaid; research on regulation's effects on health care cost, access and quality; practitioner data collection; education funding; and other initiatives. A simple example of the Federal regulatory effect is the mandate for States to license nursing home administrators, and to regulate nurse aides as a condition for Medicare and Medicaid reimbursement.

Concerns over excessive or intrusive Federal regulation into States' and private market affairs are most likely sufficient to effectively eliminate the possibility of "Federalized" health professions regulations. It will be more important for Federal agencies – through reimbursement and facility licensing, education funding and other efforts– to facilitate the development, dissemination, and evaluation of uniform (non-Federal) entry-to-practice standards, model scopes of practice, and innovations in education and workplace design.

States, who have the authority to determine who will be granted a professional health care license and what will be the requirements for licensure, often look to national professional groups to set standards of education and training as prerequisites to licensure, and to create accrediting bodies that can set standards and evaluative criteria for professional educational institutions. This process of licensure ostensibly creates a distinction between professional and non-professional occupations based on technical training and qualification.

The Federation of State Medical Boards of the United States, Inc., is a national organization comprised of the 69 medical boards of the United States, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands. The Federation primarily serves to establish and promulgate professional standards of quality, safety and integrity of health care through physician licensure and practice. Recognizing the growing interest of the public in CAM practices and products, as well as that of many licensed physicians, some of whom may be incorporating CAM approaches and products into their practices, the Federation also has underway an initiative to develop model guidelines for State medical boards to use in regulating the use of "unconventional medical practices." These guidelines, currently under review, are expected to be released in 2002.

In keeping with its overall mandate, in its draft guidelines to States regarding CAM practices, the Federation recognizes and preserves a wide latitude in physicians' exercise of their professional judgment, not precluding the use of methods that are "reasonably likely to benefit patients without undue risk." The States are encouraged to establish and apply standards for effectiveness and safety equally to conventional and CAM practices and products. Therefore, licensed physicians should not be found guilty of "unprofessional conduct to practice medicine in an acceptable manner" solely on the basis of utilizing unconventional practices, but rather on a uniform set of professional guidelines that emphasize patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

[ED. NOTE: should we include some reference to the experiences of some CAM practitioners from Minnesota and New York whom experienced negative interactions with State Medical Boards?]

Most licensed CAM providers must follow a legal and ethical code to refer the patient to a licensed medical doctor when the patient's clinical condition exceeds the provider's scope of competence. If the provider violates this duty to refer and the patient is injured, the patient may sue for malpractice. In addition, the provider who fails to refer when necessary may face professional discipline from the relevant regulatory board. The duty to refer helps to ensure that all providers remain within the scope of their competence.

The discussion and debate stimulated by the Pew Health Commission's 1995 recommendations have also had an effect on States' considerations of CAM, especially as practiced by licensed physicians. Pre-empting even the FSMB guidelines, the Texas State Board of Medical Examiners published Standards for Physicians Practicing Integrative and Complementary Medicine in November 1998. These standards recognized "health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of such methods." The guidelines to determine violations focused on patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

[ED NOTE: Ask FSMB if there is currently any survey of how many states regulate CAM (such as Texas, and what is the range of the regulation. Also, should we include a table describing the oversight/regulatory bodies of licensed CAM practices, State-by-State? ie, American Jrl of Law and Medicine most recent article states that 12 of the more popular CAM techniques are strictly regulated, 13 others seem difficult to regulate to any practical degree.]

The Mechanics of Regulation

Currently, there are five fundamental mechanisms used by States to regulate the health care workforce:

and is the standard for conventional medical practice.

Mandatory Licensure prohibits the practice of a profession without a license. Using **Title Licensure**, anyone can practice the profession, but one may not use the designated title without a license. **Registration** typically imposes lower educational and training requirements than licensure, and requires that a provider register his or her name, address and training with a designated State agency, which has the power to receive consumer complaints and revoke registration. Most States provide religious healers with **Exemption** from medical licensing statutes provided they practice within the tenets of a recognized church (i.e., praying vs recommending medication). The most recently developed form of regulation being considered by several States is similar to registration. Already adopted by Minnesota, and being considered by California, the **"Minnesota Model"** allows CAM providers to practice without licensure, provided they meet a number of requirements. Providers: 1) May not render a medical diagnoses; 2) May not recommend discontinuation of medically prescribed treatments; 3) May not engage in fraudulent advertising or deceptive conduct harmful to the public; 4) Must disclose training and theory of practice.

Ostensibly, the goal of regulating CAM practices is to establish standards that protect consumers from incompetent practitioners, however, current regulatory schemas have been used quite effectively by organized professional groups as entry barriers of other potential health care providers into the competitive market. The Commission believes that the highest priorities to consider are the quality of care, treatment and patient safety, and that a regulatory infrastructure for CAM practices and products is necessary to do so. However, the Commission also believes that any such regulatory scheme must consider and promote efforts toward a more coordinated care approach that incorporates and appropriately integrates the best of conventional medicine and CAM approaches. To ensure that this goal remains primary, at least two regulatory issues must be addressed: **Professional practice authority, and regulatory and oversight structures.**

George DeVries statement

need a regulatory structure to protect the public needs to be coordinated between states

Before making recommendations on these primary issues, it is important to note several unique challenges that face regulation of CAM practices and products. First, dispute amongst CAM practitioners, themselves, continues as to how much training should be required for licensure in any given field; the extent to which such training should be required for licensure in any given field; and whether and how such education and training can incorporate intuitive and individualized expression of professional health care services. From the CAM provider's perspective, licensure presents a tension between the desire to increase standardization of CAM education, training, and practices across States and the desire to keep CAM practice flexible, non-standardized, and linked to subjective, interpersonal and intuitive aspects of care. While increased licensure of CAM may help facilitate research and ease referrals, enhance patient access and increase consumer protection, it also may decrease the inherent differentiation of CAM (individualization of services, time spent per patient, range of patient options).

Secondly, the ambiguity and variance of what is considered "CAM" along a health professional continuum makes the useful assessment of CAM as value-added services difficult, at best. In September 2001, the University of

while limiting the prerogatives of

* Clinicians/practitioners, the Commission offers the following framework

California, San Francisco's Center for Health Professions published "Profiling the Professions: A Model for Evaluating Emerging Health Professions," which discusses this evolutionary process. In addition to questions to help characterize the viability and growth trends of an emerging profession, the UCSF report outlined the need for a professional consensus descriptions. Questions posed by the UCSF report included: How does the profession describe itself in terms of the types of care it provides, and the types of care beyond its professional scope? Are there differences of opinion within the profession about the range of care that is appropriate for the profession to provide? What interventions and modalities does the profession use? What is the diagnostic range and scope of pathology of the profession? Such descriptive statements are essential tools that enable both the public and other health professionals evaluate and understand, not only the practice itself, but how and whether the practice provides a value-added service.

