development at accredited CAM and conventional institutions could be achieved through Federally sponsored workshops and conferences.

The challenges facing efforts to increase support for CAM faculty, curricula, and program development at accredited CAM and conventional institutions include:

- Limited availability of funding in an era of diminishing resources and increased competition,
- Resistance from conventional health professions' organizations and institutions,
- Equitable identification and prioritization of appropriate recipients for funding, and
- The need for Federal legislation and appropriations to support such programs.

Action

10.4 Increased Federal, state, and private sector support should be made available to expand and evaluate CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

CAM Student Participation in Existing Loan and Scholarship Programs

CAM students, institutions, and professional organizations have expressed considerable interest in participating in loan and scholarship programs. Chiropractic students were eligible for participation in the Health Education Assistance Loan (HEAL) program,* the program has been phased out, and no initial loans are available. Chiropractic students at participating institutions now may be eligible for Stafford loans. Currently, the only CAM students eligible for the Scholarship for Disadvantaged Students (SDS) program are chiropractic students.** No CAM students are eligible for the National Health Service Corps (NHSC) scholarship program at this time,*** because it is limited to U.S. citizens enrolled in or accepted for enrollment in fully accredited U.S. allopathic or osteopathic medical schools, nurse practitioner programs, nurse-midwifery programs, physicians assistant programs, or dental schools. In other words, only students of a health profession that is named specifically in authorizing legislation can be awarded an NHSC scholarship.

The purpose of the NHSC scholarship program is to provide primary health care to underserved and vulnerable populations in rural and urban areas designated by the Federal government as health professions shortage areas. As a result of program requirements and limitations as well as other factors, NHSC, which recently was transferred within HRSA from the Bureau of Primary Health Care to

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* As authorized by the Public Health Service Act, Title VII, Section 705.

** As authorized by the Public Health Service Act, Title VII, Section 737.

*** As defined in the Public Health Service Act, Title III, Section 301.

BHPr, meets approximately 12-15 percent of the identified need for health care in underserved areas. Because of the enormous unmet need, especially for primary care, and the limited number of NHSC positions and funds available, the government's and medically underserved communities' clear preference for conventional health care providers should not be unexpected.

Any policy changes regarding CAM participation in Federal loan and scholarship programs would have to be mandated legislatively. Expansion of eligibility for loan programs administered by BHPr, such as Loans for Disadvantaged Students, Health Professions Student Loans, or Primary Care Loans, to CAM students would require, at a minimum, financial impact analyses by the Congressional Budget Office (CBO), determination of which CAM professions should participate, determination of which loan programs should be expanded, and amendment of the Public Health Service Act, Title VII. Since participation in these programs is based in part on financial need, only CAM students meeting the financial eligibility criteria would be eligible. Expansion of eligibility for the Stafford loan program administered by the Department of Education would have to be preceded by similar CBO evaluations, determination of which CAM professions should participate, and legislative changes. In addition, CAM institutions would have to be accredited by an approved accreditation agency, apply and be approved for participation in Title IV of the Higher Education Act student assistance program, and sign a participation agreement.

In general, expansion of Federal loan programs to CAM students appears easier than participation in the NHSC scholarship program. However, before considering any changes in NHSC policy or legislative, a number of critical aspects of CAM participation must be examined. Since the chief purpose of this program is not education, but the provision of health care to medically underserved and vulnerable populations, current participants must be able to provide the necessary health care services, which generally are described as or included as a component of primary care.

Section 330 of the Public Health Service Act defines primary care by delineating required community health center primary care services and 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.

The Department of Health and Human Services should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners enhance and/or expand health care provided by primary care teams. These primary care teams typically consists of family practitioners, internists, pediatricians, and obstetrician gynecologists as well as physicians assistants, nurse practitioners, nurse midwives, dentists, and mental health professionals. The feasibility study could be followed with demonstration projects to determine the type of practitioners, their education and training requirements, appropriate practice sites, minimal clinical competencies, and health outcomes attributable to the addition of these practitioners and services to comprehensive care. Then, the CBO should estimate the financial impact of CAM practitioner participation in these programs. Guidelines have been set for determining the number of a given type of conventional health care provider for a defined population size or geographic area (for example, an area that has a population to full-time-equivalent primary care physician ratio of at least 3,500 to 1), but not for CAM practitioners. Such guidelines would need to be developed for each type of CAM practitioners.

The challenges to expanding the eligibility of CAM students to participate in existing loan and scholarship programs include:

- A preference for conventional health care providers to fill the largely unmet need,
- Required changes in legislation 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.

Action

10.5 Expansion of eligibility of CAM students at accredited institutions for existing Federal loan programs should be explored.

10.6 The Department of Health and Human Services should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners enhance and/or expand health care provided by primary care teams.* This feasibility study could lead to demonstration projects to identify: 1) the type of practitioners, 2) their necessary education and training, 3) the appropriate practice settings, and 4) the health outcomes attributable to the addition of these practitioners and services to comprehensive care.

* Typically, these primary care teams consists of family practitioners, internists, pediatricians, and obstetrician gynecologists as well as physicians assistants, nurse practitioners, nurse midwives, dentists, and mental health professionals.

National Guidelines for CAM Educational and Training

Questions about national guidelines for CAM education and training are by no means unique to the United States. In Great Britain, the House of Lords Select Committee on Science and Technology considered a number of issues related to CAM education and training.[12] Despite the exceedingly complex mosaic of CAM practices, therapies, modalities, disciplines, and professions, the committee recommended that CAM training courses, whether for conventional health professionals or CAM professionals, should be made more uniform and should be accredited by appropriate professional bodies.

National standards for CAM education and training may not be attainable in the United States for a number of reasons. For example, each of the 50 States has varying educational requirements for licensure for a multiplicity of professions. In addition, a given CAM modality or therapy may involve numerous CAM and conventional disciplines; but there may be no agreement among or between disciplines on accreditation requirements, processes, or body for that particular modality or therapy.

In an attempt to provide some uniform guidance, the Federation of State Medical Boards' Special Committee for the Study of Unconventional Health Care Practices has begun to develop guidelines for the use of CAM. These guidelines address education, but they focus on the scientific basis of treatment methods without delineating any specific education or training requirements. Simultaneously, nascent efforts by physician organizations to standardize CAM education and training for allopathic and osteopathic physicians have emerged. The American Board of Holistic Medicine, for example, 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, the American Board of Medical Acupuncture has developed and administered a board certification examination.

Chiropractic has the most extensively developed and implemented national education and training standards of any CAM profession. Traditional Chinese acupuncture, therapeutic massage, and naturopathic medicine perhaps have moved closer than other CAM professions to establishing national education and training standards. Because of their progress, these CAM professions are appropriate candidates for conferences convened by DHHS and other Federal Departments and Agencies, although CAM professions and disciplines that are still in the process of developing standards should be included as well. Such conferences would assemble the leadership of CAM, conventional health, public

health, evolving health professions, and the public; educational institutions; and appropriate organizations to facilitate establishing CAM education and training guidelines. Subsequently, these guidelines would be made available to the states and professions for their consideration.
The challenges of establishing national CAM educational and training guidelines include:

- Their similarity to education and training requirements for licensure and therefore perceived encroachment on states' rights,
- Complexity-that is, the numerous disciplines or professions that may be associated with a given modality,
- Lack of educational standardization within professions,
- Absence of a clearly delineated scope of practice for each profession;
- Funding requirements, and
- Resistance from CAM and conventional professions and organizations.

Action

10.7 The Department of Health and Human Services and other Federal Departments and Agencies should convene conferences of the leaders of CAM, conventional health, public health, evolving health professions, and the public; of educational institutions; and of appropriate organizations to facilitate establishment of CAM education and training guidelines. Subsequently, the guidelines should be made available to the states and professions for their consideration.

Demonstration Projects of Postgraduate Training for Appropriately Educated and Trained CAM Practitioners

To improve education and training, the competency of practitioners, and the quality of services, CAM education and training should continue beyond the entry, professional school, or qualifying degree level. However, as previously noted, there are very few opportunities for postgraduate CAM education and training. Currently, the chiropractic profession appears to have the most extensive full-time postgraduate CAM education and training, offering residencies in radiology, orthopedics, family practice, and clinical sciences. A typical chiropractic residency program is two to three years in duration and includes outpatient care and inpatient clinical rotations at chiropractic and conventional medical facilities, along with classroom and research experiences.
Residencies in naturopathic medicine are less well developed. Postgraduate training has been in existence since 1979 and consists of a limited number of mainly one-year and some two-year residency programs with an emphasis on naturopathic family practice. Most of these residencies are based in outpatient clinics, some of which are affiliated with a hospital. Utah now requires at least a one-year residency for licensure of naturopathic physicians.

Before establishing new or expanding current CAM postgraduate education and training programs, appropriate CAM candidates for postgraduate education and training should be identified and the feasibility, type, duration, and impact of postgraduate education and training for these CAM practitioners should be determined. For example, should one-year postgraduate training programs be available for traditional Chinese acupuncturists or doctors of oriental medicine? Should three-year primary care or family practice residencies be available for naturopathic, Ayurvedic, or Tibetan medicine physicians?

The process of determining likely candidates could include demonstration projects of residencies and postgraduate training for appropriately educated and trained CAM practitioners. Federal Agencies and Departments such as NCCAM, BHPr, the Bureau of Primary Health Care, the Department of Defense, and the Department of Veterans Affairs could sponsor the projects. Because community health centers represent a unique opportunity 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, any current or proposed CAM postgraduate education and training program affiliated with such centers should be given special consideration.

Demonstration projects should be awarded on a competitive basis and funded with monies that are distinct from the current graduate medical education funding streams. In addition, projects should include funds for financial analyses and longitudinal studies to assess the types of CAM practitioner, feasibility of residencies and postgraduate training, competency-based educational effectiveness, impact on health care quality, and collaboration between CAM and conventional providers.

The challenges to establishing demonstration projects of residencies and postgraduate training in CAM for appropriately educated and trained CAM practitioners include:

- Determining which practitioners should participate in postgraduate education and training demonstration projects,
- Developing and applying selection criteria and processes,
- Funding, and
- Limited availability of a sufficient number of training sites, patients, and faculty.

Action

10.8 Feasibility studies of postgraduate training for appropriately educated and trained CAM practitioners should be conducted to determine the type of practitioners, practice setting, and their impact on clinical competency, quality of health care, and collaboration with conventional providers.

Continuing Education in CAM for All Practitioners Who Provide CAM Products and Services

Continuing education represents a powerful means of affecting conventional and CAM practitioners' behavior, thereby enhancing public health and safety. Britain's House of Lords affirmed the importance of continuing education for CAM practitioners.12 The Josiah Macy, Jr. Foundation Conference on Education of Health Professionals in Complementary/Alternative Medicine recommended that professional and educational health care associations include high-quality, evidenced-based CAM information in continuing education programs.5

There are more programs in CAM continuing education for conventional health professionals than for CAM practitioners. However, the number, type, and availability of programs with content appropriate for all practitioners who provide CAM services and products are not sufficient to enhance and protect the public's health and safety regarding CAM. Therefore, continuing education needs to be improved and made available to all conventional health professionals as well as all practitioners who provide CAM services and products.

Action

10.9 Practitioners who provide CAM services and products should complete appropriate CAM continuing education programs that include critical evaluation of CAM to enhance and protect the public's health and safety.

REFERENCES:

1 Berman B. Complementary medicine and medical education. British Medical Journal. 2001;322:121-122.

2 Wetzel MS, Eisenberg DM, Kaptchuk TJ. Courses involving complementary and alternative medicine at US medical schools. Journal of the American Medical Association. 1998;280:784-787.

3 Chez RA, Jonas WB, Crawford C. A survey of medical students' opinions about complementary and alternative medicine. American Journal of Obstetrics and Gynecology. 2001;185:754-757.

4 Bhattacharya B. M.D. programs in the United States with complementary and alternative medicine education opportunities: An ongoing listing. The Journal of Alternative and Complementary Medicine. 2000;6:77-90.

5 Chairman's Summary of the Conference, Education of Health Professionals in Complementary/Alternative Medicine, Josiah Macy, Jr. Foundation, 44 east 64th Street, New York, NY 10021 Grollman AP. Is

there wheat among the chaff? Academic Medicine. 2001;76:221-223.

6 Marcus DM. How should alternative medicine be taught to medical students and physicians? Academic Medicine. 2001;76:224-229.

7 Sampson W. The need for educational reform in teaching about alternative therapies. Academic Medicine. 2001;76:248-250.

8 Gaudet TW. Integrative medicine: The evolution of a new approach to medicine and medical education. Integrative Medicine. 1998;1:67-37.

9 Kligler B, Gordon A, Stuart M, Sierpina V. Suggested curriculum guidelines on complementary and alternative medicine: Recommendations of the society of teachers of family medicine group on alternative medicine. Family Medicine. 1999;31:30-33.

10 Caspi O, Iris RB, Rychener D, Gaudet TW, Weil AT. The tower of Babel: Communication and medicine. Archives of Internal Medicine. 2000;160:3193-3195.

11 House of Lords Select Committee on Science and Technology. Sixth Report: Complementary and Alternative Medicine, 21 November 2000, Chapter 6: Professional Training and Education.

Table 1. CAM Topics Included in Required or Elective Courses at Medical Schools Accredited by the Liaison Committee on Medical Education.

Medical Schools Covering Topics

Topics	Required Course Only	Elective Course Only	Both
Acupuncture	18	54	28
Herbal medicine	28	45	33
Homeopathy	17	48	18
Meditation	13	53	17
Manual healing techniques	15	50	11
Nutritional supplement therapy	30	42	36
Spirituality	25	43	35

Source: 2000-2001 Liaison Committee on Medical Education Annual Medical School Questionnaire.

Chapter 5: CAM Information Development and Dissemination

One of society's greatest achievements - and one of its greatest challenges - has been the dramatic improvement in the development and dissemination of information. Over the past several decades, new technologies have enabled people all over to world to gain rapid access to information. Not only does information travel faster, significantly more of it has become available in the United States because of increased population, higher educational levels, and changes in the workforce and economic structure. This is especially true of health information, including information about complementary and alternative medicine (CAM).

In a desire for improved quality and length of life, the public has sought increased information on healing systems, practices, and products from other cultures and healing traditions. Many Americans use these in the context in which they were originally developed. Others have borrowed practices and products from these systems and adapted, changed, or used them in ways that are very different from their original design or intent. New therapies, practices, and products that lie outside the conventional health care system have also been developed. All of these fall under the rubric of CAM, and people have both benefited and suffered from information about their usage, benefits, safety, and effectiveness.

To ensure public safety in the continually evolving area of CAM, accurate information must be available so that people can make informed choices. This includes choosing the most appropriate type of practitioner, deciding what type of approach can benefit certain conditions, ascertaining the ingredients in a product (such as a dietary supplement), and determining whether ingredients are safe and can assist in maintaining health. Yet far too often information to help make these choices is nonexistent, inaccurate, or difficult to find.

The ready availability of accurate information is especially important to people who are confronting a life-threatening illness. For someone newly diagnosed with a serious or life-threatening illness, seeking information about the disease and treatment options is often their first course of action. Many people quickly become overwhelmed by the vast array of often-conflicting information that is available, and yet for some diseases and conditions, there is a scarcity of information. Getting accurate and useful information should not be an additional burden during this difficult time.

To be effective, information must be tailored to the population it seeks to reach. People of different cultural, ethnic, and socio-economic backgrounds often have different views of health and healing, different patterns of use of health care services and products, and different ways of acquiring information. People's views and behavior also vary with their age, literacy, and specific health

conditions. Informational materials need to reflect the characteristics and behavior of the target population in content, style, language, and format.

The Internet has given people access to vast amounts of health care information that would not have been available to them previously. Along with the advantages of being able to find information on virtually any topic quickly, the Internet presents concerns about quality, particularly in regards to CAM information. People may be making life-and-death decisions based on information from the Internet that may be misleading, incomplete, or inaccurate. This is particularly true in the case of CAM, for which a significant amount of evidence-based material is not yet available. As people become more interested in CAM and explore the Internet looking for information about its usefulness, efforts should be made to ensure that they have access to the most reliable information possible.

Other avenues of finding information about CAM are also important. The Federal government is one of the largest developers of health information, and efforts should be made to expand its coordination of existing CAM resources. Public libraries are an important source of information in many communities. Training librarians in how to find information on CAM would help people navigate through the maze of available resources.

Advertising and marketing are another means through which people learn about CAM products and services. Although only a small percentage of the approximately $200 billion spent yearly on advertising [1] is for CAM products and services, that percentage nonetheless is significant. The vast majority of advertisers of CAM products and services comply with current laws, yet misleading and fraudulent health claims exist and are cause for great concern.

Some people, particularly those who are ill, have limited language or educational skills, or lack access to the conventional health care system, are especially susceptible to advertisements that promise to cure a disease, symptom, or problem. Not only are some of these products, services, and treatments ineffective, some may even be harmful, especially if they delay necessary treatment or take money away from those with limited resources. Efforts to enforce existing laws curbing such abuses should be increased.

One of the fastest growing areas in CAM has been dietary supplements. Sales of these products totaled $17 billion in 2000 [2], and more than 158 million consumers used them [3]. Because they are classified as dietary supplements, these products are not subject to the rigorous testing and oversight required of prescription drugs, which are targeted toward disease conditions. For this reason, complete and accurate labeling and package insert information on ingredients and on potential benefits and risks is essential. The current system does not make such information easily available to consumers.

The use of CAM practices and products is a growing part of the American lifestyle. As CAM continues to grow and evolve, the development and dissemination of accurate, complete, and useful information on products, practices, and practitioners will be one of the most important mechanisms for ensuring the public's safety.

Availability of Reliable, Useful, and Accessible Information for the Public on CAM Practices and Products

CAM Information from the Federal Government

Consumers, health professionals, and the media often look to the Federal government for reliable and authoritative information on a wide range of health topics. The government produces thousands of fact sheets, reports, pamphlets, posters, books, and other materials that provide useful, accurate information on specific diseases, health care delivery services, research findings, and other health care topics. Information is also available though various government Internet sites and toll-free numbers, many of which are associated with a clearinghouse.

The National Center for Complementary and Alternative Medicine (NCCAM), located in the National Institutes of Health (NIH), has a congressional mandate to "establish a clearinghouse to exchange information with the public" about CAM [4]. The clearinghouse has a toll-free telephone number and provides fact sheets, information packages, and publications on CAM research and NCCAM activities. Consumers and health care professionals can also obtain CAM- related information from NIH's National Cancer Institute and the Office of Dietary Supplements. The Food and Drug Administration's (FDA) Center for Food, Safety, and Applied Nutrition has a website with information on dietary supplements. Other government entities, such as the Department of Agriculture and the Federal Trade Commission (FTC), also have information related to specific CAM topics.

Despite these resources, information on CAM from the Federal government is inconsistently available and often difficult to locate. For a variety of reasons, including limited awareness or acceptance of CAM by Federal staff or leadership, lack of agency policy on the inclusion of CAM information, and limited availability of research on many of the CAM products and services people are using, government agencies with oversight responsibilities for various aspects of health care often do not include any information on CAM in their materials. This has resulted in significant gaps in information on diseases, health conditions, practitioners, and products. Existing materials should be reviewed and, where appropriate, CAM information should be added and new materials developed.

Even when high-quality, comprehensive information on CAM is available from the Federal government, it is often difficult for the public to navigate the system and locate the desired information in a timely manner. Greater efforts should be made to promote the use of the Firstgov.gov search engine, an easy-to-use government-wide search engine. For people who do not use the Internet, a centralized, toll-free telephone number would help direct callers to the appropriate department or agency to answer their questions. Consumers, health care practitioners, the media, and other members of the public have expressed a desire for a centralized place in the Federal government to get objective, comprehensive information on CAM quickly.

