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Groft, Stephen (NCCAM)

From: Sharon [admin@amfoundation.org]
Sent: Friday, November 30, 2001 1:12 PM
To: Groft, Stephen (NCCAM)
Cc: Bmsp8@Erols. Com
Subject: Proofs for the Journal of Alternative and Complementary Medicine

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Billie Spaight
(b)(6)
Valley Stream, NY 11580
(b)(6)

Should you have any questions please let me know.

Thank you for your time and attention in this matter.
Sharon

Sharon Bourke
Office Manager
Alternative Medicine Foundation
5411 West Cedar Lane 205A
Bethesda, MD 20814
p 301.581.0116 f 301.581.0119

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Complementary/alternative medicine use in a comprehensive cancer center and the implications for oncology.

Richardson MA, Sanders T, Palmer JL, Greisinger A, Singletary SE.

Centers for Alternative Medicine Research and Health Promotion Research and Development, The University of Texas-Houston School of Public Health, Houston, TX, USA.

PURPOSE: Oncologists are aware that their patients use complementary/alternative medicine (CAM). As cancer incidence rates and survival time increase, use of CAM will likely increase. This study assessed the prevalence and predictors of CAM use in a comprehensive cancer center. SUBJECTS AND METHODS: Subjects were English-speaking cancer patients at least 18 years of age, attending one of eight outpatient clinics at The University of Texas M.D. Anderson Cancer Center, Houston, TX, between December 1997 and June 1998. After giving written informed consent, participants completed a self-administered questionnaire. Differences between CAM users and nonusers were assessed by chi(2) and univariate logistic regression analysis. A multivariate logistic regression model identified the simultaneous impact of demographic, clinical, and treatment variables on CAM use; P values were two-sided. RESULTS: Of the 453 participants (response rate, 51.4%), 99.3% had heard of CAM. Of those, 83.3% had used at least one CAM approach. Use was greatest for spiritual practices (80.5%), vitamins and herbs (62.6%), and movement and physical therapies (59.2%) and predicted (P <.001) by sex (female), younger age, indigent pay status, and surgery. After excluding spiritual practices and psychotherapy, 95.8% of participants were aware of CAM and 68.7% of those had used CAM. Use was predicted (P <.0001) by sex (female), education, and chemotherapy. CONCLUSION: In most categories, CAM use was common among outpatients. Given the number of patients

combining vitamins and herbs with conventional treatments, the oncology community must improve patient-provider communication, offer reliable information to patients, and initiate research to determine possible drug-herb-vitamin interactions.

PMID: 10893280 [PubMed - indexed for MEDLINE]

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- JAMA. 2000 Feb 16;283(7):884-6

Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey.

Eisenberg DM, Davis RB, Ettner SL, Appel S, Wilkey S, Van Rompay M, Kessler RC.

Center for Alternative Medicine Research and Education, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, Mass 02215, USA.

CONTEXT: A prior national survey documented the high prevalence and costs of alternative medicine use in the United States in 1990. OBJECTIVE: To document trends in alternative medicine use in the United States between 1990 and 1997. DESIGN: Nationally representative random household telephone surveys using comparable key questions were conducted in 1991 and 1997 measuring utilization in 1990 and 1997, respectively. PARTICIPANTS: A total of 1539 adults in 1991 and 2055 in 1997. MAIN OUTCOMES MEASURES: Prevalence, estimated costs, and disclosure of alternative therapies to physicians. RESULTS: Use of at least 1 of 16 alternative therapies during the previous year increased from 33.8% in 1990 to 42.1% in 1997 (P < or = .001). The therapies increasing the most included herbal medicine, massage, megavitamins, self-help groups, folk remedies, energy healing, and homeopathy. The probability of users visiting an alternative medicine practitioner increased from 36.3% to 46.3% (P = .002). In both surveys alternative therapies were used most frequently for chronic conditions, including back problems, anxiety, depression, and headaches. There was no significant change in disclosure rates between the 2 survey years; 39.8% of alternative therapies were disclosed to physicians in 1990 vs 38.5% in 1997. The percentage of users paying entirely out-of-pocket for services provided by alternative medicine practitioners did not change significantly between 1990 (64.0%) and 1997 (58.3%) (P=.36). Extrapolations to the US population suggest a 47.3% increase in total

