

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 the 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 through 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 CAM⁴. 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 education⁵. 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

- 1.1 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.
- 1.2 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.
- 1.3 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.
 - 1.4 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 label⁸. 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 all⁹. An analysis of 25 ginseng products showed substantial variability in the concentration of marker compounds¹⁰.

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 diabetes¹¹. Two other herbal products were found to contain warfarin and alprazolam, prescription drugs that can cause serious health effects if not taken under medical supervision¹². 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 products¹³. In April and May 2001, two manufacturers recalled several products as a result of Salmonella contamination¹⁴.

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 substance¹⁵. Certain pyrrolizidine alkaloids, which are found in numerous plants used medicinally around the world, have been found to be harmful to the liver¹⁶.

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 1997¹⁷ and more recently by a scientific conference¹⁸. 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

- 1.1 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.
- 1.2 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.
- 1.3 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.
- 1.4 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.
- 1.5 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 osteoarthritis¹⁹, 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 hyperplasia²⁰. 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 become available, as in the case of the potential interaction between St. John's Wort (*Hypericum perforatum*) and certain prescription drugs²¹, 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 it²². 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

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 supplements²³ and an estimated \$700 million was spent by these companies in 2000 to advertise their products on television and in print²⁴. 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 sales²⁵. 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 statements²⁶. 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 hearing²⁷ 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 million²⁸.

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 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.

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