CAM Information From Public Libraries

Many people, especially elderly and low-income people, do not have access to the Internet or do not know how to use a computer to get CAM information on the Internet. People without access to the Internet at home or at work often use publicly available resources - such as libraries - to find information. Public libraries exist in most communities and are a source of Internet access and guidance. However, many librarians lack training in how to find reliable information about CAM on the Internet. They may also be unaware of other sources of information on CAM such as books, periodicals, and newsletters. The National Library of Medicine has begun working directly with public libraries through the American Library Association to train local librarians in how to use the Internet to find health information. This effort should be expanded to include more training and focus on how to find information about CAM, both on the Internet and in other resources.

The Role of Public and Private Organizations in Developing and Disseminating Information about CAM

Differences in how people find and use information are an important consideration in the development, distribution, and evaluation of information about CAM. According to the most recent National Adult Literacy Survey, 48 percent of U.S. adults, or close to 100 million people, have very limited literacy because they lack English skills, have reading disabilities, or lack sufficient education [5]. In addition to varying literacy skills, differences in how information is located and used can exist among men and women, people in different age or income groups, and people with different racial, ethnic, and cultural backgrounds.

Health information materials (print, radio, television, or other media) are often targeted toward specific audiences, particularly populations at higher risk of developing a particular disease or condition or those with a higher propensity for using a particular practice or product. Materials may be produced in different languages, and the content, illustrations, and style may be altered to reach the intended population.

Currently available demographic data do not provide adequate information about CAM usage among various population subgroups or the range of methods and patterns in accessing CAM information. However, it is known that the use of CAM varies significantly by racial, ethnic, and cultural background, age group, health status, income, and literacy. CAM materials should be developed for each of these specific groups.

Some populations are particularly susceptible to advertisements of CAM products such as herbs, tonics, and vitamins that have not been shown to be effective or that, in some cases, are even harmful. These populations may also be vulnerable to the fraudulent claims of services that promise to cure disease and treat health care problems not addressed through the conventional health care system. The involvement of trusted community leaders is essential to any effort to educate vulnerable consumers and develop strategies to prevent them from being targeted by marketing of unnecessary, harmful, exorbitantly priced, or otherwise detrimental products.

CAM Information from Other Countries

Lack of information on the effectiveness of CAM therapies is often cited as the reason for not providing them or reimbursing consumers for them. However, a potentially significant amount of high-quality CAM information has been published in other countries but is not available in English or in the United States. As globalization of information increases, the research, findings, and experiences of people in other countries can provide valuable information on the safety and efficacy of CAM. Identifying and analyzing studies published in languages other than English requires expertise in both languages and science. Greater efforts should be made to make these resources available.

Recommendation 11: The Federal government should make available accurate, useful, and easily accessible information on CAM practices and products, including information on safety and effectiveness.

Actions

11.1 The Secretary of Health and Human Services should establish a task force to facilitate the development and dissemination of CAM information within the Federal government and to eliminate existing gaps in CAM information. The task force should include consumers, CAM providers, scientists, and conventional health care practitioners. Resources should subsequently be provided to close identified gaps and improve the availability, coordination, and dissemination of information.

11.2 Federal Departments and agencies with missions or activities relevant to CAM should 1) develop informational materials about CAM that are easy to understand and use, and 2) support and collaborate with national and

local community leaders and CAM leaders and organizations to identify strategies for enhancing the development, availability, and accessibility of information on the safety and effectiveness of CAM practices and products.

11.3 Increased funding should be provided to the National Library of Medicine and the American Library Association to expand training of librarians to include helping consumers find information on CAM.

11.4 The Secretary of Health and Human Services should direct resources to streamline the process of identifying and making available relevant, high-quality CAM information from other countries and in other languages.

Quality and Accuracy of CAM Information on the Internet

The Internet has emerged as a major source of information about health care, including information related to CAM, for both consumers and providers. According to the most recent estimates by the U.S. Census Bureau, over half of all households in the United States have computers, 90 percent of all children age 6 to 17 have access to computers through their home or school, and 42 percent of all households can log onto the Internet [6]. An estimated 60 million U.S. adults used it to obtain health-related information last year [7]. Most Internet sites are general health information sites that include CAM information, but some sites are specific to CAM.

The quality, accuracy, accessibility, and timeliness of Internet information vary greatly. Some sites provide accurate, up-to-date information, while many others contain information that is inaccurate, misleading, or outdated. The ability to ensure the quality of information on the Internet is extremely limited, both because of the nature of the technology and the First Amendment's protection of free speech.

Several organizations have developed standards on ethics-related issues such as privacy and financial sponsorship of health sites on the Internet. However, some of these same organizations have developed websites that have been cited as having problems with quality, accuracy, accessibility, or timeliness of CAM-related information. Some do not have any qualified CAM practitioners on their review boards, and the standards do not appear to have had much impact on the quality of information on these Internet health sites.

Public-private partnerships that include industry groups, consumers, and governments have been successful in developing guidelines and establishing standards for many products and services. Examples include the World Wide Web Consortium, a group of more than 500 public and private organizations that have developed guidelines to make web content accessible to people with

disabilities, and the Healthy People Consortium, composed of hundreds of public and private organizations that have developed objectives for the Nation's health. The government can play an important role in bringing key people together to develop voluntary, non-binding guidelines that will assist industry in setting minimum standards for quality, accuracy, accessibility, and timeliness of CAM-related information on the Internet.

Regardless of efforts to develop standards and ensure quality, consumers will always need to evaluate and validate information they receive from the Internet. Public education in using the Internet as a source of health information can help individuals search for knowledge and make decisions about their health. Internet users are concerned not only about the quality and accuracy of the information they are getting, but also about the information they may unwittingly be giving out. In a recent study, 85 percent of people seeking health information on the Internet said they are concerned about their employer or health insurance company tracking their site visits and using that information to change their insurance status or rates [7].

Unfortunately, privacy protections for people seeking health information on the Internet are limited. The Health Insurance Portability and Accountability Act of 1996 protects the privacy of consumer information collected by health plans, health care clearinghouses, and health care providers conducting electronic transactions, but it does not protect consumers seeking health information on the Internet. In 1998, Congress enacted the Children's Online Privacy Protection Act, which prevents the collection of personally identifiable information from young children without their parents' consent. The FTC has filed four civil penalty actions this year to enforce the act, and additional cases are under investigation. Congress should take steps to expand privacy protection for health information seekers on the Internet.

Recommendation 12: The quality and accuracy of CAM information on the Internet should be improved by establishing a voluntary standards board, a public education campaign, and actions to protect consumers' privacy.

Actions

12.1 The Secretary of Health and Human Services should form a public-private partnership to review new and existing websites and to develop voluntary standards promoting accuracy, fairness, comprehensiveness, and timeliness of information on CAM web sites, as well as the disclosure of sources of support and possible conflicts of interest. Sites reviewed and found in compliance with the standards could publicize the fact and display a logo denoting their merit.

12.2 Funding should be provided to the Department of Health and Human Services and the Department of Education to conduct a joint public education campaign that teaches consumers how to evaluate health care

information, including CAM information, on the Internet and elsewhere.

12.3 Congress should protect consumers' privacy by requiring all health information sites, including CAM sites, to disclose whether they track users and if so, how that information is used and stored, including whether it is sold to third parties.

Availability of Information on the Training and Education of Providers of CAM Health Services to Enhance Consumer Knowledge and Choice

Training, licensing requirements, certification, scope of practice, regulations, and even definitions of CAM practitioners can vary considerably. For example, traditional or lay naturopaths and naturopathic physicians have significantly different levels and types of training, yet most consumers are unaware of the difference. In some states, acupuncture can be practiced by professional acupuncturists who have spent several years in training or by practitioners of another health modality (e.g., a physician, dentist, podiatrist, physical therapist, or chiropractor) with less, limited, or no additional training or experience in acupuncture. Herbalists may have years of informal training and experience or no formal training and little experience. The situation is further complicated by state variations in licensing requirements and scope-of-practice regulations.

Navigating the maze of titles and certificates among the various types of practitioners is a challenge for consumers, most of whom are unfamiliar with the nuances of these professions. Information on a practitioner's qualifications should be readily available to help consumers make informed choices in their selection and use of a practitioner. Information on state regulations, requirements, and disciplinary actions should be readily available to help ensure consumers' safety.

CAM practitioners without any formal training may be reluctant to make that fact known. Moreover, consumers may not be able to distinguish between a degree or certificate obtained from an accredited organization and a degree or certificate purchased from an organization with no requirement that students meet appropriate educational standards. However, disclosure of such information will help consumers evaluate the qualifications of practitioners and make informed choices. In addition to practitioners, people such as vendors, retailers, and multi-level marketers of CAM products should disclose their qualifications for providing health-related information.

Recommendation 13: Information on the training and education of providers of CAM services should be made easily available to the public.

Actions

13.1 The Commission recommends that states require all persons providing CAM services to disclose information regarding their level and scope of training and to make it easily available to consumers.

13.2 The Commission recommends that states disclose information on state guidelines, requirements, licensure, certification, and disciplinary actions of health providers, including CAM providers, and make it easily accessible to the public.

Availability of CAM Products That Are Safe and Meet Appropriate Standards of Quality and Consistency

The availability and use of dietary supplements in the United States has grown significantly in the past several years. As a result, public interest in the safety and effectiveness of dietary supplements has also increased. Because they are regulated as foods rather than drugs, dietary supplements are regarded - from a regulatory perspective - as generally safe for human consumption. Yet problems with the composition and purity of some of these products have been reported and raise questions about their safety.

Some dietary supplements do not contain the ingredients or the amount of the ingredients declared on the label. For example, in laboratory testing of 25 separate Echinacea products, only 14 (56 percent) were found to have the amount and type of Echinacea and polyphenol (or marker compound) claimed on the label [8]. Testing of 13 SAMe (S-adenosyl-L-methionine) products showed that 5 had less than half the amount listed on the label and 1 had no detectable level at all [9]. An analysis of 25 ginseng products showed substantial variability in the concentration of marker compounds [10].

Some herbal preparations contain ingredients other than those listed on the label, including undeclared pharmaceuticals. Herbal products claiming to contain only natural ingredients were found to contain the prescription drugs glyburide and phenformin, which are used to treat diabetes [11]. Two other herbal products were found to contain warfarin and alprazolam, prescription drugs that can cause serious health effects if not taken under medical supervision[12]. Dietary supplements have been found to be contaminated with heavy metals, microorganisms, and pesticides, and toxic levels of mercury have been reported in some imported herbal products [13]. In April and May 2001, two manufacturers recalled several products as a result of Salmonella contamination [14].

Public concern with dietary supplements includes not only possible contamination and adulteration, but also active ingredients that may be toxic or cause unwanted side effects. For example, aristolochic acid, a naturally occurring

compound associated with cancer and renal failure, has been found in several herbal products, prompting a nationwide recall of products containing this substance[15]. Certain pyrrolizidine alkaloids, which are found in numerous plants used medicinally around the world, have been found to be harmful to the liver [16].

Such examples raise questions about whether current regulations are adequate to ensure the safety of dietary supplements and whether regulatory agencies can respond quickly when a problem is identified. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, a manufacturer is responsible for determining that the dietary supplements it produces or distributes are safe and that its claims are substantiated by adequate scientific evidence. However, DSHEA does not require manufacturers to disclose the source of the information they used to determine the safety of their products. The failure to require safety data weakens the current regulatory system, making it unable to provide consumers with sufficient and scientifically valid information.

Even though dietary supplements are regulated as foods, which are subject to the standards of Good Manufacturing Practices (GMP), DSHEA encouraged the FDA to develop separate GMPs for dietary supplements. The process of development has been an effective collaboration between many members of the dietary supplement industry and the Federal government. Implementation of GMPs for dietary supplements will help ensure the identity, purity, quality, strength and composition of these products. Formal publication and implementation of the GMPs are pending.

While implementation of GMPs for dietary supplements will address domestically produced products, finished products imported from some other countries may not meet these standards or the standards of responsible manufacturers. Such products may find their way into commerce. Appropriate government entities should work with manufacturers and importers to improve the monitoring of imported dietary supplements and prevent naturally or accidentally contaminated or adulterated products from entering the United States. Cooperation with appropriate international organizations should be encouraged in order to establish standards of quality for the ingredients in dietary supplements. These standards should include preventing the exploitation of endangered animal and plant species for the manufacture of dietary supplement products.

Since the passage of DSHEA in 1994, many new dietary supplements have been introduced into the United States. For many of these supplements, particularly botanicals, validated analytical methods have not been developed. Moreover, different analytic methods are used by different manufacturers, leading to varying test results regarding concentrations of active ingredients or other marker compounds.

Government, industry, and scientific organizations have begun developing analytical methods for botanicals and other dietary supplements so that

consensus can be reached regarding the chemical and physical standards for composition and quality. These efforts need to be accelerated. Congress has included language in the fiscal 2002 appropriation bill for the Department of Health and Human Services in support of the development of standards, and the Commission recommends that this progress be continued.
A framework for reviewing data on the safety of ingredients in dietary supplements is being developed by the Institute of Medicine. While this is an important step that will assist in improving the safety of specific ingredients of dietary supplements, the Commission believes that an independent review process is needed to evaluate the safety of dietary supplements, many of which contain multiple ingredients that can interact with drugs, foods, and other ingested products. An external review process was recommended by the Presidential Commission on Dietary Supplement Labels in 1997 [17] and more recently by a scientific conference [18]. Continuous, enhanced cooperation between government and industry is needed to make certain that dietary supplements are safe.

Recommendation 14: CAM products that are available to U.S. consumers should be safe and meet appropriate standards of quality and consistency.

Actions

14.1 The efforts of both the public and private sectors to ensure the development, validation, and dissemination of analytical methods and reference materials for dietary supplements should be accelerated.

14.2 The proposed Good Manufacturing Practices for Dietary Supplements should be published expeditiously, followed by a timely review of comments and completion of a final rule. The Food and Drug Administration should be provided with adequate resources to complete this task.

14.3 Adequate funding should be provided to appropriate Federal agencies, including U.S. Customs and Food and Drug Administration inspection authorities, to enforce current laws monitoring the quality of imported raw materials and finished products intended for use as dietary supplements.

14.4 Manufacturers should have on file and make available to the FDA upon request scientific information to substantiate their determinations of safety, and current statutory provisions should be periodically reexamined to determine whether safety requirements for dietary supplements are adequate.

14.5 An objective process for evaluating the safety of dietary supplement products should be developed by an independent expert panel.

Availability of Accurate Information on Potential Benefits, Risks, and Appropriate Use of Dietary Supplements and Other CAM Products

The regulation of products such as foods, drugs, vitamins, minerals, and botanicals is determined by the intended use of the product, and the label must conform to the laws and regulations governing the product's intended use. Thus, the same product can be marketed as a prescription drug, dietary supplement, or food, depending on the manufacturer's statements regarding the product's intended use.

Any product that claims to diagnose, prevent, mitigate, treat, or cure a disorder must be approved as a drug by the FDA; otherwise, such claims cannot be included on the label. Statements that a nutrient will reduce the risk of disease, such as "diets high in calcium may reduce the risk of osteoporosis" or "diets low in sodium may reduce the risk of high blood pressure" are known as health claims and must be approved under the provisions of the Nutrition Labeling and Education Act of 1990. This act applies to dietary supplements as well as conventional foods and it allows health claims to be made only after extensive FDA review of the scientific literature, using the "significant scientific agreement" standard to determine that the nutrient - disease relationship is well established.

Recent Federal legislation allows a product to claim a health benefit if the manufacturer provides evidence of an "authoritative statement" from a Federal agency or scientific organization such as the National Academy of Sciences. However, claims about treating, preventing, curing, or mitigating diseases are reserved only for drugs. Dietary supplements may make claims related to structure and function of the body, such as "improves immune function," or make no claim at all on the label.

Not having to undergo approval as drugs has greatly increased the accessibility of dietary supplements to the public, yet it has limited the availability of label information on potential risks, benefits, and appropriate use. For example, because it is distributed as a dietary supplement, glucosamine sulfate (2-amino-2-deoxyglucose), which has been shown in numerous scientific studies published in peer-reviewed journals to be effective in treating osteoarthritis [19], can claim only that it helps to maintain joint health. Likewise, numerous scientific studies, a monograph by the U.S. Pharmacopeia, and a meta-analysis published in the Journal of the American Medical Association show that Saw palmetto (Serenoa repens) is an effective treatment for benign prostatic hyperplasia [20]. This information cannot be included on the label because dietary supplements are limited to structure-function claims.

Manufacturers of products such as these have no incentive to petition the FDA for a health or drug claim because the products are not patentable and the manufacturers are therefore unlikely to recover the cost of additional research to

support the claim. This situation also acts as a deterrent to investment in research on risks, benefits, and appropriate conditions of use. Yet, even when such information is known, manufacturers are limited by current regulations as to what they can claim.

When information about substantial, documented risks does becomes available, as in the case of the potential interaction between St. John's Wort (Hypericum perforatum) and certain prescription drugs [21], it should be included on the label of both the prescription drug and the dietary supplement. Labels should provide information about significant interactions with prescription or over-the-counter drugs, foods, or other health products, as well as information about likely, significant risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

Under current law, which holds the manufacturer responsible for ensuring the safety of products before marketing, the provision of such information is primarily the responsibility of the manufacturer. As with labeling for all products covered by the Federal Food, Drug, and Cosmetic Act, dietary supplement labels must include all facts that are material in light of consequences (such as potential risks and interactions) that may result from use of the product or representations made about it [22]. However, some manufacturers believe that insufficient scientific evidence is a justification for not informing the FDA of a potential problem. Greater emphasis should be placed on this important responsibility of manufacturers.

The public expects that products sold in the United States have been deemed safe. Most people are unaware of the complexities and implications of existing regulatory guidelines or recent court decisions that have upheld the right of commercial free speech in the advertising and labeling of dietary supplements. Since many dietary supplements are purchased without the knowledge or advice of an appropriately trained and credentialed provider, information on benefits, appropriate use, and potential risks should be made easily available to consumers at the time of purchase.

Although product labeling is of primary importance, labels have only limited space for information. Other options such as package inserts and point-of-sale information should be considered to ensure that consumers receive all pertinent information.

Some imported products have labels with information in a language other than English. Current regulations requiring information on labels to be in English should be enforced. This does not preclude another language from being used also, but it does ensure that the majority of consumers, providers, and regulators can understand the information.

Because the use of dietary supplements has grown so dramatically since the enactment of DSHEA, Federal and State regulatory agencies need more well-trained, highly skilled professionals with expertise in dietary supplements to safeguard the public. Expert staff are needed, particularly in the rapidly evolving area of botanicals, to help develop mutually supportive relationships between regulatory agencies and industry, thus engendering consumer confidence. Providing accurate information to consumers on CAM products is a complex technical, legal, and regulatory matter that requires ongoing participation by and consultation with the public.

Recommendation 15: Provisions of the Federal Food, Drug, and Cosmetic Act, as modified by the Dietary Supplement Health and Education Act of 1994, should be fully implemented, funded, enforced, and evaluated.

Actions

15.1 The Food and Drug Administration and other agencies with regulatory responsibilities should be provided with additional resources to 1) enforce the Dietary Supplement Health and Education Act's regulations regarding labeling of dietary supplements, 2) enforce current provisions requiring that dietary supplements be labeled in English, even if the same information is also included in another language, and 3) employ additional professionals with expertise in dietary supplements.

15.2 Current provisions requiring disclosure of material facts by manufacturers of CAM products should be enforced, and manufacturers should meet their responsibility to disclose material facts on the label, package, and/or package insert, so that the public will have information about known risks and well-documented significant interactions. Information on potential benefits of dietary supplements should also be made easily available at the time of purchase.

15.3 Congress should periodically evaluate the effectiveness, limitations, and enforcement of

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The Dietary Supplement Health and Education Act of 1994, including its impact on public health, and take appropriate action to ensure the public's safety.