visits to alternative medicine practitioners, from 427 million in 1990 to 629 million in 1997, thereby exceeding total visits to all US primary care physicians. An estimated 15 million adults in 1997 took prescription medications concurrently with herbal remedies and/or high-dose vitamins (18.4% of all prescription users). Estimated expenditures for alternative medicine professional services increased 45.2% between 1990 and 1997 and were conservatively estimated at $21.2 billion in 1997, with at least $12.2 billion paid out-of-pocket. This exceeds the 1997 out-of-pocket expenditures for all US hospitalizations. Total 1997 out-of-pocket expenditures relating to alternative therapies were conservatively estimated at $27.0 billion, which is comparable with the projected 1997 out-of-pocket expenditures for all US physician services. CONCLUSIONS: Alternative medicine use and expenditures increased substantially between 1990 and 1997, attributable primarily to an increase in the proportion of the population seeking alternative therapies, rather than increased visits per patient.

PMID: 9820257 [PubMed - indexed for MEDLINE]

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1: Arch Intern Med 2001 Mar 26;161 (6):805-10

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Americans' views on the use and regulation of dietary supplements.

Blendon RJ, DesRoches CM, Benson JM, Brodie M, Altman DE.

Department of Health Policy and Management, Harvard School of Public Health, 677 Huntington Ave, Boston, MA 02115, USA.

This article presents the views of Americans on what the government's future role should be in regulating or overseeing the growing sales of dietary supplements for health purposes. Based on results of multiple national opinion surveys, including the views of both users and nonusers of supplements, we found that a substantial percentage of Americans surveyed reported that they regularly take dietary supplements as a part of their routine health regimen. However, they reported that they do not discuss the use of dietary supplements with their physicians because they believe that the physicians know little or nothing about these products and may be biased against them. Many users felt so strongly about the potential health benefits of some of these products that they reported that they would continue to take them even if they were shown to be ineffective in scientifically conducted clinical studies. However, there also was broad public support for increased government regulation of these products. We found that a majority of Americans surveyed supported the following: to require that the Food and Drug Administration review the safety of new dietary supplements prior to their sale; to provide increased authority to remove from sale those products shown to be unsafe; and to increase government regulation to ensure that advertising claims about the health benefits of dietary supplements are true.

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[Drug interactions of Hypericum perforatum (St. John's wort) are potentially hazardous.]

[Article in Dutch]

Baede-van Dijk PA, van Galen E, Lekkerkerker JF.

College ter Beoordeling van Geneesmiddelen, Den Haag.

Hypericum can lower the plasma levels of simultaneously administered drugs by induction of metabolism. Combinations of hypericum products with warfarin, cyclosporin, oral contraceptives, theophylline, fenprocoumon, digoxin and indinavir have led to reported interactions and reduced therapeutic activity. It is therefore not advisable to combine hypericum products with other drugs, especially CYP3A4 and p-glycoprotein substrates. Discontinuing hypericum after protracted use may lead to higher plasma levels of the drugs used simultaneously, with the risk of adverse effects. Registered homeopathic preparations with a dilution of 1 in 10,000 or weaker may be regarded as safe.

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THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 7, Number 6, 2001, pp. 000–000
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CONFERENCE REPORT

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

~~September 18, 2001.~~ DELETE DATE +

~~STEPHEN C. GROFT, PharmD.~~ NO SINGLE AUTHOR

I. INTRODUCTION

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

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

This Interim progress report provides a brief overview of CAM as well as the Commission and its activities. It also discusses the Commission's progress to date on developing recommendations around the four major topic areas outlined in former President Clinton's Executive Order. Individuals and organizations are encouraged to provide written comments on this interim progress report for consideration by the Commission through its Web site or by letter to the Commission staff (see Reprint Address).

AU: Please provide Web site

HTTP://WHCCAMP.HHS.GOV

The Commission's Charge

Former President Clinton's Executive Order charged the Commission to consider four broad topics related to CAM:

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

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

A. Overview of complementary and alternative medicine

Definitions of CAM continue to evolve. CAM generally refers to modalities, practices, techniques, and systems of healing that are used together with ("complementary to") or instead of ("alternative to") conventional medicine. Among the modalities that are associated most often with the term CAM are chiropractic, acupuncture, massage therapy, mind–body techniques (e.g., biofeedback, guided imagery, yoga, and meditation), some forms of nutritional therapy, and dietary supplements (in-

White House Commission on Complementary and Alternative Medicine Policy, Bethesda, MD.

cluding herbs), as well as homeopathy, naturopathic medicine, various forms of energy healing, and the indigenous healing systems of the many ethnic groups in the United States.