Relatedly, a third concern is the overlap of approaches and technique between CAM modalities. For example, homeopathy and acupuncture are included in many States' definition of the practice scopes for naturopathy or chiropractic. Currently, even licensed CAM providers can be prosecuted for unlicensed medical practice if they are considered to have exceeded their scope of practice (e.g. massage therapists who offer emotional counseling and support, chiropractors who provide nutritional advice, nurses who offer therapeutic touch). The potential for criminal liability creates fear and uncertainty in CAM practice; it is often difficult to predict boundary violations. (Licensed professionals inherently overlap in their scope of practice even in conventional care). If "whole person" medicine is the goal, these boundaries become even more ill-defined.

Professional Practice Authority

The determination of just which CAM practitioners are permitted to provide what specific services remains among the most controversial and complex issues when considering regulation. Often characterized as "turf battles," the argument over scopes of practice is not unique to CAM. The Pew Health Commission's Taskforce on Workforce Regulation found that, despite the ostensible goal of regulation to protect consumer interests, regulatory changes to practice acts always occurred at the request of professions, and never were done as a result of the public or consumer advocates.[Pew Oct 1998, pg 23] The Taskforce found that every proposal by one party for changes to one practice act is viewed by another as expansions, encroachments, and infringements, regardless of the competence or qualification of the first party.

Contributing to this confusion is the use of terms to describe levels and functions of regulation, not only among States, but between professions. This lack of uniformity in language limits effective professional practice and mobility, creates barriers to high quality health care, and confuses regulators, legislators, professionals and the public.

Conceptualize

The inconsistency of State regulatory schemas and the lack of uniformity in terms have direct impact on efforts toward collaborative care. For example, hospitals that attempt to make CAM treatments available to patients may face liability for negligent referrals within the institution to potentially unqualified practitioners. [American Journal of Law and Medicine, 2001 section B] At issue is the variability, inconsistency and reliability of the wide range of certifications and licenses available from CAM professional organizations, especially those which do not carry national consensus even among a given CAM modality. The liability, then, falls on the hospital or clinic, who must formulate and defend credentialing standards and procedures of each CAM practice for which it would like to refer. Similarly, managed care organizations face the same task of selecting which CAM practices and practitioners to include in their payment networks from among a diverse assortment of variously-certified providers. This task is compounded for those organizations that operate across State lines, and which must then contend with completely divergent occupational certification and licensure regimes State-to-State.

The Commission recognizes an urgent need to move from exclusive professional domains into a more collaborative team approach to health care. The Commission believes that CAM practitioners need the appropriate level of legal authority granted by the State in order to practice. It seems clear that, given the diversity within the field, no single, overarching system of regulation, such as the medical licensing act, is appropriate to encompass all the different CAM professional and therapies. Also, the Commission recognizes that these different CAM practices may aspire to widely differing roles within the healthcare system, and involve very different levels of intervention. For example, the scope of practice and education of some CAM providers, such as naturopathic physicians or acupuncturists, allow them to examine a patient, diagnose a health condition and treat the condition (all States include these functions under the definition of the "practice of medicine.") This type of scope of practice reflects a greater level of potential risks to and needs of patients, and therefore may require more regulatory oversight than a CAM practice that does not involve invasive therapeutic techniques. Such practices may also already have established the types of professional cohesivenss, evidence of effectiveness and safety, educational, ethical and practice standards that allow it to be more easily titled and regulated. An increasing number of CAM professional organizations are moving toward such professional status, adopting national standards for examination, certification, and accreditation. Such credentials may be easily transported from one State to another and serve as reliable credentialing standards.

From the consumer's perspective, access to competent CAM practitioners must be improved, as well as their ability to choose from among many types of CAM practitioners, or from among coordinated care plans that integrate conventional and CAM care. The public has a reasonable expectation that the care they access is provided by a competent practitioner able to help them navigate through multiple choices and decisions about the care they can receive.

CAM practitioners need authority

The Commission, therefore, recommends the following:

Recommendation1.

Congress should establish a national policy advisory board that will research, develop and publish a set of national standards for the practice of complementary and alternative medicine. These standards will establish minimum educational, ethical and practice guidelines for any practitioner wishing to provide health care via CAM approaches. These standards ~~will not protect professional titles, but~~ should focus simply on ensuring patients with safeguards. States will be encouraged to use ~~implement~~ these standards in providing broad legal authority for qualified CAM practitioners to provide their services.

Include Protection Act

The Advisory should

Recommendation 2.

The Federal Government should foster consensus conferences among CAM professions to promote consensus and practice standards. A primary goal of this effort should be to foster each CAM profession to establish a single, national, voluntary self-regulatory body, funded by registration fees, that will contribute to and uphold national standards for the practice of CAM; determine training and minimum levels of clinical competence for its specific modality; foster collaborative opportunities between its members and conventional practitioners; support, promote and publicize evidence for effectiveness, safety, and efficacy; serve as a national data bank for all practitioners under that profession and as the official liaison between its members and State regulators and professional oversight institutions; and provide an effective, accessible, supportive, and publically accountable mechanism (including disciplinary sanctions and publication of the findings of professional conduct committees) for addressing complaints about practitioners from members of the public. Again, this body will not protect professional titles, but should work to advance public confidence in its practitioners, and demonstrate the readiness and ability of the profession to self-regulate. The establishment of a single lead organization should not preclude the continuation of healthy, progressive debate and exploration within the profession's members of divergent mechanisms and approaches, but should seek simply to organize its general philosophy around a consensus scope of practice, and provide accountability to the public.

Recommendation 3.

States are encouraged to acknowledge and recognize the self-regulating authority of national, voluntary CAM organizations by requiring that CAM practitioners must be registered through such organizations, if such exist for their profession.

Recommendation 4.

The national policy advisory board also will be charged with fostering the development of national uniform scopes of practice for CAM practices, primarily to address those practices deemed to present the most potential risks to

patients, i.e., those practices and modalities that involve invasive therapeutic techniques, such as spinal manipulation, the insertion of needles, or the prescribing of medicinal products, such as herbals and botanicals. States are encouraged to use these scopes of practice to provide the necessary legal authority-and-licensure of such practitioners.

Regulatory and Oversight

In addition to assuring the competence and qualifications of the CAM practitioner, the consumer expects that the facility through which care is delivered also is safe and accountable. Most health care facilities and organizations are regulated by private organizations through accreditation processes that substitute for licensure.