Advertising of Dietary Supplements and Other CAM Practices and Products

The FTC is responsible for ensuring that advertising is truthful, not misleading, and substantiated so that consumers can make informed decisions about the products being marketed. The FTC does this by enforcing laws that prohibit unfair or deceptive acts or practices in print and broadcast advertisements (including the Internet), catalogs, and similar direct-marketing materials.

Since the passage of DSHEA, the FTC has placed increased emphasis on monitoring the advertising of dietary supplements. More than 1,500 businesses in the United States manufacture dietary supplements [23] and an estimated $700 million was spent by these companies in 2000 to advertise their products on television and in print [24]. Almost $192 billion was spent on direct marketing of all health care products in 2000, including mail, catalogs, teleservices, and the Internet. This marketing is estimated to have generated $1.7 trillion in sales [25]. To help the dietary supplement industry conform to its standards of truthful and not misleading advertising, the FTC has produced a guide that provides detailed explanations and descriptions of acceptable statements [26]. Still, abuses have been identified, particularly on the Internet and in direct-mail advertising materials. Deceptive advertising by this small segment of the industry can not only hurt consumers, but also cause manufacturers and distributors that comply with current anti-deception and substantiation standards to lose market share and suffer financially.

Deceptive advertising comes in many forms. Some advertisements promise to treat or cure a disease or condition without scientific backing for the claim. Others claim to slow or reverse the aging process and increase longevity, energy, memory, and sexual function. Although some products may be beneficial for such conditions, others have no effect. In some cases, these products cause serious unintended effects, ranging from the consequences of delayed treatment to interactions with prescription drugs to increased risk of developing other conditions.

A recent Government Accounting Office (GAO) report and Senate hearing [27] highlighted the potential for physical and economic harm posed by certain dietary supplements marketed and advertised as anti-aging therapies. In addition to the potential medical consequences of these supplements, the GAO reports, 20 companies marketing the products have been targeted by law enforcement agencies and have cost consumers approximately $36 million [28].

Because of the proliferation of health fraud on the Internet, the FTC has established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims. Although Operation Cure.all is not aimed specifically at CAM- related sites, many of the fraudulent claims uncovered by the program are for CAM products and services to cure cancer, AIDS, and other chronic diseases. Although the FTC has identified hundreds of Internet sites with questionable or clearly fraudulent health claims and has sent out e-mail advisories to more than 500 of them, the agency has brought formal action against only 16 since 1997.

In addition to the Internet cases, the FTC has brought 40 enforcement actions since 1997 against companies for deceptive marketing of dietary supplements in other media, including radio, television, newspapers, magazines and direct mail.

The advertising challenged by the FTC promoted products for such conditions as attention deficit-hyperactivity disorder, colds and allergies, impotence, diabetes, vascular diseases, and obesity.

Current FTC efforts should be significantly expanded to decrease the amount of false or deceptive advertising, to solicit public comments on CAM advertising, and to expand the use of CAM experts in the process of examining advertisements.

Recommendation 16: Activities to ensure that advertising of dietary supplements and other CAM practices and products is truthful and not misleading should be increased.

16.1 Congress should provide additional support to the Federal Trade Commission to 1) expand efforts to identify false and deceptive advertising of CAM-related health services and products and take appropriate enforcement action when necessary, 2) use appropriate CAM experts in the process of examination of CAM-related advertising, 3) increase activities to help consumers distinguish useful and reliable information from deceptive and unsubstantiated advertising in all forms of marketing and advertising, including at the point of purchase; and 4) seek additional public comment on the benefits and potential problems in the advertising of CAM-related services and products.

Collection and Dissemination of Information on Adverse Events Stemming from the Use of Dietary Supplements

Most dietary supplements are likely to be safe for human consumption, yet, as with any biologically active substance, adverse events can and do occur. The rigorous pre-market testing and review process required for pharmaceuticals is not required for dietary supplements. Therefore, monitoring of adverse events after supplements reach the market is critical to understanding their effects and interactions and to responding quickly when problems do occur.

The FDA uses the Adverse Events Reporting system to identify emerging problems with specific products and general trends in illness and death related to dietary supplements. However, reporting is voluntary - manufacturers and distributors are not required to notify the FDA of adverse reactions that are reported to them. In April 2001, the Inspector General of the Department of Health and Human Services issued a report calling adverse event reporting for dietary supplements "an inadequate safety valve" [29]. The report identifies the limitations of the Adverse Events Reporting system in detecting serious adverse events and recommends ways of improving it.

Serious adverse events (as defined under Medwatch and the FDA's Standard Operating Procedures of 1999) related to dietary supplements need to be identified and, when necessary, contained in a timely manner to prevent unnecessary illness and death. Since manufacturers are not required to register themselves or their supplements with the FDA before producing or selling them, a potentially dangerous situation could be extremely difficult to contain. Manufacturers and suppliers should be required to register their products with the FDA so that the agency can quickly notify other manufacturers and suppliers and the public when a serious adverse event occurs. In addition, information from poison control centers needs to be linked with the Adverse Events Reporting system.

Recommendation 17: The collection and dissemination of information about adverse events stemming from the use of dietary supplements should be improved.

Actions

Congress should require dietary supplement manufacturers and suppliers to register with t the Food and Drug Administration, and the agency should encourage voluntary registration until such a requirement is in effect, so that manufacturers, suppliers, and consumers can be promptly notified if a serious adverse event is identified.

17.1 Recent congressional support for improving the Food and Drug Administration's adverse events reporting system should be enhanced by requiring dietary supplement manufacturers and suppliers to maintain records and report serious adverse events to the agency.

17.2 Additional resources and support should be provided to 1) the Food and Drug Administration to simplify the adverse events reporting system for dietary supplements, and to streamline the database for timely review and follow-up on received reports; and 2) the Food and Drug Administration, the Centers for Disease Control and Prevention, and other appropriate Federal agencies to increase outreach activities to consumers, health professionals (including poison control centers, emergency room physicians, CAM practitioners, and mid-level marketers) in order to improve both manufacturers' and the public's awareness of and participation in voluntary event reporting.

References

1 Coen Robert, The Insider's Report, Universal McCann, Dec 3, 2001. http://www.mccann.com/insight/bobcoen.html.

2 U.S. Dietary Supplements Market Size Expressed as Dollar Sales by Top Six Product Categories for 1994 to 1998 and Forecast for 1999 and 2000", National Business Journal, 2000, Dialog file No. 93, San Francisco: The Dialog Corporation, 2000.

3 Survey of Consumer Use of Dietary Supplements, Prevention Magazine. Emmaus, Pennsylvania. 2000, p1-79.

4 P.L. 105 - 825, "Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year, 1999" Conference Report.

5 U.S.Department of Education, National Center for Educational Statistics. Adult Literacy and Education in America: Four Studies Based on the National Adult Literacy Survey, NCES 1999-469, U.S. Department of Education, National Center for Education Statistics, 2001. NCES 2001-534. 288p.

6 Newburger, EC, Current Population Reports: Home Computer s and Internet Use in the United States: August 2000. Census Bureau Report P23-207, September 2001.

7 Fox, S. and Raine, L. The Online Health Care Revolution: How the Web Helps Americans Take Better Care of Themselves. Washington DC: Pew Charitable Trusts; 2000.

8 Product Review: Echinacea, http://www.ConsumerLab.com, LLC, 2001.

9 Product Review: SAMe, http://www.ConsumerLab.com, LLC, 2000.

10 Harkey MR, Henderson GL, Gershwin ME, Stern JS, Hackman RM. Variability in commercial ginseng products: an analysis of 25 preparations. American Journal of Clinical Nutrition 2001, 73 (6):1101-1106.

11 California Department of Health Services, State Health Director Warns Consumers About Prescription Drugs in Herbal Products, February 2000. http://www.fda.gov/oc/po/firmrecalls/Herbal.html.

12 FDA Medwatch, February 2002. http://www.fda.gov/medwatch/SAFETY/2002/safety02.html.

13 Huggett DB, Khan IA, Allgood JC, Block DS, Schlenk D. Organochlorine Pesticides and Metals in Select Botanical Dietary Supplements, Bulletin of Environmental Contamination and Toxicology 2001, 66:150-155.

14 U.S. Food and Drug Administration, FDA News, "Solgar Vitamin and Herb Company Recalls Solgar's Digestive Aid 100's Dietary Supplements

Because of Possible Salmonella Contamination". FDA Talk Paper, Food and Drug Administration April 27, 2001. http://www.cfsan.fda.gov.

15 U.S. Food and Drug Administration, FDA News, "FDA Issues a Nationwide Alert on the Recall of Thirteen "Treasure of the East" Herbal Products Because of Possible Health Risk", FDA Talk Paper, Food and Drug Administration June 20, 2001. http://www.cfsan.fda.gov.

16 McGuffin M, Hobbs C, Upton R, Goldberg A. American Herbal Products Association's Botanical Safety Handbook. CRC Press, Boca Raton, FL, 1997; 149-151.

17 Report of the Commission on Dietary Supplement Labels, Report to the President, Congress, and Secretary of the Department of Health and Human Services, Nov 1997, Washington, DC.

18 Falk, M. Model for a Third-Party Review of the evidence Substantiating Food and Dietary Supplement Claims. Journal of Nutrition 131:2219-2223, 2001.

19 McAlindon T. Glucosamine and Chondroitin for Osteoarthritis?, Bulletin on the Rheumatic Diseases 2001 Jul; 50 (7): 1-4.

20 Wilt TJ, Ishani,A, Stark, G, MacDonald,R, et al. Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. Journal of the American Medical Society 1998; 280 (18):1604-9.

21 Ang-Lee M, Moss J, Yuan C. Herbal Medicines and Perioperative Care, Journal of the American Medical Association 2001, 286 (2): 208-216.

22 Federal Food, Drug, and Cosmetic Act, Sections 201(n) and 403(a)(1). http://www.fda.gov/opacom/laws/fdcact/fdctoc.html.

23 Survey of Manufacturing Practices in the Dietary Supplement Industry: Final Report, RTI Task Order No. 6, May 17, 2000.

24 Dietary Supplement Market View 2 (10): 1-9; October 2000.

25 The WEFA Group. Economic Impact: U.S. Direct & Interactive Marketing Today, Direct Marketing Association, 2001.

26 Dietary Supplements - An Advertising Guide for Industry, Federal Trade Commission, Bureau of Consumer Protection, 1998.

27 Special Committee on Aging, U.S. Senate, September 10, 2001.

28 Health Products for Seniors; Potential Harm from "Anti-Aging Products, GAO-01-1139T, September, 2001.

29 Office of the Inspector General, Adverse Event Reporting for Dietary Supplements, An Inadequate Safety Valve, April 2001, OEI-01-00-00180.

Chapter 6: Access and Delivery

In Town Hall meetings across the country during the past two years, people voiced a number of concerns about access of the public to Complementary and Alternative Medicine (CAM) practitioners and products. Issues raised include access to qualified CAM practitioners, state regulation of CAM practitioners, integration of CAM and conventional health care, collaboration between CAM and conventional practitioners, and the cost of CAM services. Many people who testified, including those who have only limited access to "basic health care", expressed a desire for increased access to safe and effective CAM, along with conventional services.

As is true for conventional health care, many factors influence access to CAM services and their delivery. The distribution and availability of local providers, regulation and credentialing of providers, policies concerning coverage and reimbursement, and characteristics of the health care delivery system all affect the quality and availability of care and consumer satisfaction. Equally important, access is limited by income, since most CAM practices and products are not covered under public or private health insurance programs. As with conventional care, access to CAM is more problematic for rural, uninsured, underinsured, and other special populations. The issue of access is further compounded by lack of scientific evidence regarding safety and effectiveness of many CAM practices and products.

A better understanding of how the public uses CAM is needed in order to determine what can be done to improve access to safe and effective CAM within the context of other public health and medical needs. In addition, more information is needed on what constitutes "appropriate access" to CAM services.

Most CAM practices have developed independently of the conventional health care system and are not uniformly regulated by the states or the Federal government. A variety of market mechanisms and other arrangements have developed to pay for these services, including out-of-pocket payments, discounted fees, insurance reimbursement, and donated services. Where the public has had access to CAM services it has often been with little assurance of safety, quality, or efficacy. Moreover, because most consumers have had to pay for CAM services directly, access often has been limited to those with higher discretionary income.[1] An overview of insurance coverage and reimbursement for CAM is presented in Chapter 7.

As interest in CAM grows and as CAM increasingly enters the mainstream of American health care, mechanisms that worked in the past to help ensure safety and quality may no longer be adequate. For example, if CAM practices become eligible for reimbursement through the health insurance system, issues that now confront the conventional health care system - including safety, fraud, and

practitioner malpractice or incompetence - will need to be addressed for CAM. In addition, if private health insurance reimbursement for CAM services increases, questions of equity arise for beneficiaries of Federal - and state- sponsored health care programs, the underinsured, and uninsured.

Some people believe that existing practice structures have worked well for those who use CAM and that no further action is required. But market demand for CAM is already reshaping the dynamics of health care delivery, requiring that some issues be addressed. For example, insurers and managed care plans are offering CAM options more frequently, and integrated medical clinics and private practices are spreading. As more evidence is published on the safety and effectiveness of CAM practices, they are more likely to be incorporated into health care treatment protocols.

Now is the time to look at policy options for the future and to design strategies for addressing potential issues of access and safety. Beyond these basic concerns, protecting the public, maintaining free competition in the provision of CAM services, and maintaining the consumer's freedom to choose appropriate health professionals are issues to be considered when developing strategies and policies. Moreover, the need to maintain CAM styles of practice, rather than allowing them to be subsumed into the conventional medical model, also must be considered when addressing these issues.

If approached with both imagination and caution, the policy planning process could not only address these issues more effectively, but also a broader set of health issues affecting the nation, such as whether access to safe and effective CAM services can:

- Benefit vulnerable populations including those with chronic diseases, the terminally ill, and other populations with special needs;
- Lower health care costs and possibly increase access to conventional health care services for some segments of the population, such as the chronically and terminally ill; and,
- Help solve issues of equity and quality that do not set up a zero-sum struggle over limited resources.

The present state of evidence concerning the safety and effectiveness of various CAM practices precludes any final assessment of their contributions to and limitations in addressing these broader health issues. The process of gathering evidence is on-going, however, and as evidence increases concerning ways that various CAM approaches do or do not affect health, processes of living and dying, and costs for other care, access to and delivery of some CAM practices and services are likely to become more pressing public policy issues.

Meanwhile, public interest in CAM, and the market dynamics that have evolved in response to it, have brought issues of access to the forefront. Policy-makers

should begin to address these issues and examine the implications of different kinds of policy for consumers and practitioners, for clinics, hospitals and other organizational settings where health care is now delivered, and for the system as a whole.

CAM Practitioners and Public Safety

The public has expressed interest in maintaining easy access to CAM practitioners and in having sufficient information about them to make informed choices. Perceptions of the relative importance of being able to take responsibility for one's own health and health decisions, yet be protected from incompetent practitioners, underlie differences in consumers' response to possible state or Federal regulation of CAM. Public sentiment on the need for and degree of regulation ranges, with some calling for more regulation of CAM, to others who are opposed to any regulation. The Commission recognizes that Americans want to be able to choose from both conventional and CAM practices and that they want assurances that practitioners are qualified.

CAM practitioners have raised additional issues that are important to the public because they affect freedom of access to CAM providers. Some health care practitioners, both CAM and conventional, are concerned about liability and prosecution if the services they provide are not commonly accepted within conventional medical practice. Another concern of some CAM professionals is that they are licensed to practice in some states but not others, and that even where licensed, their scope of practice may vary across the country.

While some CAM professions endorse licensure requirements in order to participate fully in the health care delivery system, several people testified that licensure is not feasible for some categories of CAM practitioners, such as Native American and other traditional healers. Some CAM practitioners consider their disciplines to be educational (Alexander Technique) or spiritual (Reiki) and have expressed concerns about being licensed as health professionals. Some conventional health care practitioners who incorporate CAM modalities into their practices want to broaden the scope of practice laws to allow these modalities to be used.

Establishing legal authority to practice requires states to establish standards of practice, including training, education and continuing education requirements, as well as scope of practice. Some CAM professionals believe that to reorganize CAM on the conventional professional model, with the kind of licensure, registration, or exemption procedures that this implies, will damage the fundamental character of much of CAM. Some believe that in the past, legislation to "protect the public" was often used to restrict competition in the provision of services.

Five important issues of access and delivery concern both the public and practitioners:

- Protecting the public from the inappropriate practice of health care,
- Providing opportunities for appropriately trained and qualified health practitioners to offer the full range of services in which they are trained and competent,
- Maintaining competition in the provision of CAM and other health services,
- Preserving CAM styles and traditions that have been valued by both practitioners and consumers, and
- Determining the extent of the public's choice among health care modalities.

If addressed separately, these concerns can lead to very different public policies, and state legislation that affects access to CAM practices varies in its emphasis on these concerns. Therefore, when developing strategies to address problems of access to CAM practitioners, all of these criteria should be considered.

Evaluating State Approaches

Legislative and regulatory policies that affect conventional and CAM practitioners fall largely under the aegis of state governments, primarily through regulation of practice. In recent years, a few states have passed legislation and enacted regulations that affect access to CAM practitioners. These regulations provide a natural experiment for solutions to access and delivery of CAM. If properly documented and evaluated, these ventures could provide information that may guide other states and the Federal government in future policy development.

Minnesota provides almost unlimited freedom to practice. Unlicensed practitioners must inform clients of their education, experience, and intended treatments, as well as possible side effects or known risks of the treatments. Clients must sign an informed consent statement acknowledging the practitioner is unlicensed, that complaints may be filed with the Minnesota Department of Health if treatment is unsatisfactory, and that they have the right to seek licensed care at any time. Requirements for practice are minimal, but practitioners are not exempted from liability for untoward outcomes. Licensed health professionals also may provide CAM services, as long as their provision of the services is consistent with regulations governing their licensure. In short, the Minnesota law preserves maximum freedom for CAM practitioners and consumers and relies primarily upon informed consent for protection of health care consumers.

In contrast, Washington provides licensure, registration, or exemption for various categories of CAM professionals, based on their education and the extent to which their profession prepares practitioners to assume responsibility for the total health care of clients. Regulations delineate standards of practice, the scope of practice allowable, education and training requirements for licensure, registration,

or exemption, and required professional oversight. Four CAM professional groups (naturopathic physicians, acupuncturists, massage therapists, and chiropractors) are licensed and regulated.

The emphasis in Minnesota is placed on granting all CAM professionals the freedom to practice with minimal restrictions, while holding them accountable for outcomes. The Washington law emphasizes licensure as the route to protecting consumers and the practice rights of some CAM professionals. The Minnesota law preserves the range of CAM practices without distinguishing among them, whereas the Washington law requires CAM practitioners to fit into a professional model in order to receive the rights and responsibilities granted conventional health care professions.

Other states vary considerably in their 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. (Table 1 shows the distribution of CAM specialties by state.) These variations affect access to and delivery of CAM by limiting practitioners' ability to practice lawfully and to obtain malpractice insurance. On the Federal level, several bills have been introduced into recent sessions of Congress that could affect access to CAM, including some that allow greater latitude for unconventional treatments. Any Federal legislation drafted in the future should consider the experience states are acquiring through their various legislative initiatives.

A number of factors should be studied when evaluating state models of creating access and delivery and protecting the public. Health services research should document how different legal frameworks affect access to CAM and how this different access affects health outcomes. Other issues to be considered include how state regulations affect the supply and distribution of various CAM practices and practitioners over time, as well as competition and costs of services. Also important are the effects of different regulatory models on the safety of the population, problems that may arise from use of different models, and the impact on conventional health care practitioners. Changes in the amount of time and quality of interaction with consumers of CAM services might also be assessed through periodic surveys. As evidence becomes available about the impact each regulatory model is having, the lessons learned can help inform choices that other states and the Federal government will be making.