Over the past decade, several nationwide surveys have documented a substantial and growing usage of CAM practices and products by the American public (Astin, 1998; Eisenberg et al., 1993; Eisenberg et al., 1998; Paramore, 1997). These surveys have found that most CAM users seek conventional medical treatment first and then turn to CAM practitioners. Most people appear to use CAM in conjunction with, not as a replacement for, conventional medical therapy and many seek out care that integrates the best of a variety of approaches (Astin, 1998). The use of CAM modalities, practices, and products by the general population varies in the published literature, ranging from 6.5% (Druss and Rosenheck, 1999) to 42% (Eisenberg et al., 1998, Fairfield et al., 1998) depending on the population studied and the criteria used to define CAM. Other studies have documented even higher use of CAM therapies among people with chronic and life-threatening conditions (Rao et al., 1999; Richardson et al., 2000). For example, a recent study at a major cancer center indicated that 69 percent of patients included CAM approaches as part of their cancer care (Richardson et al., 2000).

B. An overview of the commission: its membership and activities to date

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

Activities to date. The Commission has held seven formal meetings in Washington, D.C., all of which have included sessions for open public comment and four Town Hall meetings, where hundreds of people gave testimony. In total, the Commission has heard from more than 1000 speakers and received nearly 2000 individual comments and recommendations from the public. In the coming months, the Commission plans to review reports from previous commissions and authoritative bodies on the topics identified in its charge and to solicit additional written comments and suggestions from the general public by e-mail, fax, and regular mail.

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

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

At the four Town Hall meetings held in San Francisco, Seattle, New York City, and Minneapolis, testimony was presented on subjects related to all four topics. The transcripts, agenda, and other information pertaining to all Commission meetings and Town Hall meetings are available on the Commission's Web site. Additional information, such as Commissioner biographies and a schedule of future meetings, also is readily available at the Web site, which is periodically updated to reflect ongoing activities. Comments, recommendations,

Au: pls. provide e-mail address (1) and suggestions can be sent though the Web site, or to WHCCAMP@mail.nih.gov (2) HTTP://WHCCAMP.HHS.GOV website

II. THE COMMISSION'S PROGRESS TO DATE

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

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

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

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

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

A. Coordination of complementary and alternative medicine research

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

Testimony to the Commission described a growing interest in and support for CAM research, not only on the part of the CAM community and the public, but also at the Federal level, in academic health centers, in community

hospitals, and in mainstream private practices. This interest has further stimulated CAM professional schools and manufacturers of CAM products to enhance their own research capacities. The NIH research Institutes and Centers, including the NCCAM, plans to fund more than $220 million for CAM research and research training in Fiscal Year 2002. The importance of public input into the research agenda was discussed often during testimony.

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

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

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

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

A number of speakers, including many from the dietary supplement industry, asked that the FDA establish regulations on Good Manufacturing Practices for quality control and guidelines on processing and production as approaches to ensuring the safety and integrity of all products during manufacture. These speakers also called upon federal agencies and the private sector to coordinate efforts to establish and implement guidelines standardizing the composition and purity of products and to address possible contaminants and adulterants. Researchers asked for standards that will result

in a readily available supply of products with consistent composition to assure reliable research results. There was also support for the establishment of a dedicated CAM-related office and/or CAM-related core review teams to facilitate the regulatory review of CAM products.

Although the number of adverse events reported from the use of dietary supplements is relatively small, any adverse event can become a public health issue. Several speakers asked for a strengthening and expansion of the FDA's adverse event reporting (AER) system and for this information to be made widely available. This is consistent with a recent report from the Office of the Inspector General of the Department of Heath and Human Services that describes the current limitations of the AER system for all products and provides recommendations to improve it (Office of Inspector General, 2001).

Testimony focused on the need for manufacturers to make information on the benefits and risks of herbs and dietary supplements readily available to consumers and health care professionals through methods such as improved labeling, package inserts, and information at points-of-sale. This information should include any limitations; known interactions with drugs, foods, and other health products; and possible risks to vulnerable populations, including children, the elderly, pregnant and nursing women, and people with certain health conditions or compromised immune systems (Blendon et al., 2001).