The largest such private organization is The Joint Commission on the Accreditation of Health Care Organization (JCAHO), which evaluates and accredits nearly 18,000 health care organizations and programs in the United States. An independent, not_for_profit organization, JCAHO uses professionally based standards against which compliance of health care organizations are measured.

JCAHO's evaluates and accredits a long list of organizations, including general, psychiatric, children's and rehabilitation hospitals; health care networks (including Health Maintenance Organizations (HMOs); Integrated Delivery Networks (IDNs), Preferred Provider Organizations (PPOs), and managed behavioral health care organizations; home care organizations, including those that provide home health services, personal care and support services, home infusion and other pharmacy services; durable medical equipment services and hospice services; nursing homes and other long term care facilities, including subacute care programs, dementia programs and long term care pharmacies; assisted living facilities that provide or coordinate personal services, 24_hour supervision and assistance (scheduled and unscheduled), activities and health_related services; behavioral health care organizations, including those that provide mental health and addiction services, and services to persons with developmental disabilities of
various ages, in various organized service settings; ambulatory care providers, including outpatient surgery facilities, rehabilitation centers, infusion centers, group practices and others; and clinical laboratories. CAM is delivered primarily through out-patient (private practitioners) facilities, and easily could be included on this list, yet little or no standards exist to regulate them. [ED NOTE: *Information from JCAHO is pending on this issue. No formal guidelines exists*]

JCAHO and most other accreditation organizations that are used by regulatory bodies to ensure quality health care require that staff of such facilities be licensed, meet relevant training and experience standards, demonstrate current

competence, and have acceptable health status. In addition, the Health Plan Employer Data and Information Set (HEDIS 2.0) reports on general consumer satisfaction with provider accessibility and interaction, turnover, and board certification status. In some cases, individual health plans may also require medical and other staff to provide information on disciplinary or other actions taken against them, and many plans include some degree of "economic credentialing" to assess practice patterns against the organization's philosophical principles or business plans. None of these regulatory and quality control mechanisms currently are applied to CAM service delivery.

Recommendation 5.

JCAHO is governed by a 28_member Board of Commissioners that includes nurses, physicians, consumers, medical directors, administrators, providers, employers, labor representatives, health plan leaders, quality experts, ethicists, health insurance administrators and educators. This composition is reflective of most accrediting bodies, and presently most do not include CAM practitioners or experts in these fields.

URAC

NCQA

Nationally Recognized Accrediting Body

The Commission recommends that the Joint Commission on Accreditation of Health Care Organizations serve in a leadership role to review the most commonly used and evidence-based CAM modalities, especially those with particular relevance to a coordinated care approach, with respect to establishing accreditation standards.

integration of Care, in Settings

Issue 2: Access to CAM Products

An increasing number of consumers are using dietary supplements – in many cases – as adjuncts to pharmaceutical treatment prescribed by their physicians. Issues regarding the potential risks and need for better research and monitoring of such practices is addressed elsewhere in this report, as is the overall question of improving access to dietary supplements by improving what is known about them – from both regulatory and consumer perspectives. However, this chapter introduces the issue of access to a limited number of safe and effective CAM products, mostly in the dietary supplement category, in clinical settings, and as part of collaborative, coordinated care. Currently, no supplement formulations exist from which [*ED NOTE: need some examples here of safe and effective supplements– calcium? what else??*] physicians or clinic administrators can develop practice guidelines, or under which reimbursement can be developed.

It is well known that the bioavailability of supplements vary widely, thus complicating efforts to track interactions. [*Pending literature on this issue to flesh out key challenges and build support for recommendations]*

The Commission recommends that :

Recommendation 6.

The Secretary of Health and Human Services should establish an Advisory Council to examine supplements and

herbals that are covered by the DSHEA (Drug Supplement Health Education Act) to develop specific formulations for the use of such supplements in clinical settings. Given the current variability of products, this body should determine a "prescribed" list of manufacturers.

Recommendation 7.

In collaboration with insurers and managed care organizations, the Federal Government should fund demonstration projects to determine the efficacy and value-added benefits from incorporating specific CAM supplements in clinical settings. These projects also should track adverse events.

Issue 3: Coordinated Delivery Systems:

Increasingly, health providers are being challenged to develop practice protocols and other methodologies that coordinate care across the continuum. The foundation of such care is built best by first establishing a strong base of primary care. As defined by the Institute of Medicine in 1996, primary care involves the "provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing sustained partnership with patients, and practicing in the context of family and community" [Institute of Medicine, 1996] All health care practitioners, including CAM providers, should adequately understand and appropriately value the role of primary care, which should remain the launching point for all care, regardless of the providers. Integrative, or collaborative health care should not be about promoting complementary therapies but about providing comprehensive, collaborative, personalized care by drawing on the resources, skills and perspectives of a wide variety of disciplines, specialties and therapies, including complementary and alternative therapies when clinically appropriate. In the same vein, defining integrative, or collaborative health care should not be either polarizing or divisive. By pairing a holistic philosophy (comprehensive, collaborative and personalized) with a systematic and well reasoned clinical strategy, integrative health care treats illness and promotes health in a manner that always keeps the patient and community at the center.

The emergence of CAM approaches as a consumer movement suggests a shift from the application of only science and technology to overcome disease and dysfunction, to the acknowledgment of an integrated, self-healing life system with the role of internal self-regulation, personal attitudes and beliefs, and the healing nature of relationships as paramount. Consumers are doing their own research, and serving as individual research models, trying alternatives to conventional treatments, and pressing for more options. Nutrition, exercise and lifestyle changes that include increasingly more CAM products and practices play a significant role in preventing and treating disease, and improving quality of life. In most instances, health care providers can be used to guide consumers to safe and effective paths to recovery and health. In all cases, providers should be well-trained, highly qualified practitioners.

In response to growing patient (and health practitioner) dissatisfaction with the current system, innovative centers and practitioner groups are emerging at a growing rate. The trend toward patient-centered (rather than diagnosis-centered) and self-healing care is beginning to be reflected in employee assistance programs, hospice centers and community-based public health clinics and services.