Authority to practice has real impact on access to and delivery of services. The Department of Health and Human Services should gather and assess information about effects of these laws on the public's health as well as on access to CAM and CAM practitioners.

Recommendation 18: The Department of Health and Human Services should evaluate current barriers to consumer access to safe and effective CAM practices and to qualified practitioners and should develop strategies for removing those barriers in order to increase access and to ensure accountability.

Actions

18.1 The Department of Health and Human Services should assist the states in evaluating the impact of legislation enacted by various states on access to CAM practices and on public safety.

18.2 The Department of Health and Human Services and other appropriate Federal agencies should use health care workforce data, data from national surveys on use of CAM, regional public health reports on CAM activities and other studies to identify current and future health care needs and the relevance of safe and effective CAM services for helping address these needs.

Regulatory Frameworks

States, in exercising their authority over health care practitioners, should consider where a regulatory infrastructure for CAM practitioners might be necessary in order to promote quality of care and patient safety. The primary mechanisms used by states to regulate health care practitioners are:

- Mandatory Licensure, which prohibits the practice of a profession without a license. Licensure denotes a high degree of professional development, including consensus within the profession concerning standards of education, training, and practice, and the ability to self-regulate.
- Title Licensure, which permits anyone to practice the modality, but allows only those granted a license to use the title. A demonstrable level of skill or training normally is required for title licensure.
- Registration, which is granted in some states to professionals such as dieticians and pharmacists upon completion of required training and exams, is in other states simply a requirement that a provider register his or her name, address, and training with a designated state agency. This type of registration prohibits non-registered individuals from practicing and gives the agency authority to receive consumer complaints and revoke registrations.
- Exemption, which accords special status to religious healers. Medical licensing statutes do not apply to these healers, provided they practice within the tenets of a recognized church.

State and Federal policy-makers and others with an interest in these issues should recognize three unique challenges that face regulation of CAM

practitioners. First, views vary among CAM practitioners regarding how much training should be required for licensure in any given field, the extent to which such training should be required for licensure, and whether and how such education and training can incorporate intuitive skills and individualized approaches to providing health care services. For many CAM providers, 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, ease referrals, enhance patient access, and increase consumer protection, it may decrease individualization of services, time spent per patient, and range of patient options, qualities of CAM practice valued by practitioners and patients alike.

Second, variation in what constitutes "CAM" makes any assessment of CAM as value-added services difficult. Disagreement also surrounds the nature and scope of various CAM professions. In 2001, the University of California, San Francisco Center for Health Professions published a report that addresses this issue[2]. Questions it raised include: How does the profession describe itself in terms of the types of care it provides, and the types of care that are 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? Answers to these questions will help define the various CAM professions.

A third, related concern involves the confusion and potential legal consequences that arise from the overlap of approaches and techniques used by CAM practitioners. For example, some states include homeopathy and acupuncture within the definition of the practice scopes for naturopathy or chiropractic, whereas others do not. Practitioners from states with a broad scope of practice who move to states with a more limited one may be unsure whether they risk state censure by providing these services. Confusion and legal risk can occur within a state if the legal authority to practice is not well defined or lacks clarity as to boundaries for practice. The potential for liability creates fear and uncertainty for some CAM practitioners. All providers, CAM and conventional, can be prosecuted if they are considered to have exceeded their scope of practice.

To address some of these issues the Pew Health Professions Commission, established in 1989, conducted an in-depth study of reform in the regulation of health care practitioners. They recognized that health care workforce reform would necessitate regulatory reform and created a task force to propose new approaches that would better serve the public's interest. In 1995, they published 10 recommendations for regulatory reform and offered policy options, hoping to stimulate debate and discussion by states.[3] The recommendations focus primarily on regulation of conventional health care practitioners but they are

applicable to CAM practitioners as well. Recommendations from the Pew Commission Taskforce are in Appendix B.

Recommendation 19: The Federal Government should offer assistance to states and professional organizations in 1) developing and evaluating guidelines for practitioner accountability and competence in CAM delivery, including regulation of practice, and 2) periodic review and assessment of the effects of regulations on consumer protection.

Actions

19.1 The Secretary of Health and Human Services should create a policy advisory committee, including CAM and conventional practitioners and representatives of the public, to address issues related to providing access to qualified CAM practitioners, provide guidance to the states concerning regulation possibilities, and provide a forum for dialogue on other issues related to maximizing access.

19.2 The Secretary of Health and Human Services, in collaboration with states, should assist CAM organizations that wish to develop consensus within their field of practice regarding standards of practice, including education and training. The conclusions reached by CAM professional groups concerning these matters should be considered by states and regulatory bodies in determining the appropriate status of these practitioners for such regulatory options as registration, licensure or exemption.

Recommendation 20: States should evaluate and review their regulation of CAM practitioners and ensure their accountability to the public. States should, as appropriate, implement provisions for licensure, registration, and exemption consistent with the practitioners' education, training, and scope of practice.

Actions

20.1 The Department of Health and Human Services' policy advisory committee, in partnership with state legislatures, regulatory boards, and CAM practitioners, should develop model guidelines or other guidance for the regulation and oversight of licensed and registered practitioners who use CAM services and products. This guidance should balance concerns regarding protection of the public from the inappropriate practice of health care, provide opportunities for appropriately trained and qualified health practitioners to offer the full range of services in which they are trained and competent, maintain competition in the provision of CAM and other health services, preserve CAM styles and traditions that have been valued by both practitioners and consumers, and determine the extent of the public's choice among health care modalities.

Hospitals, Nursing Homes, Hospice, Community Health Centers, and other Health Care Delivery Organizations

Hospitals and Other Conventional Health Care Settings

Because of the increased use of CAM, access and safety issues involving delivery of CAM in hospitals, hospices, nursing homes, community health centers, and other health delivery organizations are increasing. Patients sometimes bring CAM products and even CAM practitioners into inpatient settings. Health delivery organizations vary in their policies and procedures regarding such situations, and there is little monitoring of interactions between CAM and conventional health care in these settings.

Health care facilities credential practitioners who provide services at their facilities. The question of who may practice and under what conditions within health delivery facilities is not addressed consistently for CAM practitioners. In some facilities, CAM practitioners who are not credentialed are permitted to provide services to patients; in others, only practitioners already credentialed by the facility may provide services.

Issues of safety and quality of care also arise when conventional practitioners who are credentialed by a facility use CAM in their practice. An increasing number of physicians use CAM practices for their patients in both inpatient and outpatient settings.

One way to address the growing number of issues related to the use of CAM interventions in hospitals, nursing homes, hospices, other clinical settings, and home health care is through the initiatives and leadership of nationally recognized accrediting organizations, including those that accredit health care networks and managed care organizations. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), an independent nonprofit organization, surveys and accredits nearly 18,000 facilities, other health delivery settings, and health plans using professionally based standards to measure compliance. Other nationally recognized accrediting organizations include the National Committee for Quality Assurance and the American Accreditation HealthCare Commission. The efforts of these organizations to address CAM in all health care settings will contribute greatly to the public's safety. In addition, these efforts will assist state and Federal regulators of health delivery organizations and health plans, who often use accreditation as a proxy for government oversight.

One important initiative that national accrediting organizations may take is to review their standards, guidelines, and interpretations for areas that affect or are affected by trends in CAM. For instance, one JCAHO standard addresses "the

relationship of the hospital staff and its staff members to other health care providers, educational institutions, and payers." In this case, more specific guidance is needed as to how a facility can meet the standard when incorporating CAM interventions into hospital services, serving as a component of an integrated delivery system that includes CAM, or participating in collaborative treatment plans with CAM providers.

The work of national accrediting organizations includes not only a wide range of standards and guidance, but also measurement tools, quality and performance improvement initiatives, and surveys. The work usually is conducted by staff along with representatives of the health care industry, other industry experts, and consumers who serve on various committees and special working groups. It is important for national accrediting organizations to include CAM experts and representatives of CAM organizations on any group that addresses issues related to CAM.

Recommendation 21: Nationally recognized accrediting bodies should evaluate how health care organizations under their oversight are using CAM practices and should develop strategies for the safe and appropriate use of qualified CAM practitioners and safe and effective products in these organizations.

Actions

21.1 National accrediting bodies, in partnership with other public and private organizations, should evaluate present uses of CAM practitioners in health care delivery settings and develop strategies for their appropriate use in ways that will benefit the public.

21.2 Nationally recognized accrediting bodies of health care organizations and facilities should consider increasing on-going access to CAM expertise to ensure that processes to develop accreditation standards and interpretations reflect emerging developments in the health care field.

21.3 Nationally recognized accrediting bodies, using CAM experts, should review and evaluate current standards and guidelines to ensure the safe use of CAM practices and products in health care delivery organizations.

Community Health Centers, Hospices, Independent Centers and Other Programs

A growing number of Americans use community health centers and other public health programs to meet their health care needs, including help with mental health and substance abuse treatment. These centers and programs often emphasize patient-centered care. A few community health centers have begun to

use the services of CAM practitioners such as chiropractors, naturopathic physicians and acupuncturists. These centers might serve as models for the use of CAM practitioners by other community health centers and other public health service programs; however, they need to be evaluated to determine their impact on health care access and cost-benefits.

Hospice care for the terminally ill is another important model that should be evaluated further. Some hospice programs are beginning to include CAM practitioners on the treatment team. Some of the CAM practices they use are chiropractic, acupuncture, music therapy, meditation, and visualization. In some instances, these services are believed to help reduce anxiety and pain.

Some independent CAM centers, which may not have any direct hospital affiliation and may not have a physician on staff, also offer a variety of CAM services. These centers tend to be client-oriented with flexible hours and a broad spectrum of practitioners available. Many of the centers encourage patients to actively improve their health and concentrate on health maintenance rather than disease care and encourage coordination and collaboration among CAM practitioners who are seeing the same patient or client. More information is needed on who uses these centers, their impact on access and delivery, whether appropriate referral procedures are in place, and the quality of care provided. Only when more systematic data are available can the advantages and disadvantages of independent CAM centers be assessed.

Special and Vulnerable Populations

Special populations, such as racial and ethnic minorities, and vulnerable populations, such as the chronically and terminally ill, have unique challenges and needs regarding access to CAM. Efforts to address access to CAM need to be balanced with the need for access to conventional health care. Scarce resources need to be carefully allocated so that these populations are not denied opportunities available to others to access safe and effective conventional and CAM services.

Increased information on CAM use and barriers to access for these populations is needed. Although some studies have described CAM use among African Americans, Native Americans, Hispanics, and Asian Americans, reliable access and utilization data are largely lacking. In the case of Native Americans, information gathering is limited by their status as sovereign nations. Nonetheless, the Indian Health Service has a program to encourage communication with practitioners of traditional Indian medicine, which will help ensure safety when both Native American and conventional medical systems are used.

Surveys of CAM use in the general population indicate that it is being used disproportionately by highly educated, and upper-income Americans.[4] However,

early studies used telephone interviews with English speakers, thus providing little information about CAM use among those who do not speak or have limited ability in English, who have lower income, or who lack telephones.[5] Later studies corrected for these biases, but they did not use adequate statistical sampling to estimate the use of CAM in minority populations.[6, 7, 8, 9, 10, 11] Other surveys have focused on low-income and ethnic groups, but these studies frequently had small, unrepresentative samples.[12, 13, 14, 15] The National Center for Health Statistics is conducting a nationwide survey on access to and use of CAM among racial and ethnic minorities that is expected to provide statistically reliable estimates of CAM use in these groups.

In an October 2000 letter to community health centers and other public health programs, the Health Resources and Services Administration's Bureau of Primary Health Care (BPHC) endorsed the use of CAM in these centers where appropriate. [16] In 2001 they began surveying the use of CAM by persons receiving health services from BPHC-funded community health centers. Information being gathered includes participants' use of six modalities (acupuncture, manual healing, botanicals and herbs, homeopathy, traditional healing, and mind-body techniques); whether the CAM service was provided onsite or by referral, either with or without payment by the community health center; and demographic data. Results should be available in 2002 and will provide a significant, statistically reliable portrait of the use of a variety of CAM services and products by community health center clients, whose come disproportionately from rural, low-income, and minority populations. It is important to continue collecting this kind of information in the future.

Discussions are currently underway between BPHC and the National Center for Complementary and Alternative Medicine to include clients of community health centers in CAM clinical trials, in order to increase the relevance of findings for application to the health needs of minority populations.

Use of CAM is especially high among populations with potentially life-threatening diseases. Surveys show that people with cancer use CAM practices and products more frequently than the population as a whole, with CAM most often being used in conjunction with conventional therapies.[17, 18,19] Similarly, there is high use of CAM by people who are terminally ill and their care-takers. Many people in these vulnerable populations are using CAM services regardless of whether they have insurance coverage and sometimes without the knowledge or cooperation of their conventional physician.

The chronically and terminally ill consume more health care resources than the rest of the population. Approximately 75 percent of all health care spending in the U.S. currently is for the treatment of chronic disease [20], and 25 percent of Medicare spending is for costs incurred during the last year of life.[21] The great interest in CAM practices among the chronically ill, those with life-threatening conditions, and those at the end of their lives suggests that increased access to

some CAM services among these groups could have significant implications for the health care system. Health services research, demonstrations, and evaluations are needed to assess whether CAM services can improve care and quality of life for people in these groups, and possibly lessen the use of expensive technological interventions.

With the number of older Americans expected to increase dramatically over the next 20 years, alternative strategies for dealing with end-of-life processes will be increasingly important in public policy. This demographic shift should influence priorities for the kinds of research and demonstration projects that would be carried out in the near future. A more careful assessment of the potential and limitations of CAM approaches in the health care system as a whole might lead to more effective use of resources. For example, Congress could direct the Center for Medicare and Medicaid Services to develop a demonstration project to study evidence-based CAM interventions as part of comprehensive care of persons with chronic disease in both the Medicare and Medicaid programs. The demonstrations would assess health outcomes and total costs of care for beneficiaries in settings where physician leaders are committed to evidence-based medicine, high quality, client-centered care, and openness to CAM approaches. If evaluations show that some uses of CAM can lessen the need for more expensive conventional care in these populations, the economic implications for these Medicare and Medicaid could be significant.

If safe and effective CAM practices become more available to the general population, special and vulnerable populations should also have access to these services, along with conventional healthcare. CAM would not be a replacement for conventional health care, but would be part of the options available for treatment. In some cases, CAM practices may be an equal or superior option.

Evidence for assessing the potential of CAM interventions in treating vulnerable and special populations is still being gathered. While it is too early to judge the effectiveness of CAM in addressing their health care needs, CAM nonetheless offers the possibility of a new paradigm of integrated health care that could affect the affordability, accessibility, and delivery of health care services for millions of Americans.

Recommendation 22: The Federal government should facilitate and support the evaluation and implementation of safe and effective CAM practices to help meet the health care needs of special and vulnerable populations.

Actions

22.1 The Department of Health and Human Services and other Federal Departments should identify models of health care delivery that include safe and effective CAM practices, evaluate them, and then support those

models which are successful for use with special and vulnerable populations, including the chronically and terminally ill.

22.2 The Department of Health and Human Services should sponsor the development and evaluation of demonstration projects that integrate the use of safe and effective CAM services as part of the health care programs in hospices and community health centers.

22.3 The Department of Health and Human Services should identify ways to support the practice of indigenous healing in the United States and to improve communication among indigenous healers, conventional health care professionals, and CAM practitioners.

Table 1. Provider Licensing by State and Specialty

STATE	CHIRO-PRACTORS	ACUPUNCTURISTS				MASSAGE THERAPISTS				NATUR O-PATHS	DIETITIANS		
	Licensing Laws	Licensing Laws	Access Requires MD Referral and/or Prior Diagnosis	MD Supervision Required	May dispense TCHS	MD Supervision Required	Licensing Laws	Regulated	Licensing Laws Pending	Licensing Laws	Registration Laws	Licensing Laws	Certification Laws
Alabama	✓						✓				✓	✓	
Alaska	✓	✓						✓		✓	✓	✓	
Arizona	✓	✓			✓			✓		✓	✓		
Arkansas	✓	✓			✓		✓				✓	✓	
California	✓	✓			✓			✓			✓		
Colorado	✓	✓			✓			✓			✓		
Connecticut	✓	✓					✓			✓	✓		✓
Delaware	✓						✓				✓		✓
Florida	✓	✓			✓		✓				✓	✓	
Georgia	✓	✓			✓			✓			✓	✓	
Hawaii	✓	✓			✓		✓			✓	✓	✓	
Idaho	✓	✓			✓			✓			✓	✓	
Illinois	✓	✓	✓					✓			✓	✓	
Indiana	✓	✓	✓					✓			✓		✓
Iowa	✓	✓					✓				✓	✓	
Kansas	✓							✓			✓	✓	
Kentucky	✓							✓			✓	✓	
Louisiana	✓	✓		✓		✓	✓				✓	✓	
Maine	✓	✓					✓			✓	✓	✓	
Maryland	✓	✓					✓				✓	✓	
Massachusetts	✓	✓			✓			✓			✓	✓	
Michigan	✓							✓			✓		
Minnesota	✓	✓			✓			✓			✓	✓	
Mississippi	✓							✓	✓		✓	✓	
Missouri	✓	✓					✓				✓	✓	
Montana	✓	✓			✓			✓		✓	✓	✓	
Nebraska	✓						✓				✓	✓	
Nevada	✓	✓			✓			✓			✓		
New Hampshire	✓	✓			✓		✓			✓	✓	✓	
New Jersey	✓	✓	✓		✓		✓				✓		
New Mexico	✓	✓			✓		✓				✓	✓	
New York	✓	✓					✓				✓		✓
North Carolina	✓	✓			✓		✓				✓	✓	
North Dakota	✓						✓				✓	✓	
Ohio	✓	✓	✓	✓		✓	✓				✓	✓	
Oklahoma	✓							✓			✓	✓	
Oregon	✓	✓			✓		✓			✓	✓	✓	
Pennsylvania	✓	✓		✓		✓		✓			✓		
Rhode Island	✓	✓					✓				✓	✓	
South Carolina	✓	✓	✓	✓		✓	✓				✓		
South Dakota	✓							✓			✓	✓	
Tennessee	✓	✓					✓				✓	✓	
Texas	✓	✓	✓		✓		✓				✓	✓	
Utah	✓	✓					✓			✓	✓		✓
Vermont	✓	✓			✓			✓		✓	✓		✓

References

1 Eisenberg, DM, Kestrel RC, Foster C, et al. Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use. New England Journal of Medicine 1993; 328(4): 246-252.

2 University of California, San Francisco. The Center for the Health Professions. Profiling the Professions: A Model for Evaluating Emerging Health Professions. 2001.

3 University of California, San Francisco. The Center for the Health Professions. Reforming Health Care Workforce Regulation Policy: Considerations for the 21st Century. 1995.

4 Eisenberg DM, Davis RB, Ettner SL, et al. Trends in Alternative Medicine Use in the United States, 1990-1997: Results of a Follow-up National Survey. Journal of the American Medical Association 1998; 280:1569-1575.

5 Wootton JC, Sparber A. Surveys of Complementary and Alternative Medicine: Part I. General Trends and Demographic Groups. Journal of Alternative and Complementary Medicine 2001; 7(2): 195-208.

6 Allen R, Cushman LF, Morris S, et al. Use of Complementary and Alternative Medicine Among Dominican Emergency Department Patients. American Journal of Emergency Medicine 2000; 18:51-54.

7 Cushman LF, Wade C, Factor-Litvak P, et al . Use of Complementary and Alternative Medicine Among African-American and Hispanic Women in New York City: Pilot Study. Journal of the American Medical Women's Association 1999; 54 (4): 193-195.

8 Keegan L. Use of Alternative Therapies Among Mexican-Americans in the Texas Rio Grande Valley. Journal of Holistic Nursing 1996; 14 (4): 277-294.