B. Providing reliable, useful information on CAM to health care professionals and the public

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

Internet, radio, television, and print media. The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and health care providers. The Federal Trade Commission (FTC) predicts that 30 million Americans will seek health information online in 2001 and that this number is increasing dramatically (FTC, 1999). There are numerous CAM-specific Web sites as well as a variety of general health information sites that include some CAM information. According to public testimony, some of these sites provide accurate and current information, while many others contain inaccurate, misleading, self-serving, or outdated information.

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

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

Many people from the conventional and CAM professional communities, the public, and the media asked the federal government to assume a greater leadership role in providing and coordinating authoritative information about CAM practices and products in an eas-

ily accessible forms that ensure consistent, quality information.

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

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

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

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

C. Access to and delivery of complementary and alternative medicine

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

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

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

While some CAM professions endorse licensure and certification to participate more fully in the health care delivery system, several witnesses testified that licensure or certification is not feasible for some categories of CAM prac-

titioners such as Native American and other traditional healers. Some CAM practitioners consider their disciplines to be educational (e.g., the Alexander Technique) or spiritual (e.g., Reiki) and have expressed concerns about licensing as health professionals. The Commission also heard from several conventional practitioners who incorporate CAM modalities in their practices and who are concerned that their integrative approach does not lend itself to the licensure process. Some, but not all, of the conventional practitioners who testified recommended that scope of practice laws be broadened to allow latitude for CAM modalities to be used.

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

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

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

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

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

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

surance Program. States usually enhance the federally mandated benefits available under Medicaid and extend Medicaid coverage to the medically indigent.

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

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

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

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

D. The education and training of health care practitioners in CAM

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

Consumer testimony revealed that many people are reluctant to disclose their CAM use to their conventional health care providers whom they believe are not knowledgable about CAM or interested in CAM approaches to healing. This represents a potential health hazard because conventional practitioners often do not know that their patients may be taking dietary supplements or using CAM practices and products that may interact with medical treatments (Fugh-Berman, 2000; Office of Inspector General, 2001; Piscitelli et al., 2000), or perioperative care associated with anesthesia or surgical procedures (Ang-Lee, et al., 2001; Baede-van Dijk et al., 2000; Fugh-Berman, 2000).

Another issue that emerged during testimony was the need to educate CAM practi-

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

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

E. Coordinating and centralizing federal CAM efforts

The Commission heard testimony recommending a centralized process at the federal level to coordinate CAM activities to ensure optimal access to safe and effective CAM products, services, and modalities. The Commission will continue to consider a range of administrative options to promote this level of coordination, including the creation of a centralized federal office. The Office on Women's Health or the Office on Minority Health, both established within the Office of the Secretary for Health and Human Services, may provide useful models on which the Commission can develop an operational proposal. These Offices primarily serve to coordinate, support, and enhance ongoing and new federal efforts relevant to their missions at all levels of the federal sector. Thus, a centralized coordinating entity for CAM would neither preempt nor supplant those federal efforts already in place, particularly the research activities or agenda of the NIH's NCCAM. Nor would a new office supplant the responsibilities of regulatory agencies, such as the FDA amd FTC.

F. CAM in wellness, self-care, health promotion and disease prevention

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

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

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

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and disease prevention. Many feel that one of the most important and enduring contributions of CAM will be its emphasis on maintaining wellness and the important role of self-care.

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

III. CONCLUSION

The Commission continues to deliberate on all of the issues discussed in the interim progress report and others to comply fully with the Executive Order. The Commission continues to study working models from many sources, including those from other countries. The final report will provide detailed recommendations regarding the four topics identified in the Executive Order: (1) coordinating research on CAM; (2) providing access to and delivery of CAM practices and products; (3) developing and providing reliable information on CAM; and (4) educating all health care practitioners in CAM. The recommendations will reflect principles that guide good health care; promote sound scientific inquiry related to CAM; maximize access and delivery of safe and efficacious health care; and promote health and prevent illness by encouraging the well-being of the whole person. As the Commission develops final recommendations and proposals for legislative and administrative actions, it will continue to solicit and consider the advice of the public.

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