CAM, like all health care services, is delivered through the public or private health care sectors. The public delivery system, in this context, includes Federal health systems (including those of the military and Veterans Administration), public hospital systems, community health centers, local public health clinics, home care, etc. Private sector systems include office-based practices of medical and health professionals, hospitals, multiple-facility health care systems, clinics, nursing homes, home health agencies, etc. These systems continuously evolve, especially in response to the mechanisms under which the systems are financed and other market pressures. For example, managed care has had a significant impact on systems of delivery, and managed care itself has changed in response to market pressures. CAM practitioners are most often found in private sector settings, and are usually in solo or small office-based practices. Increasingly, hospitals, managed care organizations, health insurers and large, self-insured corporations are developing models whereby CAM therapies are made available to members/subscribers/
employees. These models bring CAM to the practice of conventional medicine through referral, consultation, co-management, and adjunct (supportive) therapies. The spectrum of existing models, all relatively new, is broad and includes:

1. Consumer/Patient controlled: "integrated" medical services that typically include both conventional and CAM patient treatment services, as appropriate, usually in an office-based practice or outpatient (ambulatory) setting;

2. System/Organization controlled: the incorporation of CAM (aka "integrative") services as part of an individual medical practice, a group medical practice, a managed care organization, a PPO, an insurance product, a community hospital, or university affiliated teaching hospital;

3. Specialized integrative care teams consisting of conventional and complementary care providers who share a single clinical focus (i.e., the treatment of musculoskeletal pain, cancer, cardiovascular disease, women's health issues, etc.). This model most resembles current conventional care frameworks based on disease management.

Because most of CAM is delivered through the private practice arena, it is less readily available to the populations served by community health centers and others who cannot afford to pay out-of-pocket for services. CAM

practitioners who participate in referral or practitioner networks usually do so at discounted rates, a system that works as a disincentive for most CAM practitioners. Currently, few incentives exist to encourage more CAM practitioners into either the public or managed care delivery systems. Until these issues are resolved, CAM services and products will remain largely inaccessible to the populations in most need.

As new delivery models for CAM develop, the need to assure accountability and quality will become even more critical. The Institute of Medicine's report, *Crossing the Quality Chasm*, identifies six aims for improvement, all of which apply equally to conventional and CAM care [National Academy Press. Crossing the quality chasm: a new health system for the 21st century. Committee on Quality Health Care in America, Institute of Medicine. Washington, DC 2001]:

1. *Safe*: avoiding injuries to patients from the care that is intended to help them.

2. *Effective:* providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).

3. *Patient-centered*: providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

4. *Timely*: reducing waits and sometimes harmful delays for both those who receive and those who give care.
5. *Efficient*: avoiding waste, including waste of equipment, supplies, ideas, and energy.

6. *Equitable*: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.

A particularly salient example of both the need for collaborative care, and of how well CAM approaches can be incorporated into a care system can be found in end-of-life care. While the incorporation of CAM is applicable throughout the life-cycle, by the year 2020, 20% of the world's population will be older than 65 years. In this country, 8% of the population currently is older than 65 years and in 2020, it is estimated that 25% will be older than 65 years (roughly 65 million older adults). As the population ages, problems in end of life care have been increasingly well-documented, from under-treated pain to unwanted or futile therapies. Among the concerns for older adults is polypharmacy, the use of multiple medications. Older adults consume approximately 25% of prescription medication each year. In this country, it has been estimated that older adults take an average of 5 medications at any one time, often mixing them with over-the-counter medications and nutriceuticals. Given the significant increase in the number of adverse drug effects known to occur with the number

of medications, this presents a particular public safety concern. The potential for CAM therapies to reduce the number of medications older adults take provides an important and cost-sensitive opportunity.

End-of-life care is not limited to the elderly. A report by the Association of American Medical Colleges defined end-of-life issues as those that the individual person faces when confronted with a condition in which dying is a distinct possibility. [Association of American Medical Colleges. Report III: Contemporary Issues in Medicine: Communication in Medicine. Medical School Objectives Project, October 1999.] In this context, no clear demarcation exists between active treatment of an illness and the end of life. Rather, end-of-life refers to the entire time, even during treatment of an illness, when dying becomes an important consideration. For the patient, personal spirituality and culture may significantly affect his beliefs, attitudes and behaviors toward end-of-life health care interventions.

Indeed, there is evidence to suggest that spirituality may be helpful to people as they cope with dying or with loss. For example, patients with advanced cancer who also found comfort from their religious and spiritual beliefs had diminished pain; women with breast cancer reported that their spiritual beliefs helped them cope with their illness and with facing the possibility of death. In a national survey by the American Pain Society, prayer was stated as the most common non-drug method for dealing with pain, followed by relaxation response, meditation, touch and massage. The work of Dr. Herbert Benson on the role of meditation, specifically the relaxation response, as an adjunct to treatment of patients with serious disease is well-known in the medical community. Despite clear evidence of the important role of spirituality in end-of-life care, and the availability of Clinical Pastoral Education (CPE)-trained chaplains and other spiritual care providers, current systems of care do not easily incorporate spirituality into the care of patients.

The 1999 report of the Association of American Medical Colleges (Report III of the Medical School Objectives Project) suggested strategies to improve medical student education on spirituality, cultural issues and end-of-life care. Demonstration projects that further explore the potential benefits and opportunities of collaborative care (that incorporates or coordinates conventional and CAM approaches) is both appropriate and of critical value.

The Commission recommends:

Recommendation 9:

Hubbard Hyde Beth Israel

The Secretary of Health and Human Services should expand current models of integrated services networks to incorporate safe and effective CAM services as appropriate. Special attention should be directed to address the needs of vulnerable or underserved populations.

Recommendation 8:

The Secretary of Health and Human Services should authorize and fund detailed and expanded epidemiologic surveys of CAM patterns of use, with special attention to ethnic populations. This information is essential to inform public policy and to protect particularly vulnerable populations. Additional surveys also should be funded that evaluate the cost-benefit ratio of collaborative care systems.

Recommendation 9:

The Secretary of Health and Human Services should establish demonstration projects to evaluate the usefulness and effectiveness of collaborative care models, such as hospice care, and convene strategic planning conferences to address the needs of seriously ill and dying patients, as well as other special populations, that includes all relevant Federal and State agencies, non-governmental organizations, professional societies and a broad base of palliative care professionals, including qualified CAM providers.

Recommendation 10:

The Secretary of Health and Human Services report within 3 years on the use of indigenous healing traditions in the United States to identify common use, best practices, and challenges and potential areas for collaborative learning between such traditions and conventional care. The Commission urges the Secretary's report to include recommendations for the future as regards appropriate protection of such traditions, as well as research and development of such practices as part of community-based health care. Members from such traditions should be involved closely in this endeavor.

Groft, Stephen (NCCAM)

From: Chang, Michele (NCCAM)

Sent: Tuesday, November 13, 2001 3:28 PM

To: 'aallen@palladianpartners.com'

Cc: Jean; Axelrod, Corinne (NCCAM); Fisher, Ken (NCCAM); Gerry Pollen (E-mail); Jim Swyers (E-mail); Joe Kaczmarczyk (E-mail); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Steve Groft (E-mail)

Subject: RE: WHCCAMP December Meeting

Anita, you read my mind! I was JUST putting together the email for you!