9 Kim C, Kwok YS. Navajo Use of Native Healers. Archives of Internal Medicine 1998; 158:2245-2249.

10 Ma GX. Between Two Worlds: The Use of Traditional and Western Health Services by Chinese Immigrants. Journal of Community Health 1999; 24(6): 421-437.

11 Risser AL, Mzur LJ. Use of Folk Remedies in a Hispanic Population. Archives of Pediatric Adolescent Medicine 1995; 149: 978-981.

12 Breunner CC, Barry PJ, Kemper KJ. Alternative Medicine Use by Homeless Youth. Archives of Pediatric Adolescent Medicine 1998; 152: 1071-1075.

13 Burg MA, Hatch RL, Neims AH. Lifetime Use of Alternative Therapy: a Study of Florida Residents. Southern Medical Journal 1998; 91(12): 1126-1131.

14 Johnson JE. Older Rural Women and the Use of Complementary Therapies. Journal of Community Health Nursing 1999; 16(4): 223-232.

15 Pourat N, Lubben J, Wallace SP, Moon A. Predictors of Use of Traditional Korean Healers Among Elderly Koreans in Los Angeles. Gerentologist 1999; 39(6): 711-719.

16 Program Assistance Letter, Bureau of Primary Health Care, October 2001 Friedman T, Slayton WB, Allen L, et al. Use of Alternative Therapies for Children with Cancer [abstr] Pediatrics 1997; 100(6) E1.

17 Kelly KM, Jacobson JS, Kennedy DD, et al. Use of Unconventional Therapies by Children with Cancer at an Urban Medical Center. Journal of Pediatric Hematology and Oncology 2000; 22(5): 412-416.

18 Wyatt GK, Friedman LL, Given CW, et al. Complementary Therapy Use Among Older Cancer Patients. Cancer Practice 1997; 7(3): 136-144.

19 Hoffman C, Rice D, Sung HY. Persons with Chronic Conditions: Their Prevalence and Costs. Journal of the American Medical Association 1996; 276(18): 1473-1479.

20 Hogan C, Lunney J, Gabel J, et al. Medicare Beneficiaries' Costs of Care in the Last Year of Life. Health Affairs 2001; 20: 188-195.

Chapter 7: Coverage and Reimbursement

The coverage and reimbursement policies of public and private organizations that pay for, provide or insure conventional health care services have played and will continue to play a crucial role in shaping the health care system in this country. Likewise, policies influencing coverage of and reimbursement for non-conventional health care therapies will play an increasingly important role in the future of complementary and alternative medicine (CAM), as well as the future structure of the nation's health care system.

Today, coverage of CAM is evolving in benefit design, type and number of interventions offered, and availability. Consumers and health care providers may use available coverage for a CAM therapy as a principal intervention or as an integral part of the treatment of certain health conditions, such as acupuncture for management of chronic pain. The direction taken by health plan coverage of CAM in the future will shape consumer access to CAM services, the degree of integration of CAM and conventional medicine, and the philosophical foundation of the nation's health care system.

Although a considerable segment of the U.S. population is uninsured -- a significant public policy issue in itself -- health care coverage is widely available in this country. Recent census data indicate that 86 percent of the population had some type of health insurance during the year.[1] Included in that number are 32 million people (11 percent of the population) covered by Medicare, the federal insurance program for the elderly and for eligible persons who are disabled or who have end-stage renal disease. Other significant sources of health care coverage include private employer and sponsors of benefits, the Office of Personnel Management (OPM) for Federal employees, State and other public employers, the Department of Defense (DOD) for the military community, the Department of Veterans Affairs (VA) for veterans, and Federal and State programs providing Medicaid and other health coverage for the economically disadvantaged. Researchers estimate that, in 2001, Federal and State programs (i.e., Medicare, Medicaid, and the State Children's Health Insurance Program) accounted for 44 percent of the nation's health expenditures and that insurers and other private sources were responsible for 40 percent.[2*] The entities, whether public and private, that pay for or bear most of the cost of coverage are the purchasers of health care.

With some exceptions (e.g., fee-for-service Medicare), purchasers obtain health care coverage for their employees or eligible persons by "buying" health plans in the private market. Less commonly, purchasers directly contract with, or employ, health care providers.

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* The remainder, or approximately 14 percent of national health expenditures, were paid out-of-pocket.

The entities that sell health plan coverage to purchasers are insurance and managed care companies, which include preferred provider organizations (PPOs) and health maintenance organizations (HMOs). These companies undertake all the tasks associated with operating health plans, including marketing, enrollment, paying or operating networks of thousands of providers (physicians, hospitals, clinics, nursing homes, therapists, and so on), and bearing -- or sometime sharing with providers -- most of the financial risk of health care coverage. That is, they shift the potential for financial loss from purchaser to themselves. Even federally sponsored programs such as Medicare, and Federal sponsors such as DOD (for the military, retirees, and dependents), have in place special programs that shift not only delivery of care but financial risk to managed care companies. Some purchasers, including a number of employers, self-insure and assume the risks inherent in providing health care coverage, although these purchasers are the exception rather than the rule.

Consumers are sheltered from most of the costs associated with conventional health care, as well as from the risks of future, unknown expenses because purchasers, insurers, and managed care companies shoulder them. In contrast, most fees for CAM services and products are paid by consumers. This direct financial relationship between provider and consumer has the merit of enhancing the consumer's interest and participation in his or her treatment. Furthermore, some CAM practitioners feel that their ability to control fees -- and to avoid time-consuming claims payment and network participation requirements -- enables them to spend more time with clients and to maintain a high level of individualized care. On the other hand, without insurance coverage, access to CAM services is limited by the consumer's ability to pay. Many consumers are unable, or perhaps unwilling, to obtain CAM treatments or to or integrate them into their care because the treatments are not covered under their health plan.

Coverage of CAM

In the last several years, a number of health plans have begun to cover certain CAM services, although the prevalence of this coverage is relatively low, compared to coverage of conventional therapies. Information on this trend is available from an annual survey of employer-sponsored health plans that recently began to include questions regarding a few specific CAM services offered in benefit packages. In 1998, 49 percent of survey respondents indicated that chiropractic was covered; by 2000, the number had risen to 70 per cent. Over the same time period, coverage of acupuncture rose from 12 per cent to 17 percent, and coverage of massage therapy increased from 10 percent to 12 percent. The survey also found that large employers (those with more than 20,000 employees) were more likely to offer CAM benefits than medium and smaller employers. PPOs and indemnity insurers were more likely than HMOs to offer health plans that include CAM benefits.[3]

Insurance and HMO coverage of CAM will very likely have an impact on use of CAM services. It has been reported that fully covered persons made twice as many visits to chiropractors as individuals with no health plan coverage or those required to pay 25 percent of costs.[4] In a recent survey of over 2,000 households, health insurance coverage was found to be the strongest correlate for frequent use of CAM practitioners.[5]

Even where there is health plan coverage, it is often limited. For example, the CAM benefit may cover only one or a few CAM services as the data above indicates. Other limitations include ceilings on the number of visits covered, restrictions on clinical applications, and fixed qualifications for the type of practitioner; for example, ten acupuncture visits might be covered for pain management provided by a medical doctor, and thus would not be covered if provided by a professionally-trained acupuncturist.

Why have employers begun to ask their health insurance and managed care companies to cover CAM benefits? Surveys indicate that they do so primarily in response to employee requests. Other reasons cited in the findings include: 1) attracting and retaining employees, 2) State mandates, and 3) the potential medical benefits of CAM. Although most respondents anticipated increasing their coverage of CAM programs in the future, they cited a number of obstacles to such increases, including inadequate research, regulatory concerns (e.g., licensure), lack of understanding and knowledge about CAM, and lack of data on utilization and costs.[6] A recently published survey of health plans new to offering CAM benefits supports these findings: The plans are offering CAM benefits in response to market research, consumer demand, to attract and retain enrollees, and at the request of purchasers.[7]
At present, CAM is being offered as part of a health plan in several ways, including:

- As a rider, or supplement, to the basic benefit package, often with controls on usage, such as copayments, benefit limits (e.g., visit limits, annual limits), or use of an approved network of CAM providers.
- As a discount program whereby covered employees (or members) pay out-of-pocket but are eligible for discounts off professional CAM fees and CAM products (discounted fees are usually tied to an approved network of CAM practitioners).
- As a defined, core benefit. This benefit is managed by limiting the type of CAM services covered (e.g., only chiropractic, or only chiropractic and acupuncture), requiring a preauthorization or a referral by a primary care physician, or setting visit or dollar limits and higher co-payments than for routine physician visits.
- As a CAM benefit account, typically an annual dollar amount.

Employers also may offer prevention, wellness, or health promotion programs, on-site or off-site. These typically include smoking cessation, weight control,

stress reduction, yoga, health club memberships, and other special programs. More recently, employers have become interested in educational programs to help employees with chronic diseases manage their conditions. Employers who have introduced such programs do so to decrease absenteeism, improve productivity and morale, and achieve some cost savings. Like health benefit coverage, employer-based programs to promote health are often limited in scope and restricted to certain modalities.

Overcoming Barriers to Coverage of Safe and Effective CAM

Health care interventions known to be safe and beneficial should be reviewed and considered for coverage under health benefit programs, regardless of whether the interventions are considered conventional medicine or CAM. Such consideration has not occurred often for CAM interventions, and may continue to occur infrequently because of numerous barriers inherent in the health care industry. The Commission believes that these barriers to coverage and reimbursement of CAM should be addressed. Doing so does not imply that CAM should be treated differently from conventional medicine -- on the contrary, CAM should be held to the same standards as conventional medicine.

The fundamental barriers to coverage and reimbursement identified by the Commission are addressed in the remainder of this chapter. They are clustered into two broad issue areas that must be addressed as purchasers, insurers, managed care organizations, Federal agencies, States, and others respond to consumers' increasing use of CAM interventions. The first area involves the need for health services research to test the benefits and cost-effectiveness of CAM interventions, and to effectively communicate the findings. The second area is the need for equivalent and impartial consideration of safe, effective CAM interventions, especially in developing coverage policy.

Testing the Benefits and Cost-Effectiveness of CAM Services and Products, and Communicating the Findings

Effectiveness of CAM Therapies

A growing body of evidence shows that many CAM interventions are effective in treating or helping to treat a range of health conditions. However, insurance and managed care executives have indicated to the Commission that CAM services and products are not covered, or receive limited coverage, because there is not enough evidence of "medical effectiveness." [8, 9, 10]

Understandably, decision-makers for organizations that purchase health plans or for the health plans themselves are concerned that their limited dollars be spent on care that has been shown to be safe and efficacious. In the face of ever-rising health care costs and the vicissitudes of the economy, purchasers and payers

also want value and accountability for their investment. The addition of State-mandated benefits, as well as the constant stream of new technologies, drugs, and treatment protocols, has left these parties cautious about expanding any health care benefits.

At the operational level, government agencies like the Centers for Medicare and Medicaid Services (CMS), insurers, and managed care organizations invest significant time and resources to determine which benefits are covered, for how long, which practitioners are authorized to perform the services, and how payment will be made. Except for chiropractic and, increasingly, acupuncture and massage therapy, much of CAM is not covered. The services that are covered are often accompanied by limitations, such as global visit limits that are unrelated to individual patient needs or course of treatment.

With the rising cost of health care and heightened sensitivity to price in the market place, the addition of new benefits is a major undertaking. Taken together, economic and market forces, as well as pressures to manage the use of services in today's health insurance world, are creating the need for more evidence of the clinical effectiveness of CAM interventions. Evidence of clinical effectiveness in the treatment of illnesses and injuries will form the basis for sound coverage and reimbursement policies for CAM.

The Commission strongly supports more health services research to establish the medical and clinical efficacy of CAM therapies. Because research dollars are limited, cooperative efforts between the public and private sectors are needed to identify and resolve methodological issues that challenge health services research and to establish research priorities.

In addition to research on safety and efficacy, health services research is needed to evaluate the outcomes of CAM interventions in improving health status, treating acute and chronic conditions such as with heart disease, diabetes, and HIV infection, and supporting the care of persons with life-threatening diseases such as cancer. Research and demonstrations are needed to develop and test models of providing CAM (including integrative and collaborative programs), to compare conventional and CAM approaches for the same condition, to test the effectiveness of individual and combined CAM interventions, to test CAM offered in conjunction with conventional therapies, and to conduct population-based studies. Likewise, research is needed on whether CAM, health promotion programs, and prevention efforts increase worker morale, reduce stress, lessen the incidence of workplace disabilities and workmen's compensation claims, shorten treatment duration for illness and injuries, and improve productivity.

To maximize resources, vested parties should be brought together to develop a comprehensive, cohesive agenda. The parties would, at a minimum, identify priority questions for research and demonstrations, issues in applying common research methodologies, data needs, and ways in which the public and private

sectors could coordinate their efforts. The parties will need to commit to carrying out this agenda and invest financial resources to build the needed research base. Participants should include the Department of Health and Human Services (DHHS), including the Agency for Health Research and Quality (AHRQ), the National Institutes of Health (NIH), CMS, the Health Resources and Services Administration (HRSA), DOD, VA, private research and other foundations, health industry associations, medical associations and experts, CAM associations and experts, and representatives for employers, States, and consumers.

Lifestyle Modification and Heart Disease

- Comprehensive lifestyle changes have been used successfully as an alternative to coronary artery bypass surgery and coronary angioplasty in treating heart disease. The lifestyle modification program tested includes exercise, a low-fat plant-based diet, stress management, and group support. A Mutual of Omaha study with 333 patients (194 followed the lifestyle changes, and 139 were a control group) demonstrated that lifestyle changes can be used to avoid invasive interventions for at least 3 years without increasing the risk of a heart attack, stroke, or death. In addition, savings were estimated at $29,500 per patient.[11]

- Preliminary findings of the Highmark Blue Cross Blue Shield lifestyle modification program include significant decreases in cholesterol, blood pressure, weight, stress and depression. Cost savings range from 30 to 60 percent, and actuaries estimate that Highmark will save over $16,000 on each person who might have required bypass surgery or angioplasty. In another study, Highmark compared claims of individuals before and after entering the program. Results show that claims dropped from an average of $546 per member to $273 in the year after entering the lifestyle modification program.[12]

- A meta-analysis of the literature concluded that " -- all the available evidence suggests that the comprehensive lifestyle program is highly likely to be cost saving, and extremely unlikely to be cost increasing."[13]

Cost Effectiveness and CAM

Public pressure to make CAM more accessible is increasing, yet without adequate information on the use, costs and overall cost-effectiveness of CAM benefits, lawmakers, health plans, and employers are ill-equipped to make decisions about offering CAM services. Costs and cost-effectiveness of health care interventions are important factors in any consideration of changes in coverage. There is growing evidence of cost-savings from CAM interventions, such as massage therapy and the use of mind-body medicine in a variety of

clinical situations.[12] For example, researchers in two randomized trials found that pre-term babies who received massage and comforting touch had greater weight gain and were discharged earlier than babies who did not receive this care. Hospital stays were shortened by 5 to 6 days, and savings averaged more than $10,000 per infant.[13] While research like this is encouraging, further evidence needs to be gathered regarding CAM interventions, especially those that are widely used by consumers or where clinical and cost effectiveness is promising.

Cost Effectiveness and Mind/Body Medicine: A Sample

- Researchers have found that a self-management course designed to help arthritis patients handle disability, pain, depression, and anxiety resulted in positive outcomes. Clinical improvement was found to correlate with a positive outlook and a strong sense of control over their disease. The best predictor of clinical improvement was the patient's belief in his or her improvement. The cost of the course was $54 per person. After 4 years, physician visits had decreased 43%, for a saving of $648 for persons with rheumatoid arthritis and $189 for those with osteoarthritis.[15,16]

- Researchers placed 109 patients with chronic pain into a group intervention program where they received information about pain and behavioral treatment approaches, as well as yoga, relaxation techniques, and life coping skills. They found that the program, while not eliminating the pain, reduced anxiety, depression, and hostility. The clinic's estimated savings from reduced clinic visits were $110 per patient the first year, and $210 per patient in the second year. Estimates did not include savings in the area of prescription drugs or diagnostic tests.[17]

- In another randomized trial, researchers found that an audiotape providing guided imagery for diminished blood loss and rapid healing had significant results. Patients using this tape lost 43% less blood and were discharged at least a day earlier.[18]

More information is needed on the cost-effectiveness of specific CAM interventions for various conditions, different models of CAM practice, the clinical and financial impact of integrating CAM with conventional medicine, and the relative costs of CAM treatments and conventional medical treatments. Information is also needed regarding whether CAM interventions reduce the use of conventional medical services and pharmaceuticals by people with heart disease, cancer, chronic pain, or other chronic illnesses, as well as by the terminally ill. The short- and long-term costs and benefits of wellness programs and self-care need to be studied, as does the impact of CAM practices on the short- and long-term health status of men, women, and children. Likewise,

employers and other purchasers need to know more about the impact of CAM and health promotion programs on workplace costs, including productivity, workmen's compensation and disability costs, and recruitment and retention. Finally, Congress, the Executive Branch, and decision makers in both the public and private sectors need information about the impact of CAM on patterns and costs of health care in the United States.

The information needed by purchasers, insurers, and managed care organizations can be obtained only through health services research, demonstrations, and evaluations in the areas of cost, cost-benefit, and cost-effectiveness of CAM practices and products. These studies, which ideally should stem from the research agenda discussed earlier, will require the support of the Federal government, States, employers, private research organizations, the insurance and managed care industries, and other entities. Participants in building cost-effectiveness research are the same as those identified above for research into the clinical effectiveness of CAM.

Cost is not always a threshold for coverage. Health plans cover a number of costly conventional medical interventions, including heart and lung transplants. The Comission believes that the cost of CAM services and products should not in itself pose a barrier to coverage. Rather, cost should be approached in the same manner as the costs of conventional interventions.

Coding for CAM Interventions

On an operational level, insurers and managed care organizations need data bases to design health benefit plans, set premiums, conduct actuarial analyses, perform quality-of-care studies, manage provider networks, and manage the costs and use of health services. Policy makers and health researchers need data bases to conduct the clinical and health services research in which public policy and programs are grounded. Much of the data used by health plans, researchers, and policy makers are drawn from claim, or transaction, forms, such as the CMS/HCFA 1500 or the UB-92.

A number of the information fields on claim forms are assigned standardized, nationally accepted codes for data management purposes. The use of such codes has helped create powerful data bases that drive much of health care. Standard coding has become even more critical now that the Secretary of Health and Human Services is implementing administrative requirements stemming from the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These requirements impact heavily on the electronic filing of claims; in particular, the act contains a provision that fines practitioners and insurance companies up to $10,000 per code for incorrectly submitting and processing claims. Practitioners are charged for miscoding, and insurance companies are fined for paying fraudulent claims.

Government agencies, insurance companies and managed care organizations use uniform coding systems -- such as the International Classification of Disease to denote diagnosis, Common Procedural Terminology (CPT) to denote medical procedures, dental codes for dentistry, national drug codes for prescriptions, and the CMS/HCFA Common Procedure Coding System for supply items and some procedures -- as part of the electronic record of information about items and services used. Because coding has evolved along with conventional health care, including reimbursement trends, these systems have limited capability to capture CAM practices and products. For example, CPT codes, a set of more than 8,000 procedure codes developed by the American Medical Association for use throughout conventional health care, provides for a few CAM services including two codes for acupuncture.

More recently, a coding system for CAM procedures, services and products (as well as nursing services) has been developed and is being used in a number of settings. This system, ABCcodes developed by Alternative Link, contains 4,000 codes and captures a large amount of detail regarding specific CAM interventions. For example, it has 37 codes reflecting acupuncture services.

Currently, there is some variation regarding which coding system is used in CAM practice settings. Some practitioners use CPT, some use ABCcodes, and some use both. As part of their reimbursement policies, insurance companies may require the use of CPT codes. There is concern that the use of conventional coding systems, such as CPT, in limits the data that can be generated for CAM interventions.

If not resolved, limited coding capability will present a barrier to health services research on the safety, benefits, and cost-effectiveness of CAM interventions, as well as on the efficiency of models of integration and collaboration, where claims data are needed by researchers. In addition, the absence of nationally recognized, standardized codes for use in claims filing creates a significant challenge for CAM practitioners as HIPAA transaction requirements move toward implementation. To address these issues, any coding system for CAM that may be adopted by the Secretary of Health and Human Services should reflect the nature and scope of identified CAM interventions, and should allow for modifications to the coding system over time. If these issues cannot be addressed in line with HIPAA implementation dates and compliance requirements, then the Secretary should consider alternative strategies that would allow CAM practitioners to comply with the law.

Supporting Coverage of CAM Through Information

Purchasers, insurers, managed care organizations, and other sponsors of health care coverage need access to timely, reliable information about safe, efficacious,

and cost-effective CAM practices and products. Such information will promote equitable consideration of safe and effective CAM interventions in developing health benefit packages, supporting executive decision-making, and guiding policy-makers.

Those who help develop benefit packages, including health benefits consultants, have well-established methods and processes for making such changes in coverage. At the same time, there are many barriers to changing the status quo, including concerns about the financial impact of a health benefit not previously offered to the public or for which few data exist. Cost estimates for a new benefit are often low because it is difficult to estimate the number of persons who will qualify for or need the new service, or who actually use the service. Purchasers and providers are willing to respond to consumer demand but find it difficult to make significant changes to benefit packages without sufficient, reliable information.

The paucity of clinical and health services research, together with publication and dissemination issues discussed in the chapter on research, have created an information vacuum. Insurers, managed care organizations, public purchasers, employers, and other sponsors are increasingly willing to consider coverage of CAM interventions, but they need an adequate base of information in order to make decisions.

Federal support is needed to bridge this information gap. The National Center for Complementary and Alternative Medicine in NIH, for example, could consider making more health services research findings available electronically. Such information is used by employers, other purchasers, insurance and managed care industries, health benefits experts, health care associations, health education institutions, health policy bodies, foundations, professionals, and consumers.

There is a need also for Congress and other government leaders to understand the use of CAM within Federal programs, as well as impediments to the coverage of safe and effective CAM interventions. Reports may be necessary from DHHS (particularly Medicare, Medicaid, and community health centers), DOD, VA, and OPM.

More generally, there appears to be a need for the health care industry to become more informed about CAM, research on CAM modalities, and the international experience with such modalities. To meet this need, the Commission encourages health care associations and provider groups to include CAM topics at annual and other pertinent health care meetings. Government leaders and Federal agencies with health care programs also need more information about CAM and are encouraged to help management and staff become more informed. These informational needs may merit or even require

Federal support and leadership to develop informational programs on the broad and complex field of CAM.

Recommendation 23: Evidence should be developed and disseminated regarding the safety, benefits, and cost-effectiveness of CAM interventions, as well as the optimum models for complementary and integrated care.

Actions

23.1 The Secretary of Health and Human Services should convene a joint public and private task force to identify and set priorities for researching health services issues related to CAM and to help purchasers and health plans make prudent decisions regarding coverage of and access to CAM.

23.2 Federal agencies, States, and private organizations should increase funding for health services research, demonstrations, and evaluations related to CAM, including outcomes of CAM interventions, coverage and access, effective sequencing and integration with conventional therapies, effective models for service delivery, and the use of CAM in underserved, vulnerable, and special populations.

23.3 Federal, State, and private entities should fund health services research on the costs, cost-benefits, and cost-effectiveness of CAM interventions and wellness programs.

23.4 Secretary of Health and Human Services and the National Committee for Vital and Health Statistics should authorize a national coding system that supports standardized data for CAM. This system should make possible the collection of data for clinical and health services research on CAM, and support compliance with the electronic claims requirements of the Health Insurance Portability and Accountability Act.

23.5 The National Center for Complementary and Alternative Medicine, through its clearinghouse, should provide information on health services research, demonstrations, and evaluations of CAM services and products.

23.6 Public agencies and private organizations should support the development of informational programs on CAM targeted to health plan purchasers and sponsors, health insurers, managed care organizations, consumer groups, and others involved in the provision of health care services.

23.7 Congress should request periodic reports from appropriate Federal departments on coverage of and reimbursement for CAM practices and products for Federal beneficiaries, Medicaid beneficiaries, Federal employees, military personnel, veterans, and eligible family members and

retirees, as well as any legislative, regulatory, or programmatic impediments to covering safe and effective CAM interventions.

Equitable and Impartial Consideration of Safe, Effective CAM Interventions

Coverage Policies and Processes

Any medical or health care intervention that has undergone scientific investigation and has been shown to improve health or functioning or to be effective in treating the chronically or terminally ill should be considered for inclusion in health plan coverage. To accomplish this, current methods, standards, and processes used to gather evidence and make decisions regarding coverage for conventional medicine should be extended to CAM. These methods, standards, and processes should not be prejudiced toward any philosophy of health care, but give equitable consideration to safe and efficacious interventions for both conventional health care and CAM. The Commission's intent, in general, is that conventional medicine and CAM be considered in a similar manner with adjustments to accommodate differences in philosophical approach, not to unilaterally propel CAM into the conventional model. This challenge should be met by private employers and sponsors of health coverage, insurers, managed care organizations, and Federal purchasers including DHHS, DOD, VA, and OPM. Within DHHS, it is particularly important for CMS and HRSA to address CAM throughout their policies and procedures, and to identify statutory and regulatory issues.

The Medicare Coverage Process

The Medicare law has 55 defined benefit categories. Within these categories, services and products must be "reasonable and necessary" in order to be covered. CMS, which administers the program, has coverage regulations and maintains coverage manuals that contain definitions, criteria for determining what is reasonable and necessary, and other guidance regarding benefits. Coverage questions not addressed by law, regulations, or manuals are answered through two methods:

- Decisions by contractors who pay claims for the Medicare program. These contractors have their own processes, and may issue their own coverage rulings, called Local Medical Review Policies (LMRPs), which are not applicable outside the contractor's area. About 90 percent of Medicare coverage decisions are made this way.

- The formal, labor-intensive, and lengthier national coverage policy process. This process is managed by CMS and is used mostly for significant advancements in treatment, expensive interventions, and situations in which there is wide disagreement or inconsistency among contractors.

Medicare Coverage Issues for CAM

- Definitional constraints: Medicare benefit and practitioner categories contain restrictions. For example, Medicare can reimburse for acupuncture if provided by a physician but not if provided by a professionally trained acupuncturist because acupuncturists are not recognized in the law.
- Expert consultation: CAM experts have not participated in coverage advisory groups at CMS or in Medicare fiscal intermediary and carrier decisions.
- Same-day billing: For office or clinic settings, Medicare requires that many services provided on the same day be bundled and billed together. This helps the program avoid paying for services which are unnecessarily fragmented in order to maximize Medicare payment. This policy, however, poses a hardship for many patients who use conventional and CAM services at integrated clinics, requiring them to make additional trips for services that may be billed separately.
- Anti-kickback rules: The restrictions on referrals and other aspects of these rules pose problems and unresolved issues for physicians and CAM practitioners in integrated practice settings.

Adequate evidence as to safety and efficacy already exist for considering coverage of some CAM interventions. Where there is such evidence, CAM practices and products should be considered for coverage and reimbursement through processes similar to those already in use, modified only to the extent necessary to accommodate the fundamental differences in philosophy and treatment approach that underpin CAM. For example, private health insurance and managed care companies conduct a number of activities that contribute to the benefit design process, including cost-benefit comparisons between current and proposed packages; appraisals of the competition; review of long-term corporate goals; estimates of potential financial liability and losses; and assessments of key factors such as employer and customer requests, potential revenues from redesigned packages, and trends in the economy and market place.

The often-engrained viewpoints within both conventional medicine and CAM may hamper efforts to modify coverage processes to consider including CAM interventions. Each health care industry has knowledge gaps and negative perceptions about the other. For example, those who are skeptical about CAM may oppose coverage on the basis that CAM interventions are not backed by

valid, reliable research. Those who support CAM may be more willing to accept preliminary research findings as persuasive evidence that CAM services should be covered. Such differences in perspective may be overcome through cooperative efforts and working relationships between CAM and conventional health care experts. The public and private sectors offer many opportunities for CAM and conventional health care experts to work together, for example, advisory committees and other workgroups related to health services research and coverage.

Determining When to Pay For or Provide CAM

Once health insurers, managed care companies, and government agencies have decided to cover a benefit, additional procedures must be followed before arriving at a decision to approve or pay for it in a particular situation. The procedures commonly include two questions: 1) Are the circumstance for use of the service or product investigational, and 2) Is use of the service or product medically necessary in the current situation? For example, a health insurance company may decide to add acupuncture to its benefit, but may limit coverage to situations in which acupuncture is no longer considered investigational, such as control of nausea during cancer treatment and treatment of certain pain conditions. In addition, the company will review each request to approve or pay for the service on a case-by-case basis to determine whether acupuncture was indeed medically necessary in that situation.

A health care service or product is considered no longer investigational if it has been proven through scientific methods to be safe and effective at improving health outcomes, or if, in cases where the scientific evidence is still unfolding, expert consensus regarding its safety and efficacy is established. Various parties, such as a national professional association, a government agency such as CMS, or an organization hired to advise a health insurance or managed care company may make such a determination. In the private health care market, insurers and managed care companies often follow one another's lead in determining whether a service or product as safe and beneficial.

The process of determining what is medically necessary is critical to controlling use of and spending on health care services, determining the cost estimates on which premiums are based, and maintaining the financial soundness of the insurance and managed care industries. Decisions are usually made by practitioners on the basis of criteria that have been developed by bodies of experts, including professional organizations, academic medical institutions, private companies, and, in some circumstances, the insurers and managed care companies themselves. Often, the criteria are developed from studies sponsored by or the work of advisory groups for government agencies, such as AHRQ, CMS, and NIH. Government-funded programs, like Medicare develop their own

coverage criteria and offer guidance either nationally or at the local level through Medicare payment contractors.

Insurers and HMOs rely heavily on medical necessity criteria to define the extent of a benefit, manage the use of it, and make claims payment decisions. Controlling health care use and expenditures is fundamental to managing a company's insurance risk and to the financial stability of managed care and third-party reimbursement systems.

Methods of determining investigational status and medical necessity work for CAM as long as interventions fit the conventional medical model, but they often restrict the integration of, and the complementary use of, "alternative" services and products. At this time, few criteria are available to guide practitioners in deciding the medical or, more generally, the clinical necessity of CAM interventions. New medical and health services research on CAM, when published, will help to fill this need. Agencies of DHHS (including NIH, AHRQ, and CMS) could convene groups of experts and hold conferences to assess the state-of-the-science of a particular CAM approach or treatment, and develop consensus statements, guidance for clinical use, and coverage policy. Other government bodies and nongovernmental organizations could sponsor similar efforts.

Federal leadership is needed to help guide changes in health plan coverage for safe and effective CAM services and products and to develop criteria for the use of CAM interventions. The Secretary of Health and Human Services, preferably through a centralized CAM office, should work with insurance companies, health care and professional associations, health insurers and managed care companies and associations, employers, other Federal departments, States, CAM professionals and associations, benefits experts, and others to accomplish these goals.

To make coverage of CAM more readily available to consumers, private and public entities should develop clinical necessity criteria or clinical appropriateness criteria for circumstances in which CAM is proven to be safe and effective. Such circumstances could include preventing a condition or the progress of a condition, allaying symptoms or side-effects of conventional treatments such as pain or nausea, and helping patients, particularly with life-threatening illnesses, cope with their conditions.

Coverage and the Need for Authority to Practice

Coverage of and reimbursement for most health care services are linked to a provider's ability to furnish services legally within the scope of their practice. This legal authority to practice is given by the State in which services are provided. Thus, even if insurers, managed care organizations, employers, and other health

plan sponsors are interested in covering safe, cost-effective CAM interventions, they cannot do so unless there are properly licensed (or otherwise legally authorized) practitioners in a State. State laws and processes that establish professional standing protect the public by ensuring that covered health benefits are provided by qualified practitioners whose services should meet recognized standards of care. Moreover, in the absence of such laws, health insurers, managed care organizations, and any other entities that provide services would be at increased risk of liability if an adverse event occurred.

CAM practitioners qualified to furnish safe, beneficial services for which purchasers, insurance companies, managed care organizations, and other payers are willing to pay should have the ability to practice legally in their State, just as conventional practitioners do.

Other Issues

The Internal Revenue Code allows employers and other health plan sponsors to deduct the costs of providing accident and health insurance. Although the Federal code includes chiropractic and acupuncture as deductible medical expenses, the current policy approach is weighted heavily toward conventional medical care and physician direction of services. This approach could be modified to allow purchasers, health insurers, and managed care companies to develop health benefit packages that include safe and beneficial CAM interventions that qualify fully for favorable tax treatment under the law and regulations. In addition, Federal policy-makers are encouraged to monitor evidence on the benefits and cost-effectiveness of CAM interventions and health promotion programs with an eye to possible modifications of the tax code in the future.

Recommendation 24: Insurers and managed care organizations should offer purchasers the option of health benefit plans that incorporate coverage of safe and effective CAM interventions provided by qualified practitioners.

Actions

24.1 Health insurance and managed care companies should modify their benefit design and coverage processes in order to offer purchasers, for their consideration, health benefit plans that include safe and effective CAM interventions.

24.2 Health insurance and managed care companies should make use of CAM expertise in the development of benefit plans that include safe and effective CAM interventions.

24.3 Health insurers, managed care organizations, CAM professional associations,

CAM experts, private organizations that develop medical criteria, and Federal agencies are encouraged to develop appropriate clinical criteria and guidelines for the use of CAM services and products.

Recommendation 25: Purchasers, including Federal agencies and employers, should evaluate the possibility of covering benefits or adding health benefit plans that incorporate safe and effective CAM interventions.

Actions

25.1 Employers, Federal agencies, other purchasers and sponsors should enhance the processes they use to develop health benefits and give consideration to safe and effective CAM interventions.

25.2 Public purchasers such as the Centers for Medicare and Medicaid Services and the Department of Defense, employers, other health benefit sponsors, and health industry organizations should include CAM practitioners and experts on advisory bodies and workgroups considering CAM benefits and other health benefit issues.

25.3 The Secretary of Health and Human Services, preferably through the Federal CAM coordinating office when established, should maintain a list of opportunities for CAM experts to participate on advisory committees and other workgroups.

25.4 The Secretary of Health and Human Services should direct agencies under his authority to convene workgroups and conferences to assess the state-of-the-science of CAM services and products and to develop consensus and other guidance on their use.

25.5 State governments should consider, as part of evaluating and reviewing their regulations, how regulation of CAM practitioners could affect third-party coverage of safe and effective CAM interventions.

References

1. Current Population Survey. Annual Demographic Survey, March Supplement. A Joint Project Between the Bureau of Labor Statistics and the Bureau of the Census. Available on-line at http://ferret.bls.census.gov/macro/032001/health/h01_001.htm.

2. Centers for Medicare and Medicaid Services, Office of the Actuary. National Health Expenditure Projections. Available on-line at: http://www.hcfa.gov/stats/NHE-Proj/proj2000/tables/t3.htm.

3. Data provided by William M. Mercer, Inc. Mercer/Foster Higgins National Survey of Employer-Sponsored Health Plans, 1998, 1999, 2000.

4. Shekelle PG, Rogers WH, Newhouse JP. The Effect of Cost Sharing on the Use of Chiropractic Services. Medical Care 1996; 34:863-872.

5. Wolsko PM, Eisenberg DM, Davis RB, et al. Insurance Coverage, Medical Conditions, and Visits to Alternative Medicine Providers. Archives of Internal Medicine 2002; 162:281-287.

6. International Society of Certified Employee Benefit Specialists. Health Benefits for Alternative Medicine: Is There a Fit? Census Survey of Certified Employee Benefit Specialists, 1999. Available on-line at: http://www.ifebp.org/knowledge/recen99a.asp.

7. Pelletier KR, Astin, JA. Integration and Reimbursement of Complementary and Alternative Medicine by Managed Care and Insurance Providers: 2000 Update and Cohort Analysis. Alternative Therapies in Health and Medicine 2002; 8(1): 38-48.

8. Korn A. Testimony before the White House Commission on Complementary and Alternative Medicine Policy, May 2001.

9. Kelly J. Testimony before the White House Commission on Complementary and Alternative Medicine Policy, May 2001.

10. Francis M. Testimony before the White House Commission on Complementary and Alternative Medicine Policy, May 2001.

11. Ornish DM. Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project. American Journal of Cardiology 1998; 82:72-76.

12. Silberman A. unpublished data of Lifestyle Advantage, Highmark Blue Cross Blue Shield, Pittsburgh; 2001 and 2002.

13. Eddy DM. Assessment of Intensive Lifestyle Changes for the Treatment of Coronary Artery Disease, 2000.

14. Sobel DS. The Cost-Effectiveness of Mind-Body Medicine Interventions. In: Mayer EA, Saper CB, eds. The Biological Basis of Mind Body Interactions: Progress in Brain Research 2000; 122: 393-412.

15. Kruger JM, Helmick CG, Callahan LF, et al. Cost-Effectiveness of the Arthritis Self-Help Course. Archives of Internal Medicine 1998; 158:1245-1249.

16. Lorig KR, Sobel DS, Stewart AL, et al. Evidence Suggesting That a Chronic Disease Self-Management Program Can Improve Health Status While Reducing Hospitalization. Medical Care 1999; 37:5-14.

17. Caudill M, Schnabel R, Zuttermeister P, et al. Decreased Clinic Use by Chronic Pain Patients: Response to Behavioral Medicine Interventions. Journal of Clinical Pain 1991; 7(4): 305-310.

18. Bennett HL. A Comparison of Audiotaped Preparation for Surgery: Evaluation and Outcomes. Paper presented at the annual meeting of the Society for Clinical and Experimental Hypnosis. Reported in H Dreher. Mind-Body Interventions for Surgery: Evidence and Exigency. Advanced Mind-Body Medicine 1998; 14:207-222.

Chapter 8: CAM in Wellness and Health Promotion

In recent years, people have come to recognize that a healthy lifestyle can promote wellness and prevent illness and disease, allowing them to enjoy a long, high-quality life. To achieve this goal, many people have used various approaches, including complementary and alternative medicine (CAM).

Wellness is defined in many different ways, but all agree that it is more than the absence of disease. For some it is the achievement of one's fullest potential, for others it is an integration of body, mind, and spirit. Wellness can include a broad array of activities and interventions that focus on the physical, mental, spiritual, and emotional aspects of one's life.

Since the publication of Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention in 1979,[1] the U.S. Public Health Service has led an initiative to define goals and objectives for the health of the U.S. population and to direct resources for improving the Nation's health. The goals and objectives are updated periodically, along with a progress report on their attainment, and have been published as Healthy People 2000[2] and 2010.[3] Long-range goals and objectives for Healthy People 2020 are currently being developed.

As the Healthy People 2000 and 2010 reports illustrate, approaches to improving health and wellness, preventing illness and disease, and managing disabilities and chronic conditions require the involvement of a wide range of disciplines and social institutions. The effectiveness of the health care delivery system in the future will depend upon its ability to make use of all approaches and modalities that provide a sound basis for promoting optimal health. People with better health habits have been shown to survive longer and to postpone and shorten disability.[4] CAM practices such as acupuncture, biofeedback, yoga, massage, and tai chi, as well as certain nutritional and stress reduction practices, may be useful in contributing to the achievement of the nation's health goals and objectives.