TABS:

Front piece: Letter to Commissioners
A: Agenda
B: Education and Training
C: Access and Delivery
D: Coverage and Reimbursement
E: Information
F: Definitions and History
G: Research
H: Wellness
I: Format and Content (Final Report)
J: Public Comments
K: General Information

Binder size: 1.5 inch

Pick up date: This Friday, Nov 16 COB (5:00 pm)
FEDEX date: Tuesday, Nov 20

Check with Doris on Roster information
Public information let's talk about week of 26th.

Anita: if there is not sufficient time to get the tabs made as above, just go with lettered tabs and a table of contents.

-----Original Message-----
From: Anita Allen [mailto:aallen@mail.palladianpartners.com]
Sent: Tuesday, November 13, 2001 3:15 PM
To: Chang, Michele (NCCAM)
Cc: Jean; Groft, Stephen (NCCAM); Kingsbury, Doris (NCCAM)
Subject: WHCCAMP December Meeting
Importance: High

Good Afternoon!!

The December meeting is rapidly approaching and I wanted to get started with the meeting binders. In order to get started I will need the following information:

- tab information
- binder size
- anticipated date information will be ready for pickup by courier
- anticipated fedex date to the commissioners
- any address changes to the roster and/or for fedex delivery
- what information will be provided for public attendees

Let me know when we can discuss. Talk to you soon!!

Anita Allen
Palladian Partners
1010 Wayne Avenue
Silver Spring, MD 20910
(301) 650-8660 ext. 121
(301) 650-8676 - fax
aallen@palladianpartners.com

ACCESS Conference Call
Friday, November 9 @ 11:00 a.m. – 1:00 p.m.
Proposed Agenda – Discussion Points

I. Recommendations (see attached)
   1. Proposed
   2. Other:
      A. Recommendations for FSMB?
      B. Delivery recommendations?

II. Background information

   1. Incorporating experiences of CAM practitioners and regulatory boards
   2. Information about licensure AND licensing bodies state-by-state
   3. JCAHO
   4. HELP! With background on access to products in clinical settings
   5. Issue of care navigators
   6. Incorporating Delivery models

III. Next Call: Wednesday, November 14 @ 10:00 a.m. –12:00 p.m.

Proposed Recommendations: Draft 1, November 7, 2001

Recommendation1.
Congress should establish a national policy advisory board that will research, develop and publish a set of national standards for the practice of complementary and alternative medicine. These standards will establish minimum educational, ethical and practice guidelines for any practitioner wishing to provide health care via CAM approaches. These standards will not protect professional titles, but should focus simply on ensuring patients with safeguards. States will be encouraged to use implement these standards in providing broad legal authority for qualified CAM practitioners to provide their services.

Recommendation 2.
The Federal Government should foster consensus conferences among CAM professions to promote consensus and practice standards. A primary goal of this effort should be to foster each CAM profession to establish a single, national, voluntary self-regulatory body, funded by registration fees, that will contribute to and uphold national standards for the practice of CAM; determine training and minimum levels of clinical competence for its specific modality; foster collaborative opportunities between its members and conventional practitioners; support, promote and publicize evidence for effectiveness, safety, and efficacy; serve as a national data bank for all practitioners under that profession and as the official liaison between its members and State regulators and professional oversight institutions; and provide an effective, accessible, supportive, and publically accountable mechanism (including disciplinary sanctions and publication of the findings of professional conduct committees) for addressing complaints about practitioners from members of the public. Again, this body will not protect professional titles, but should work to advance public confidence in its practitioners, and demonstrate the readiness and ability of the profession to self-regulate. The establishment of a single lead organization should not preclude the continuation of healthy, progressive debate and exploration within the profession's members of divergent mechanisms and approaches, but should seek simply to organize its general philosophy around a consensus scope of practice, and provide accountability to the public.

Recommendation 3.
States are encouraged to acknowledge and recognize the self-regulating authority of national, voluntary CAM organizations by requiring that CAM practitioners must be registered through such organizations, if such exist for their profession.

Recommendation 4.
The national policy advisory board also will be charged with fostering the development of national uniform scopes of practice for CAM practices, primarily to address those practices deemed to present the most potential risks to patients, i.e., those practices and modalities that involve invasive therapeutic techniques, such as spinal manipulation, the insertion of needles, or the prescribing of medicinal products, such as herbals and botanicals. States are encouraged to use these scopes of practice to provide the necessary legal authority and licensure of such practitioners.

Recommendation 5.
The Commission recommends that the Joint Commission on Accreditation of Health Care Organizations serve in a leadership role to review the most commonly used and evidence-based CAM modalities, especially those with particular relevance to a coordinated care approach, with respect to establishing accreditation standards.

Recommendation 6.
The Secretary of Health and Human Services should establish an Advisory Council to examine supplements and herbals that are covered by the DSHEA (Drug Supplement Health Education Act) to develop specific formulations for the use of such supplements in clinical settings. Given the current variability of products, this body should determine a "prescribed" list of manufacturers.

Recommendation 7.
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adverse events.

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Recommendation 10:
The Secretary of Health and Human Services report within 3 years on the use of indigenous healing traditions in the United States to identify common use, best practices, and challenges and potential areas for collaborative learning between such traditions and conventional care. The Commission urges the Secretary's report to include recommendations for the future as regards appropriate protection of such traditions, as well as research and development of such practices as part of community-based health care. Members from such traditions should be involved closely in this endeavor.

Groft, Stephen (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Thursday, November 08, 2001 3:15 PM
To: 'George Bernier (E-mail)'; 'George DeVries (E-mail)'; 'Joe Fins (E-mail)'; 'Joe Pizzorno (E-mail)'; 'Julia Scott (E-mail)'; 'Linnea Larson (E-mail)'; 'Conchita Paz (E-mail)'; 'Tierney Lancaster (E-mail)'
Cc: Axelrod, Corinne (NCCAM); Fisher, Ken (NCCAM); Pollen, Geraldine (NCCAM); Jim Swyers (E-mail); Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Groft, Stephen (NCCAM)
Subject: RE: ACCESS Conference Call tomorrow!

Please find attached a suggested agenda for tomorrow's call. Thanks!

11.9 call agenda.rtf

-----Original Message-----
From: Chang, Michele (NCCAM)
Sent: Wednesday, November 07, 2001 5:10 PM
To: 'George Bernier (E-mail)'; 'George DeVries (E-mail)'; 'Joe Fins (E-mail)'; 'Joe Pizzorno (E-mail)'; 'Julia Scott (E-mail)'; 'Linnea Larson (E-mail)'; 'Conchita Paz (E-mail)'; 'Tierney Lancaster (E-mail)'
Cc: Axelrod, Corinne (NCCAM); Fisher, Ken (NCCAM); Pollen, Geraldine (NCCAM); Jim Swyers (E-mail); Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Groft, Stephen (NCCAM)
Subject: ACCESS DRAFT 1.

REMINDER:

This Friday, November 9, Group C (ACCESS) will convene a conference call at 11:00 am –1:00 pm (EST) to discuss the attached draft.

To Connect dial: 1-888-759-2173
PASSCODE: 45139

Tomorrow I will send you a suggested call agenda, outlining the gaps that are still outstanding in the draft and specific issues that need to be discussed.

Thanks!

<< File: ACCESS 11.7R draft.rtf >>

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

Axelrod, Corinne (NCCAM)

From: Axelrod, Corinne (NCCAM)
Sent: Tuesday, November 06, 2001 11:56 AM
To: 'Bill Fair (E-mail) ' (E-mail); 'Dean Ornish (E-mail) ' (E-mail); 'Effie Chow' (E-mail); 'Joe Pizzorno' (E-mail); 'Julia Scott (E-mail) ' (E-mail); 'Marjorie Dean Ornish office (E-mail) ' (E-mail); 'Ming Tian (E-mail) ' (E-mail); Tieroana Lowdog (E-mail)
Cc: Chang, Michele (NCCAM); Fisher, Ken (NCCAM); Groft, Stephen (NCCAM); Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Wellness

Dear Wellness Workgroup,

Hope you're all doing well (!). Attached is the revised Wellness section. Please note the following:

1) In response to the comments at the last meeting, the first issue has been significantly broadened. It now calls for a National campaign to address wellness, self-care, and prevention among children. It still calls for school guidelines to be developed, but as part of the national campaign, and has also added a media component.

2) Throughout the document, I have used the phrase "wellness, self-care, and prevention, including CAM". I don't think we will ever resolve the divergent views of Commission members on how much of wellness, s-c, and prev. is CAM and how much of CAM is wellness, s-c, and prev., and perhaps we don't need to. This is also an attempt to convey that all of wellness, s-c, and prev. is sorely lacking throughout the health care system, and our recommendations apply to all of wellness, s-c, and prev., including, but not just, the CAM part.

3) There has been a lot of discussion of spirituality, but that will be addressed both in the introductory section and in the research section.

4) What was previously Issue 5 is now split into 2 issues, 4 and 5.

As you read through this section, please see if you think we can justify the statements and recommendations or if additional data is needed.

This is a work in process, and more work needs to be done, particularly with issues 4 and 5, but I wanted to get this out to you so you'd have time to look at it before our conference call, which is scheduled for Tuesday, Nov 13, from 1:15 to 3:15 EST. Looking forward to talking to you then. If you have any questions, please feel free to call me.


Wellness06Nov01.wpd


Wellness06Nov01.rtf

CDR Corinne Axelrod, M.P.H., L.Ac.
Senior Program Analyst
White House Commission on Complementary and Alternative Medicine Policy
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Tracking:

Recipient	Read
'Bill Fair (E-mail) ' (E-mail)	
'Dean Ornish (E-mail) ' (E-mail)	
'Effie Chow' (E-mail)	

Recipient	Read
'Joe Pizzorno' (E-mail)	
'Julia Scott (E-mail) ' (E-mail)	
'Marjorie Dean Ornish office (E-mail) ' (E-mail)	
'Ming Tian (E-mail) ' (E-mail)	
Tieroana Lowdog (E-mail)	
Chang, Michele (NCCAM)	Read: 11/6/2001 12:16 PM
Fisher, Ken (NCCAM)	Read: 11/8/2001 2:23 PM
Groft, Stephen (NCCAM)	Read: 11/6/2001 12:28 PM
Kaczmarczyk, Joseph (NCCAM)	Read: 11/6/2001 11:57 AM
Kingsbury, Doris (NCCAM)	
Miller, Maureen (NCCAM)	
Pollen, Geraldine (NCCAM)	

Wayne
Veronica

C-4

06Nov01

Wellness, Self-Care, and Prevention

Staff Lead: Corinne Axelrod
Members: Dean Ornish (Facilitator), Bill Fair, Julia Scott, Xiaoming Tian, Charlotte Kerr, Effie Chow, Joe Pizzorno

c - Introduction

CAM has much to offer

Prenatal

Issue 1: Wellness, self-care, and prevention among children.

Background:

Learning healthy behaviors at an early age can help children develop life-long practices that contribute to a healthy, happy, and productive life. Good nutrition, exercise, self-esteem, and positive family relationships are all important to the health and well being of our Nation's youth. Yet statistics on children's health behaviors are cause for great concern. More than 84% of children and adolescents eat too much fat and only 20% eat an adequate amount of fruits and vegetables,[1] despite research that has shown that poor nutrition can have lasting effects on children's cognitive development and school performance[2]. Daily participation in physical education classes by high school students dropped from 42% in 1991 to 29% in 1999, even though physical activity is known to have many beneficial health effects, including reduction in anxiety and stress and increased self-esteem[3]. By the time they are seven years old, almost 13 percent of children are seriously overweight[4], and studies have shown that obese children and adolescents are more likely to become obese adults[5].

Despite public health efforts to curb smoking, 36% of high school students currently smoke and 70% have tried cigarettes[6]. Seventeen percent of high school students have carried a weapon, and 19% have seriously considered suicide in the past year[7]. Among children ages 5-14, the leading causes of death are unintentional injuries, cancer, and homicide, respectively. In the 15-24 age group, the leading causes of death are unintentional injuries, homicide, and suicide, respectively[8]. Behavioral and mental health problems, especially depression, are widespread,

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[1] - Lewis CJ et al. Healthy People 2000: Report on the 1994 nutrition progress review. Nutrition Today 1994; 29 (6): 6-14.

[2] - Center on Hunger, Poverty, and Nutrition Policy. Statement on the Link between Nutrition and Cognitive Development in Children. Medford, MA: Tufts University School of Nutrition, 1995

[3] - CDCP Guidelines for School and Community Programs: Promoting Lifelong Physical Activity

[4] - Centers for Disease Control and Prevention. Update: prevalence of overweight among children, adolescents, and adults - United States 1988-1994. Morbidity and Mortality Weekly Report 1997; 46:199-202.