Helping people achieve a healthy, meaningful, and long life is the fundamental purpose of all health care systems. In the United States, great strides have been made in conquering disease and extending life, and the health care system reflects these remarkable scientific advances. Yet in the quest to conquer illness and disease, national wellness and prevention efforts have been focused primarily on immunizations, disease screening and monitoring (e.g., pap smears blood pressure checks), and services offered in response to an already identified illness or condition (e.g., physical therapy after stroke, nutritional counseling for diabetics). With some notable exceptions, wellness and health promotion have, for the most part, been left to the initiative and discretion of the individual. The

Commission believes that it is time for wellness and health promotion to be a national priority and for the role of CAM in these efforts to be explored further. The concomitant rise of interest in CAM and in wellness and prevention presents many new and exciting opportunities for the health care system. There is evidence that certain CAM practices, when administered by properly trained practitioners, may be beneficial. Evaluating safe and effective CAM practices and products to determine their applicability to wellness and health promotion activities presents new and exciting areas to explore in the quest to improve health outcomes and quality of life.

The Role of Safe and Effective CAM Practices and Products in Promoting Wellness and Helping to Achieve the Nation's Health Promotion and Disease Prevention Goals

The most recent Federal government report on the health status of the nation, Healthy People 2010, is designed to further two overarching goals: 1) increasing the quality and years of healthy life and 2) eliminating disparities in health. These goals and objectives are the blueprint for the nation's health promotion and disease prevention activities, and they influence data collection, national health policy, and program development and implementation. Healthy People 2010 addresses clinical, behavioral, environmental, and health system issues that affect health, and it emphasizes on health education and changing the health-related behaviors of individuals and communities.

The principles that underlie CAM practices are consistent with the two overarching goals of Healthy People 2010. Several CAM practices have shown promise in addressing some of the specific objectives outlined in Healthy People 2010, such as massage therapy to reduce the limited activity caused by 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). These and other CAM practices and products that have been shown to be safe and effective should be evaluated to determine their potential for helping to achieve the nation's health promotion and disease prevention goals and objectives.

The Healthy People Consortium, which includes over 600 Federal, state, and national organizations, should form a working group to evaluate the potential impact of safe and effective CAM practices and products on the nation's leading health indicators (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). Strategies, including demonstration projects, should be developed to incorporate CAM practices and products found to have potential benefit to address these indicators and promote healthy lifestyles.

Wellness and Health Promotion for Children

For no other group is the learning and adoption of healthy behaviors and lifestyle choices more important than for children and young people. Although many programs address some of the pressing issues facing American youth, the statistics remain sobering, with unintentional injuries, homicides, and suicides accounting for the majority of deaths between the ages of 1 and 24.3 Serious, chronic conditions are beginning earlier in life, as shown by the recently released The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity.[5] This report highlights many of the health issues facing children who are overweight, including heart disease, diabetes, and depression, and states that risk factors for heart disease (e.g., high cholesterol and high blood pressure) occur with increased frequency among overweight children. Numerous reports have cited the dramatic increase of Type II diabetes in children and adolescents in recent years, which is also strongly associated with being overweight.[6,7]

- Added sugar and discretionary fat make up 40 percent of the total energy intake of children in the United States, and only about 1 percent of children are meeting the recommendations of the Department of Agriculture's Food Guide Pyramid,8 despite research showing that poor nutrition can have lasting effects on children's behavior, school performance, and overall cognitive development.[9]

- Daily participation in physical education classes by high school students dropped from 42 percent in 1991 to 29 percent in 1999, even though physical activity is known to have many beneficial effects on health, including reduced anxiety and stress and increased self-esteem.[10]

- By the time they are 7 years old, almost 13 percent of children are seriously overweight.[11] Studies have shown that obese children and adolescents are more likely to become obese adults.[12]

- Despite public health efforts to curb smoking, 36 percent of high school students smoke and 70 percent have tried cigarettes.[13]

- Seventeen percent of high school students have carried a weapon in the past month, and 19 percent have seriously considered suicide in the past year.[14]

- Among children age five to 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.[3] Behavioral and mental health problems, especially depression and attention deficit disorder, are widespread, and substance abuse continues to be a problem, including the so-called performance-enhancing drugs used in sports.

Early interventions that promote the development of good health habits and attitudes could help prevent many of the negative behaviors and lifestyle choices that begin early in life. Poor dietary habits, lack of exercise, smoking, suicide, substance abuse, homicide, and depression are a silent epidemic among young people and should be considered a national priority.

While many individual programs address these problems, safe and effective CAM principles and practices should be evaluated to determine their potential role in transforming the unhealthy behavior responsible for U.S. youths' dismal health statistics. Those CAM principles and practices that have been shown to be appropriate for children and young people should be included as part of a national effort and involve all sectors of the community, especially the schools.

Parents, schools, communities, businesses, influential individuals, and the media should become part of a national campaign to heighten children's interest in and awareness of health issues, including how their behavior affects their life and environment and how they can establish good habits for coping with life's stresses. This effort could be similar to other national initiatives, such as those to increase seat belt use, decrease alcohol consumption when driving, and modify other behaviors that impact on public health.

Schools are a particularly important part of any strategy. Schools provide activities and services to promote students' physical, emotional, and social development and they usually require that some form of health education be taught. The teaching of safe and effective CAM practices in schools to improve nutrition, reduce stress, resolve conflicts, and develop healthy lifestyles should be evaluated to determine if it can complement the efforts already under way to improve the health and well-being of young people. School programs are locally designed and implemented, and what works in one community may not work in another. Therefore, it is essential that members of the local community (children, parents, teachers, school boards, and others) be involved in these activities.

The Centers for Disease Control and Prevention has developed guidelines for schools to use to increase physical activity, promote healthy eating, prevent tobacco use and addiction, and prevent HIV infection.[14] The Health Resources and Services Administration, in conjunction with the American Academy of Pediatrics, is developing guidelines for schools that address comprehensive physical and mental health and safety programs. Other Federal organizations, such as the Department of Agriculture, also produce information to assist schools in promoting health. A public-private working group should be established to evaluate the applicability of safe and effective CAM practices and products to existing guidelines. In addition to representatives from Federal organizations, CAM professionals, and parent and teacher groups should be included, and the guidelines should reflect the cultural diversity in school systems. Innovative programs that are successfully addressing wellness promotion and disease

prevention in schools should be identified so that other schools can learn from them and, if appropriate, 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 students. This is part of the Teens Eating for Energy and Nutrition at Schools (TEENS) program, which encourages adolescents to adopt good dietary habits to reduce their risk of cancer risk.[15] Some elementary, middle, and high schools in New York and California are offering yoga classes as part of their health or physical education curricula. The reported benefits include increased concentration, reduced impulsive behavior, and increased self-esteem.[16]

Wellness and Health Promotion in the Workplace

Most adults in the United States spend a large part of their lives in the workplace, and employers spend an average of $2,400 per employee for single coverage and $6,900 for family coverage annually.[17] Premiums rose an average of 11 percent from 2000 to 2001, with small firms bearing a disproportionate share of that increases.[17] Data consistently show that high levels of stress, excessive body weight, and multiple risk factors are associated with increased health care costs and absenteeism, and that health promotion programs in the workplace can lower health care and insurance costs and decrease absenteeism.[18]

- One study showed an average decrease of $129 in health care costs 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.[19] In another study, a health promotion program for retirees was introduced at a cost of $30 per person, resulting in a $164 per person decrease in insurance claims.[20]

- A national manufacturing company reported a decrease of over 12 percent in illness days for employees in a health promotion program.[21] Some health promotion programs have yielded an eightfold return on investment in the form of reduced health care costs and absenteeism.[22]

The Department of Health and Human Service's Division of Federal Occupational Health helps Federal organizations improve the health, safety, and productivity of their workforce. It provides comprehensive medical, nursing, and wellness and fitness services at Federal workplaces around the country and serves more than 300 agencies with 1.6 million employees. Other Federal organizations may offer their employees wellness programs as well.

Many health promotion programs in the workplace focus on reducing risk factors for illness by encouraging weight loss, smoking cessation, and stress reduction. Studies have shown that stress reduction techniques such as yoga and

meditation are beneficial. Evaluations should be conducted to determine the role of safe and effective CAM practices and products in the workplace, and incentives should be developed to encourage those found to be beneficial.

Incentives to include CAM in wellness programs and health coverage will vary with the size of the business. For example, larger companies that negotiate health plans through a union will require a different set of incentives than small companies that may only offer limited or no coverage. Some incentives currently exist but have not been evaluated for their effectiveness. Any additional programs or services will have start-up costs that may deter some companies from offering them.

Recommendation 26: The Department of Health and Human Services and other Federal agencies and public and private organizations should evaluate CAM practices and products that have been shown to be safe and effective to determine their potential to promote wellness and help achieve the nation's health promotion and disease prevention goals. Demonstration programs should be funded for those determined to have benefit.

Actions

26.1 The Healthy People Consortium should evaluate the role of safe and effective CAM practices and products in addressing the[10] leading health indicators and develop strategies, including demonstration programs, to encourage the use of CAM practices and products found to be beneficial in addressing these indicators.

26.2 Questions on the extent and use of CAM products and practices should be included in national surveys and other assessment tools including the National Health Interview Survey, the National Health and Nutrition Examination Survey, and the Medical Expenditure Panel Survey. Where appropriate, information from these sources should be incorporated into the Healthy People 2020 goals and objectives.

26.3 The Department of Health and Human Services, as part of the Healthy People 2010 initiative, should support the development of a national campaign to teach and encourage behaviors that focus on improving nutrition, promoting exercise, and teaching stress management for all Americans, especially children. This campaign should include safe and effective CAM practices and products where appropriate.

26.4 The Federal government, in partnership with public and private organizations, should evaluate safe and effective CAM practices and products to determine their applicability to improving nutrition, promoting exercise, and teaching stress management to children. Demonstration programs should be funded for those found to be applicable to children.

26.5 The Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Department of Agriculture, the Department of Education, and other Federal agencies that develop school health guidelines should evaluate the potential applicability of safe and effective CAM practices and products to these school health guidelines. Those found to have benefits should be included in the guidelines.

26.6 Federal agencies, in partnership with the business community, should develop incentives for schools to make lunches and snacks healthful, and to limit the sale-and eliminate the advertising-of high-fat snacks, soft drinks, and other products that do not contribute to healthy lifestyles

26.7 The Department of Health and Human Services and the Department of Labor should evaluate safe and effective CAM practices and products to determine their potential role in workplace wellness and prevention activities, and include them in Federal workplace wellness and health promotion programs and Federal health coverage plans when appropriate.

26.8 Federal agencies, in conjunction with the business community, should develop incentives for employers to include CAM practices and products found to be beneficial in wellness and prevention activities in their workplace wellness programs and health coverage.

The Role of Safe and Effective CAM Practices and Products in Health Care Delivery Systems and Health-Related Programs to Help Promote Wellness and Health and Prevent Disease

Federal/State Programs and Systems

The Federal government funds many programs that serve vulnerable populations. Among them are Head Start; Meals on Wheels; Special Supplemental Nutrition Program for Women, Infants and Children; Healthy Mothers/Healthy Babies; the State Children's Health Insurance Program, and programs for people with disabilities. These programs have a direct impact on the health and quality of life of the people they serve and may benefit from a wellness and prevention component that includes safe and effective CAM practices and products.

The agencies that administer these programs should evaluate safe and effective CAM practices and products to determine their applicability to these programs and fund demonstration programs for those found to be applicable. An example of CAM practices and products that might be considered is teaching children in Head Start programs to breathe deeply as a relaxation technique. The State Children's Health Insurance Program might consider whether chiropractic

services would be appropriate for this population, and Meals on Wheels might re-evaluate the type of food being served. Appropriately trained CAM providers should be part of the evaluation and decision-making process.

Federally funded health care delivery programs should also evaluate the applicability of CAM wellness and prevention activities into their services. This includes the Department of Veterans Affairs, which has 172 hospitals and more than 500 other health care facilities serving 25 million persons; the Indian Health Service, serving 1.5 million American Indians and Alaskan Natives; community and migrant health centers, serving more than 10 million people who otherwise would not have access to care; maternal and child health programs; and school health programs. Demonstration programs should be funded for those CAM practices and products found to benefit these populations.

Public and Private Programs and Systems

Much of the research, education, training, services, reimbursement, and information development and dissemination activities of the health care system is directed toward identifying and treating diseases and conditions. Although many hospitals have begun to offer community programs that focus on wellness and prevention, these activities often occur outside the system of primary health care and rely upon consumers' knowing that these activities exist, belief in their potential benefit, ability to pay for them out-of- pocket, and ability to access them.

Public and private health care programs and systems should evaluate safe and effective CAM practices and products to determine their role in wellness and prevention activities for individuals and communities. The Department of Health and Human Services should help bring together organizations from the private and public sectors for this purpose and help to develop strategies to promote the use of those found to be beneficial. Representatives of national, state, and local organizations of clinicians, administrators, health plans, pharmacists, nurses, mental health professionals, consumers, and others from hospitals, long-term care facilities, and programs serving the aging, the dying, and those with disabilities or chronic illness should be included with CAM professionals and institutions in this process.

Recommendation 27: Federal, state, public, and private health care delivery systems and programs should evaluate CAM practices and products to determine their applicability to programs and services that help promote wellness and health. Demonstration programs should be funded for those determined to be beneficial.

Actions

27.1 The Secretaries of Health and Human Services, Agriculture, Veterans Affairs, and Defense and the Commissioner of the Administration for Children and Families, should evaluate safe and effective CAM practices and products that contribute to wellness and health and determine their applicability to Federal health systems and programs.

27.2 The Secretary of Health and Human Services should facilitate the bringing together of public and private health care organizations to evaluate safe and effective CAM practices and products that contribute to wellness and health and determine their applicability to health systems and programs, especially in the nation's hospitals and long-term care facilities and in programs serving the aging, those with chronic illness, and those at the end of life.

27.3 CAM and conventional health professional training programs should consider offering training and educational opportunities for students in self-care and lifestyle decision-making to improve practitioners' health and to enable practitioners to impart this knowledge to their patients or clients.

The Role of Safe and Effective CAM Practices and Products in Wellness and Health Promotion and the Application of CAM Principles and Practices to the Management of Chronic Disease

Although a significant percentage of people who use CAM practices and products do so to prevent disease and promote health, more information is needed on how CAM approaches can improve wellness and promote health. A related but largely unexplored area is the application of CAM wellness and prevention practices to the management of chronic disease. CAM principles and practices may be useful not only in preventing some of these diseases and conditions, but also in enhancing recovery and preventing further illness. Increased research in this area will help to determine how CAM principles and practices can best be used to meet the goals of the health care system.

The core philosophy and orientation of many CAM systems is to support and stimulate the inherent healing capacities of the individual. For example, Traditional Chinese Medicine practitioners focus on maintaining the flow of "qi" and "blood" to balance "yin" and "yang" for the maintenance of good health. Ayurvedic medicine emphasizes early detection and balancing of "doshas" to prevent disease and pathology. Other CAM modalities, such as chiropractic and naturopathic medicine, seek to enhance the body's natural healing system to prevent, treat, and cure disease. A significant portion of the adult population takes supplements and herbs to maintain health.

Although many CAM systems and practitioners emphasize the health-promoting nature of their approaches and interventions, research is needed to determine

which ones are or might be useful for improving overall health and preventing disease. A systematic review of research to evaluate CAM approaches to health promotion would help identify promising areas for further research and development. In addition to the Federal government, private organizations such as the Institute of Medicine and the American Public Health Association should provide leadership in this area, including assistance in determining how CAM may contribute to the goals of Healthy People 2010 and the development of Healthy People 2020.

Recommendation 28: Research on the role of CAM in wellness and health promotion, the application of CAM principles and practices, and the role of CAM practitioners in the management of chronic disease should be expanded.

Actions

28.1 The Department of Health and Human Services should fund demonstration projects to evaluate the clinical and economic impact of comprehensive health promotion programs that include CAM. These studies should include underserved and special populations.

28.2 The Federal government and private health organizations should evaluate CAM practices and products that are currently being used for wellness and health promotion to determine their effectiveness and applicability to the management of chronic disease. Funding should be provided for demonstration projects in the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs, the Department of Defense, the Health Resources and Services Administration, and other Federal agencies for those CAM practices and products found to have benefit in the management of chronic disease, end of life such as hospice.

References

1 U.S. Department of Health, Education, and Welfare, Public Health Service. Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention. DHEW (PHS) Publication No. 79-55071. U.S. Government Printing Office, 1979.

2 U.S. Department of Health and Human Services, Public Health Service. Healthy People 2000: National Health Promotion and Disease Prevention Objectives. DHHS (PHS) Publication No.91-50213. U.S. Government Printing Office, 1990.

3 U.S. Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. (2nd.ed. 2 vol). Washington, D.C.:

U.S. Government Printing Office, 2000.

4 Vita A, Terry R, Hubert H, Fries J. Aging, health risks, and cumulative disability. New England Journal of Medicine 1998;338:1035-41.

5 U.S. Department of Health and Human Services. The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity. 02NLM: WD-210-S9593. Washington, D.C.:U.S. Government Printing Office, 2001

6 Deckelbaum R, Williams C. Childhood obesity: The health issue. Obesity Research 2001;9(Suppl.4):239S-43S.

7 American Diabetes Association. Type 2 diabetes in children and adolescents. Diabetes Care 2002:22(12):381.

8 Munoz K, Krebs-Smith S, Ballard-Barbash R, Cleveland L. Food intakes of US children and adolescents compared with recommendations. Pediatrics 1997:100(3): 323-329.

9 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

10 Centers for Disease Control and Prevention. Guidelines for school and community programs: Promoting lifelong physical activity. Morbidity and Mortality Weekly Report 1997;46: 1-36

11 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.

12 1Guo SS, Roche AF, Chumlea WC, Gardner JD, Siervogel RM. The predictive value of childhood body mass index values for overweight at age 35 years. American Journal of Clinical Nutrition 1994; 59:810-819

13 Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. Guidelines for School Health Programs: Preventing Tobacco Use and Addiction. February 2000.

14 Centers for Disease Control and Prevention, School Health Guidelines to Prevent Unintentional Injuries and Violence, Morbidity and Mortality Weekly Report, Vol 50: 1-46, December 7, 2001.

15 Kubik MY, Lytle LA, Story M. A practical, theory-based approach to establishing school nutrition advisory councils. Journal of the American

Dietetic Association 2001 Feb; 101 (2):223-8

16 Yoga in schools. Yoga Inside Foundation. Available on-line at: http://www.yogainside.org/who/school.html

17 Cost of Health Insurance - Employer Health Benefits 2001 Annual Survey. Kaiser Family Foundation, 2001.

18 Aldana SG. Financial impact of health promotion programs: A comprehensive review of the literature. American Journal of Health Promotion 2001;15(5):296-320.

19 Edington, DW, Tze-ching Yen L, Witting P. The financial impact of the changes in personal health practices. Journal of Occupational and Environmental Medicine 1997;39(11):1037-46

20 Fries JF, Bloch DA, Harrington H, Richardson N, et al. Two-year results of a randomized controlled trial of a health promotion program in a retiree population. American Journal of Medicine 1993;94(5):455-462.

21 Bertera R. Behavioral risk factors and illness day changes with workplace health promotion. American Journal of Health Promotion 1993;7(5):365-373.

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

Chapter 9: Coordinating Federal CAM Efforts

In the course of Commission meetings, it became clear that a wide cross-section of the population wants the Federal government to take the lead in integrating safe and effective complementary and alternative health care practices and products into the nation's health care system. Consumers, complementary and alternative medicine (CAM) and conventional practitioners, and product manufacturers testified about the need for a coordinated Federal effort to achieve this goal. This view is consistent with the findings of other groups as well. At the "Second Annual Integrative Medicine Industry Leadership Summit," held in May 2001, a major recommendation was the establishment of a Federal office of CAM and integrative health care and the selection of an advisory committee to the office.[1,2] Similarly, the creation of a Federal CAM/integrated health care office was a key recommendation of the "National Policy Dialogue to Advance Integrated Health Care: Finding Common Ground" held at Georgetown University in late 2001.[3]

Proper integration of safe and effective CAM practices and products into the nation's health care system will require an ongoing, coordinated Federal presence. The most effective means of accomplishing this goal is to establish a centralized office that would include the full range of CAM perspectives in the dialogues that guide policy formulation and implementation. Several possible locations of the office were proposed, each of which has advantages and disadvantages.