[5] - Guo SS et al. The predictive value of childhood body mass indexvalues for overweight at age 35 years. American Journal of Clinical Nutrition 1994; 59:810-9

[6] - CDCP Guidelines to Prevent Tobacco Use and Addiction

[7] - CDCP National Center for Chronic Disease Prevention and Health Promotion

[8] - CDCP, NCHS, National Vital Statistics System, 1999.

and substance abuse continues to be a problem, including so-called "performance enhancing" drugs used in sports.

Poor dietary habits, lack of exercise, smoking, suicide, substance abuse, homicide, and depression among our youth is a silent epidemic that should be a national priority. While many individual programs exist to address these problems, a comprehensive and coordinated effort is needed to increase the focus on these issues. A national campaign, similar to those that were conducted for seat belt use, drinking and driving, and other behavioral activities that impact on health, can help to get local schools, parents, community leaders, businesses, and the media involved to bring about lasting and meaningful change. While not exclusively CAM-focused, this campaign should include CAM principles and practices that may contribute to healthy behavior.

The national campaign should be a multi-focused effort utilizing schools, parents, the community, businesses, sports figures, and the media to heighten interest and awareness among children of health issues, how their behavior impacts on their life and environment, and ways to establish healthy habits for coping with life stresses. CAM has much to offer in wellness, prevention, and self-care programs and should be part of a national strategy to transform the dismal health statistics and unhealthy behaviors of our nation's youth.

Most school districts require some form of health education to be taught as part of a student's total education. School health programs include activities and services to promote students' physical, emotional, and social development. Teaching students safe and effective practices to improve nutrition, reduce stress, resolve conflicts, and develop healthy lifestyles can complement the efforts already underway to improve the health and well being of young people.

The Centers for Disease Control and Prevention has developed guidelines for schools to increase physical activity, promote healthy eating, prevent tobacco use and addiction, and prevent AIDS. The Health Resources and Services Administration has developed guidelines on comprehensive school health programs, mental health, and safety. A working group should be established to incorporate the wellness, self-care, and prevention practices of CAM into the existing guidelines. Included in this group should be Federal organizations, CAM professionals, and parents and teacher groups, and the guidelines should reflect the cultural diversity in the school systems.

Innovative programs that are addressing wellness, self-care, and prevention in schools should be identified so other schools can learn from them and, if applicable, adapt them for use in developing their own programs. For example, a group of middle schools in the Minneapolis-St. Paul metropolitan area has developed school nutrition advisory councils to promote the nutritional health of children. This is part of a Teens Eating for Energy and Nutrition at Schools (TEENS) program to promote healthful dietary behaviors among young adolescents to reduce future cancer risk[9]. As part of the health or physical education curriculum, schools in California,

[9] - Kubik MY, Lytle LA, Story M. A practical, theory-based approach to establishing school nutrition advisory councils. J Am Diet Assoc 2001 Feb; 101 (2):223-8

Study of how CAM practice can contribute to development of Healthy People 2010, etc.

New York, and Minnesota are offering yoga classes in elementary, middle, and high schools. The benefits include increased concentration, reduction in impulsive behavior, and increased self-esteem.

Challenges:

School programs are locally designed and implemented, and what works in one community may not be applicable to another. Therefore, it is essential that the local community (parents, teachers, school boards, etc.) are involved.

CAM to be integrated

Recommendations:

1) The Commission recommends that a national campaign to improve the health behaviors of children be established. National guidelines on wellness, self-care, and prevention practices for children, including CAM where appropriate, should be developed, and a media campaign be conducted that includes public service announcements and involvement of public figures to teach and encourage healthy behaviors among children.

^exercise

2) The Commission recommends that, in partnership with the business community and school boards, incentives be developed for schools to make available healthier school lunches and snacks and to limit the sale and advertising of high fat snacks, soft drinks, and other products that do not contribute to a healthy lifestyle.

Issue 2: Utilization of CAM to help achieve the Nation's health promotion and disease prevention goals

Background:

Since the publication of *Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention* in 1979, goals and objectives for the Nation's health have been defined and monitored. The most recent report, *Healthy People 2010*, was developed by an alliance of over 600 Federal, State, and national organizations. HP 2010 is designed to achieve two overarching goals: 1) Increase quality and years of healthy life, and 2) Eliminate health disparities. These goals and objectives are the blueprint for the Nation's health promotion and disease prevention activities and influence data collection, national health policy, and program development and implementation. HP 2010 is a comprehensive document that addresses clinical, behavioral, environmental, and health systems issues that impact on health. It's focus is both on individuals and communities, and there is a strong emphasis on health education and changing health behaviors.

The two overarching goals of HP 2010 are consistent with the goals of CAM. Several CAM practices, such as massage therapy to reduce activity limitation due to chronic low back pain (Objective 2-11), meditation or biofeedback to reduce high blood pressure (Objectives 12-9 through 12-12), and tai chi to increase physical activity and flexibility (Objectives 22-1 through 22-5), could contribute to the achievement of the goals and objectives outlined in HP 2010. DHHS should form a working group within the Healthy People Consortium, including CAM

professionals, to review the leading health indicators and determine the applicability of CAM to these indicators. Adding a CAM perspective to these goals and objectives would build on a component of the public health infrastructure that is well established and could have far reaching impact on policies and programs.

Despite results from several published studies, the extent of use of CAM interventions in the general population is still unknown. It would be helpful to solicit information from national surveys to determine not only the extent and intended use of use CAM by the public.

Challenges:
HP 2010 is very data driven and CAM currently does not have an extensive database.

Recommendations:
3) The Commission recommends that DHHS review the 10 leading health indicators[10] and, where appropriate, develop strategies to encourage the use of safe and effective CAM principles and practices in these areas.

4) The Commission recommends that questions on specific CAM usage be included in the national surveys that are the sources of the HP 2010 data e.g. the National Health Interview Survey, National Health and Nutrition Examination Survey, and the Medical Expenditure Panel Survey.

Issue 3: Wellness, Self-Care, and Prevention in the workplace.

Background:
Studies have repeatedly demonstrated that comprehensive worksite health promotion programs can lower health care and insurance costs, decrease absenteeism, and improve performance and productivity. [11] One study showed an average decrease of $129 per year for each employee who shifted from a high risk to a low risk status by increasing safety belt use, reducing blood pressure, and reducing cholesterol .[12] In another study, a health promotion program for retirees was introduced at a cost of $30 per person, resulting in a $164 decrease in insurance claims per person[13]. A national manufacturing company reported a decrease of 12.2% in illness days for

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[10] - The ten leading health indicators are: physical activity, overweight and obesity, tobacco use, substance abuse, responsible sexual behavior, mental health, injury and violence, environmental quality, immunization, and access to health care.