If located in the White House, the new office could be either a freestanding entity in the Executive Office of the President, following the precedent of the Office of National AIDS Policy and the Office of Faith-Based and Community Initiatives, or it could be placed in an existing office, such as the Office of Domestic Policy. A White House location would provide an opportunity to influence Federal policy, but it would not provide a permanent presence in the Federal sector. If located in the Department of Health and Human Services (DHHS), the office could be created in the Secretary's Office of Public Health and Science (OPHS), following the lead of the Office of Minority Health and the Office on Women's Health, or it could be placed within one of the 13 existing program offices that make up the OPHS-in particular, the Office of the Surgeon General. Locating it under the Surgeon General could provide links to other important public health activities, such as Healthy People 2010. While a DHHS location would provide a permanent Federal presence, it would limit the office's influence mainly to DHHS policy.

The National Center for Complementary and Alternative Medicine (NCCAM) is an example of effective Federal coordination of CAM research that evolved from an office established within DHHS. It began as the Office of Alternative Medicine in the National Institutes of Health with a $2 million budget in fiscal year 1992 and

became a national research-coordinating center with a $104.6 million budget in fiscal year 2002. The presence and focus of NCCAM in the Federal government has stimulated research well beyond the reach of its budget, with private and public organizations also contributing to increased efforts in CAM research, education, and practice in the United States and around the world.

Office of Complementary and Alternative Health Care Coordination

Three options for creating an office of complementary and alternative health care coordination are possible. First, the President could establish the office in the White House through an executive order. Second, the Secretary of Health and Human Services could establish the office in OPHS or one of its component program offices by an administrative action. Third, Congress could create the office and determine the most appropriate location through legislation, which would provide permanence, a legislative mandate, and budget appropriations.

Responsibilities of the Office

Responsibilities should include the following:

- Coordinating Federal CAM activities;
- Serving as a Federal CAM policy liaison with conventional health care and CAM professionals, organizations, educational institutions, and commercial ventures;
- Planning, facilitating, and convening conferences, workshops, and advisory groups;
- Acting as a centralized Federal point of contact for CAM for the public, CAM practitioners, conventional health care providers, and the media;
- Facilitating implementation of the recommendations and actions of the White House Commission on Complementary and Alternative Medicine Policy;
- Exploring additional and emerging topics not included in the Commission's Executive Order.

Coordinating Federal CAM Activities

Coordinating Federal CAM activities requires that the office be placed at the highest possible and most appropriate level in the Federal Government. If located in DHHS, the office would work closely with all DHHS Agencies in a manner similar to that of the minority health and women's health offices. For example, the new office would collaborate with NCCAM, the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine, the Office of Dietary Supplements at the National Institutes of Health, and other appropriate Federal Departments and Agencies.

Once established, the office will need to coordinate CAM activities all Federal CAM activities. It should form a trans-departmental CAM coordinating committee that includes representation from all Federal Departments and Agencies to facilitate its mission. Because the extent of Federal CAM activities has not been identified fully, the office should conduct a baseline survey of activities, by collecting data through the trans-departmental committee. Results of the survey could form the basis for coordinating Federal CAM activities. Because of its value to the Secretary, Administration, and Congress, this type of report on Federal CAM activities could be generated periodically to assist in making ongoing policy decisions.

Serving As a Federal CAM Policy Liaison

Another significant role of the office would be to serve as a Federal CAM policy liaison with conventional health care and CAM professionals, organizations, educational institutions, and commercial ventures. These activities are described in the recommendations and actions in the Education and Training, Information Development and Dissemination, Wellness, Access and Delivery, Coverage and Reimbursement, and Coordination of Research chapters of this report.
An important activity of the new office would be to establish an advisory council similar to NCCAM's. This group should bring together the various parties interested in CAM to develop a strategic plan that reflects public opinion. Therefore, the advisory council should include consumers and other members from outside the Federal government. The membership also should include the directors of NCCAM, the Office of Cancer Complementary and Alternative Medicine, and the Office of Dietary Supplements. In addition, it should include representatives from the Departments of Agriculture, Defense, Education, Energy, and Veterans Affairs, as well as the Centers for Medicare and Medicaid Services, the Food and Drug Administration, the White House Office of Domestic Policy, and other appropriate Federal entities.

Planning, Facilitating, and Convening Conferences, Workshops, and Necessary Advisory Groups

Public testimony stressed the importance of creating sustainable, collaborative environments in which issues of mutual concern to CAM and conventional health care can be raised, discussed, and resolved. The new office would bring together interested parties from CAM and conventional health care to design and undertake activities to meet the needs identified by the advisory council, the trans-departmental CAM coordinating committee, and the results of the survey of Federal CAM activities. By planning, facilitating, and convening conferences, workshops, and advisory groups, the new office would create unique opportunities to explore CAM issues, such as those involving product safety, licensure, or coverage and reimbursement.

Acting as a Centralized Federal Point of Contact for CAM

As a centralized Federal point of contact for CAM, the office would develop and implement a system to direct inquiries from the public, CAM practitioners, conventional health care providers, and the media to the appropriate person at the Departmental or Agency level. The office would carry out this responsibility through a network of information officers or other persons with known expertise. To transmit information readily to the public, CAM practitioners, and conventional health care providers, the office should create a website that includes information about the office and its responsibilities, a CAM events calendar, and links to Federal and other appropriate CAM websites.

Not everyone has access to the Internet, so information must be developed and made readily available to these consumers as well. Since NCCAM has a Congressional mandate "to establish a clearinghouse to exchange information with the public about alternative medicine," the new office should not undertake activities that would duplicate NCCAM's. However, additional information is needed consumes if they are to make informed decisions about CAM. The office would collaborate with Federal Departments and Agencies and the private sector to develop reliable information for dissemination through the NCCAM clearinghouse and other means that are not dependent upon the Internet.

Facilitating Implementation of Commission Recommendations and Actions

Considerable time and resources were spent in soliciting specific recommendations from the public, and this advice helped form the basis of the Commission's recommendations and actions. However, without legislative authority, staff, and a budget, the likelihood of their being successfully implemented is diminished significantly. Therefore, one of the most important roles of the new office is to facilitate implementation of the Commission's recommendations and actions.

This role would include interactions with Administration officials, members of Congress and their staffs, and relevant Departments and Agencies. Particularly encouraging is language in the Conference Report that accompanied the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2002 (Public Law 107-116), which urged the Secretary of Health and Human Services to form a coordinating unit to review the Commission's report and implement ways of improving coordination of the DHHS's many CAM-related activities.

Exploring additional and emerging topics not included in the Commission's Executive Order

Despite the comprehensive nature of the Commission's Executive Order, additional and emerging topics beyond the scope of this report will need to be addressed, and the new office would be in a position to do this. For example, the office could provide technical assistance on CAM to individual States when requested.

Recommendation 29: The President, Secretary of Health and Human Services, or Congress should create an office to coordinate Federal CAM activities and to facilitate the integration into the nation's health care system of those complementary and alternative health care practices and products determined to be safe and effective.

Actions

29.1 The office should be established at the highest possible and most appropriate level in the Department of Health and Human Services and should be given sufficient staff and budget to meet its responsibilities.

29.2 The office should charter an advisory council. Members should include CAM and conventional practitioners with expertise, diverse backgrounds, and necessary training, as well as representatives of both the private and public sectors, to guide and advise the office about its activities.

29.3 The office's responsibilities should include, but not be limited to, coordinating Federal CAM activities; serving as a Federal CAM policy liaison with conventional health care and CAM professionals, organizations, institutions, and commercial ventures; planning, facilitating, and convening conferences, workshops, and advisory groups; acting as a centralized Federal point of contact regarding CAM for the public, CAM practitioners, conventional health care providers, and the media; facilitating implementation of the Commission's recommendations and actions; and exploring additional and emerging topics not considered by the Commission.

References

1 Areas of agreement and proposed action among industry stakeholders. The Integrator for the Business of Alternative Medicine. June 2001; 5(9):2-3.

2 Weeks J. Integrative medicine industry leadership summit 2001. Accepted for publication, Alternative Therapies in Health and Medicine. March/April

2002; 8(2).

3 Zablocki E. National policy dialogue sparks discussion, finds consensus. The Integrative Medicine Consult. February 2002;4(2):13,19,23.

Chapter 10: Recommendations and Actions

COORDINATION OF RESEARCH

Recommendation 1: Federal agencies should receive increased funding for clinical, basic, and health services research on CAM.

Actions

1.1 Federal agencies should increase their activities with respect to CAM in accordance with their biomedical research, health services research, or other health care-related responsibilities and make these activities, including available technical assistance, known to CAM and conventional researchers and practitioners. Activities might include funding initiatives such as requests for applications and proposals; CAM-focused offices or centers; CAM-focused staff positions; CAM advisory committees or the representation of qualified CAM professionals on such committees.

1.2 Federal agencies should assess the scope of scientific, practice, and public interest and needs regarding CAM that are relative to their missions, examine their portfolios, and develop funding distribution strategies to address these interests and needs.

1.3 The Agency for Health Care Research and Quality together with The National Center for Complementary and Alternative Medicine should develop ways to expand health services research in CAM and explore methodologies for health services research in this area.

1.4 The Federal, private, and nonprofit sectors should support more research on (1) complex compounds/mixtures frequently found in CAM products, (2) clinical interventions consisting of multiple treatments, (3) how patient-practitioner interactions affect treatment outcomes, and (4) individualizing treatments.

1.5 In order to protect public health and maximize benefits, Congress should provide adequate public funding for research on frequently used or promising CAM products that would be unlikely to receive private research support.

1.6 The Federal government should support research on CAM practices that appear to be effective but may not be profitable to private investors, such

as biofeedback, meditation, guided imagery, art therapy, and music therapy.

Recommendation 2: Congress and the Administration should consider enacting legislative and administrative incentives to stimulate private sector investment in CAM research on products that may not be patentable.

Actions

2.1 Incentives to stimulate private sector investment in CAM research should focus on (1) research on dietary supplements and other natural products that may not be patentable; (2) research on other CAM products that may not be patentable, including therapeutic devices; and (3) the development of analytical methods for producing better quality CAM products.

2.2 The Federal and private sectors should provide support for workshops to discuss the research needed by regulatory agencies for their review and approval processes for CAM products and devices.

2.3 Federal agencies should develop outreach programs to inform manufacturers of CAM products and devices about the Federal research support available to private industry and how the agency can assist them.

Recommendation 3: Federal, private, and nonprofit sectors should support research on CAM modalities and approaches that are designed to improve self-care and behaviors that promote wellness.

Recommendation 4: Federal, private, and nonprofit sectors should support new and innovative CAM research on core questions posed by frontier areas of scientific study associated with CAM that might expand our understanding of health and disease.

Actions

4.1 The National Center for Complementary and Alternative Medicine, assisted by the Institute of Medicine of the National Academy of Sciences, should develop guidelines for establishing research priorities in CAM.

4.2 The National Science Foundation, in collaboration with The National Center for Complementary and Alternative Medicine, should examine

frontier areas of science associated with CAM that are outside the current research paradigm and methodological approaches to study them.

4.3 Multidisciplinary workshops and expert panels should be convened by Federal, private and nonprofit organizations, collaboratively or independently, to explore the challenges in design and methodology presented by research questions in CAM areas that are outside the current research paradigm.

4.4 The National Institute of General Medical Sciences of the NIH, the Department of Energy, and the Department of Defense are among the Federal organizations that should consider contributing collaboratively or independently to the support of research on core questions in areas described in many CAM systems.

4.5 The National Center for Complementary and Alternative Medicine, working with the World Health Organization, should examine investigative approaches for studying the traditional systems of medical practice from a variety of cultures.

Recommendation 5: Investigators engaged in research on CAM should ensure that human subjects participating in clinical studies receive the same protections as are required in conventional medical research and to which they are entitled.

Actions

5.1 Licensed practitioners using CAM systems and modalities who wish to conduct or collaborate in clinical research should follow the same requirements as in conventional medical research. They should develop, or partner with a research institution to develop, a scientifically valid research protocol and obtain Institutional Review Board approval to ensure that they meet accepted standards of ethical conduct and their responsibilities to protect human subjects.

5.2 Accredited CAM institutions and CAM professional organizations should establish Institutional Review Boards where possible, and guide their colleagues and members to utilize the Institutional Review Board process, which is required to conduct clinical research.

5.3 Institutional Review Boards that review CAM research studies should include the expertise of qualified CAM professionals in the review.

5.4 Research institutions, National Institutes of Health Institutes and Centers, and other Federal research and health care agencies should be more proactive in developing programs that (1) provide opportunities for expert review of promising CAM practice-based observational data by experienced researchers, (2) stimulate practitioner response to the opportunities offered by the programs and (3) facilitate communication and stimulate partnerships between CAM practitioners and conventionally-trained researchers in designing and implementing clinical studies.

Recommendation 6: The Commission recommends that state professional regulatory bodies include language in their guidelines stating that licensed, certified, or otherwise authorized practitioners who are engaged in research on CAM will not be sanctioned solely because they are engaged in such research if they:

1 are engaged in well-designed research that is approved by an appropriately constituted Institutional Review Boards,
2 are following the requirements for the protection of human subjects, and
3 are meeting their professional and ethical responsibilities. All CAM and conventional practitioners, whether or not they are engaged in research, must meet whatever State practice requirements or standards govern their authorization to practice.

Recommendation 7: Increased efforts should be made to strengthen the emerging dialogue among CAM and conventional medical practitioners, researchers and accredited research institutions; Federal and state research, health care, and regulatory agencies; the private and nonprofit sectors; and the general public.

Actions

7.1 CAM and conventional medical researchers and practitioners should adhere to the same high standards of quality and ethics in all aspects of research and related activities.

7.2 Federal agencies should develop programs to stimulate cooperation and partnerships between CAM and conventional medical professionals and accredited institutions.

7.3 Committees reviewing or advising on research, journal submissions, regulatory compliance, and health insurance coverage in both the public and private sectors should include as members or consultants trained, experienced, and properly qualified CAM health care professionals.

7.4 Multidisciplinary conferences, workshops, and expert panels on CAM research and related activities, including research methodology, should be supported independently or collaboratively by the public, private, and nonprofit sectors.

7.5 The nonprofit sector and the private sector should create funding partnerships, whether independently or with Federal agencies, to augment support for CAM research, research infrastructure and training, research conferences, and information dissemination.

7.6 The Federal government should support research, including population-based research, to learn more about why people use CAM practices and products, how they determine the safety and effectiveness of the practices and products they use, and what they find satisfying or unsatisfying about them.

7.7 To benefit patients and future research protocol development and to add to our knowledge about the use of CAM, Institutional Review Boards should consider requiring that all research subjects be asked about their use of herbal or other dietary supplements.

7.8 Federal agencies supporting biomedical and health services research should develop orientation and training programs for public representatives to enhance the effectiveness of their participation on advisory committees concerned with CAM.

Recommendation 8: Public and private resources should be increased to strengthen the infrastructure for CAM research and research training at conventional medical and CAM institutions and to expand the cadre of basic, clinical, and health services researchers who are knowledgeable about CAM and have received rigorous research training.

Actions

8.1 Funding should be made available to accredited CAM and conventional medical institutions develop programs that examine CAM research questions and that stimulate cross-institutional collaborations involving faculty and students in research and research training.

8.2 Funding should be made available to accredited CAM and conventional medical institutions support joint research and professional education and training programs to enhance the quality and clinical relevance of CAM research and link the research with evidence-based education and training of practitioners.

8.3 Federal health agencies with research training programs and responsibilities that encompass CAM-related questions should be given adequate support to increase research training in CAM.

8.4 Existing resources, such as The National Center for Complementary and Alternative Medicine-supported centers and the National Center for Research Resources' General Clinical Research Centers should be utilized to increase opportunities to conduct clinical research and training on CAM and examine the inclusion of CAM into the clinical setting.

8.5 Federal support should be increased for career development awards, including those that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards that provide the time required to mentor new CAM investigators.

Recommendation 9: Public and private resources should be used to support, conduct, and update systematic reviews of the peer-reviewed research literature on the safety, efficacy, and cost-benefit of CAM practices and products.

Actions

9.1 The Agency for Health Care Research and Quality should expand its Evidence-based Practice Center systematic reviews on CAM systems and treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria, and for identifying future research needs.

9.2 The National Center for Complementary and Alternative Medicine should issue a comprehensive, understandable, and regularly updated summary of current clinical evidence on the safety and efficacy of CAM systems and treatments for health care practitioners and the public.

EDUCATION AND TRAINING OF HEALTH CARE PRACTITIONERS

Recommendation 10: The education and training of CAM and conventional practitioners should be designed to ensure public safety, improve health,

and increase the availability of qualified and knowledgeable CAM and conventional practitioners and enhance the collaboration among them.

Actions

10.1 Conventional health professional schools, postgraduate training programs, and continuing education programs should develop core curricula of knowledge about CAM to prepare conventional health professionals to discuss CAM with their patients and clients and help them make informed choices about the use of CAM.

10.2 CAM education and training programs should develop curricula that reflect the fundamental elements of biomedical science and conventional health acre relevant to and consistent with the practitioners' scope of practice.

10.3 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.

10.4 Increased Federal, state, and private sector support should be made available to expand and evaluate CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

10.5 Expansion of eligibility of CAM students at accredited institutions for existing of loan programs should be explored.

10.6 The Department of Health and Human Services should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners enhance and/or expand health care provided by primary care teams.* This feasibility study could lead to demonstration projects to identify: 1) the type of practitioners, 2) their necessary education and training, 3) the appropriate practice settings, and 4) the health outcomes attributable to the addition of these practitioners and services to comprehensive care.

10.7 The Department of Health and Human Services and other Federal Departments and Agencies should convene conferences of the leaders of CAM, conventional health, public health, evolving health professions, and the public; of educational institutions; and of appropriate organizations to facilitate establishment of CAM education and training guidelines. Subsequently, the guidelines should be made available to the states and professions for their consideration.

10.8 Feasibility studies of postgraduate training for appropriately educated and trained CAM practitioners should be conducted to determine the type of

practitioners, practice setting, and their impact on clinical competency, quality of health care, and collaboration with conventional providers.

10.9 Practitioners who provide CAM services and products should complete appropriate CAM continuing education programs that include critical evaluation of CAM to enhance and protect the public's health and safety.

CAM Information Development and Dissemination

Recommendation 11: The Federal government should make available accurate, useful, and easily accessible information on CAM practices and products, including information on safety and effectiveness.

Actions

11.1 The Secretary of Health and Human Services should establish a task force to facilitate the development and dissemination of CAM information within the Federal government and to eliminate existing gaps in CAM information. The task force should include consumers, CAM providers, scientists, and conventional health care practitioners. Resources should subsequently be provided to close identified gaps and improve the availability, coordination, and dissemination of information.

11.2 Federal Departments and agencies with missions or activities relevant to CAM should 1) develop informational materials about CAM that are easy to understand and use, and 2) support and collaborate with national and local community leaders and CAM leaders and organizations to identify strategies for enhancing the development, availability, and accessibility of information on the safety and effectiveness of CAM practices and products.

11.3 Increased funding should be provided to the National Library of Medicine and the American Library Association to expand training of librarians to include helping consumers find information on CAM.

11.4 The Secretary of Health and Human Services should direct resources to streamline the process of identifying and making available relevant, high-quality CAM information from other countries and in other languages.

Recommendation 12: The quality and accuracy of CAM information on the Internet should be improved by establishing a voluntary standards board, a public education campaign, and actions to protect consumers' privacy.