[11] - Pelletier, Kenneth, "A Review and Analysis of the Clinical and Cost-Effectiveness Studies of Comprehensive Health Promotion and Disease Management Programs at the Worksite: 1995-1998 Update.", American Journal of Health Promotion, July/Aug 1999, Vol 13, No.6 p333-345

[12] - Edington, DW, et al. The Financial Impact of the Changes in Personal Health Practices, Journal of Occupational and Environmental Medicine, Vol 39, No. 11Nov 1997 pp1037-1046

[13] - Fries, James, et al., "Two-Year Results of a Randomized Controlled Trial of a Health Promotion Program in a Retiree Population", American Journal of Medicine, May 1993:455-462

employees in a health promotion program.[14] Some worksite health promotion programs have had a positive return on investment of up to 8.22:1 in combined reduced health care costs and absenteeism[15].

In the Federal sector, the Division of Federal Occupational Health, in DHHS, assists Federal organizations in improving the health, safety, and productivity of the Federal workforce. They provide comprehensive worksite services, including medical, nursing, and wellness/fitness services, to Federal agencies around the country and currently serve over 300 Federal agencies with 1.6 million employees. Other Federal organizations may offer their employees wellness programs as well.

The focus of many health promotion programs in the workplace are on reduction of risk factors and include weight loss, smoking cessation, stress reduction, etc. These are areas where CAM practices such as yoga, meditation, good nutrition, etc. have been shown to be of benefit. Incentives such as tax breaks or lower premiums should be developed to encourage worksite wellness programs and decrease premiums.

Challenges:

Incentives for businesses to include CAM in wellness programs and health coverage will vary depending on the size of the business. For example, larger companies that negotiate health plans through a union will require a different set of incentives than a small company that may only offer limited coverage. Some incentives currently exist but have not been evaluated for their effectiveness. Any additional program or service will have ~~start up costs that may deter some~~ companies.

Recommendations:

5) The Commission recommends that wellness, self-care, and prevention, ~~including CAM~~, be included in all Federal worksite wellness and health promotion programs and Federal health coverage plans.

6) The Commission recommends that, in consultation with the business community, incentives be developed for employers to include wellness, self-care, and prevention, including CAM, ~~in~~ worksite wellness programs and health coverage and decrease premiums.

Issue 4: Wellness, self-care, and prevention activities in hospitals, long term care facilities, primary care settings, and programs serving the aging, dying, and those with chronic illness.

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[14] - Bertera, R. "Behavioral Risk factors and Illness Day Changes with Workplace Health Promotion," American Journal of Health Promotion, May 1993:363-373.

[15] - Aldana SG. Financial impact of worksite health promotion and methodological quality of the evidence. Art of Health Promotion 1998; 2(1):1-8.

Background:
The current health care system is primarily disease-focused, with much of research, education, training, services, reimbursement, and information development and dissemination directed toward identifying and treating diseases and conditions. Wellness, self-care, or prevention activities that are incorporated into the conventional health care system are, for the most part, disease screening (e.g. pap smears), or offered in response to an already identified illness or condition (e.g. physical therapy after stroke, nutritional counseling for diabetics, etc.) While many hospitals have begun to offer community programs that focus on wellness, self-care, and prevention, these activities often occur outside of the health care system and rely upon factors such as a person's knowledge of these activities, belief in their potential benefit, ability to pay out of pocket, and their ability to gain access to the services.

Incorporating wellness, self-care, and prevention activities into the conventional health care system will make them available to more people, improve continuity of care, health outcomes, and quality of life. It could also provide significant savings in reduced health care costs. CAM practices that contribute to health, well-being, recovery from illness, and improved quality of life should be included. This may include acupuncture for pain relief, massage or meditation for stress reduction, and other practices that can be easily integrated into the clinical management of a patient.

Integrating wellness, self-care, and prevention practices, including CAM, into the conventional health care system requires expanding the way health care is viewed in this country. It has been a consumer driven movement that many health professionals and organizations support, but, with few exceptions, has not been part of the mainstream health care system.

Federal leadership can help bring together key partners, identify barriers, and develop solutions that will facilitate integrating wellness, prevention, and self-care activities, including CAM, within the conventional health care system. Representatives of national, state, and local organizations of clinicians, administrators, health plans, pharmacists, nurses, mental health professionals, consumers, and others from hospital and long term care facilities, programs serving the aging, dying, and those with chronic illness, along with CAM professionals, should be included in this process.

Challenges:
Cost savings from wellness, self-care, and prevention activities can be difficult to quantify and are usually realized over a long term period. These activities, while occurring at many institutions, currently lack sufficient emphasis and scope to demonstrate the potential benefit to the public.

Recommendations:
7) The Commission recommends that the Secretary, DHHS, establish a task force to develop strategies to incorporate wellness, prevention, and self-care activities, including CAM, in the nation's hospitals and long term care facilities and programs serving the aging, dying, and those

with chronic illness.

Issue 5: Wellness, self-care, and prevention activities in Federal health programs serving vulnerable populations.

Background:
The Federal government funds many programs that serve vulnerable populations such as Head Start, Meals on Wheels, The Special Supplemental Nutrition program for Women Infants and Children, and the State Children's Health Insurance Program. These programs directly impact on the health and quality of life of the people they serve, and could benefit from a wellness, prevention, and self-care component that includes CAM. For example, Head Start programs may choose to teach children to breathe deeply as a relaxation technique and to stretch their muscles prior to physical activity. Meals on Wheels may choose to re-evaluate the type of food being served. The State Children's Health Program may choose to provide chiropractic services. Representatives of these and other appropriate Federal programs should be brought together to identify strategies to incorporate wellness, prevention, and self-care, including CAM, into their services.

Federally-funded health care delivery programs serve large segments of the population and should be a model for incorporating wellness, self-care, and prevention, including CAM, into their services. This includes the Department of Veterans Affairs, which has 172 hospitals and over 500 other health care facilities serving 25 million veterans; community and migrant health centers serve over 10 million people who otherwise would not have access to care; maternal and child health programs, and school health programs. This may require providing training to primary care providers in these settings on integrating CAM services into their services.

Challenges:

Recommendations:
8) The Commission recommends that the Secretary, DHHS, establish a task force to develop strategies to incorporate wellness, prevention, and self-care activities, including CAM, in Federal programs such as Head Start, Meals on Wheels, Women Infants and Children, and the State Children's Health Insurance Program.

9) The Commission recommends that the Secretary, DHHS, establish a task force to develop strategies to incorporate wellness, prevention, and self-care activities, including CAM, in health care delivery programs such as the Department of Veterans Affairs Hospitals, community and migrant health centers, maternal and child health programs, and school health programs.

as a model to test CAM theory-practice