

Groft, Stephen (WHCCAMP)

From: Axelrod, Corinne (WHCCAMP)
Sent: Monday, August 27, 2001 3:05 PM
To: 'bresler@aol.com'; 'lowdogmd@aol.com'; 'georged@ashn.com'; 'chrisw@ashn.com'; 'jrsct6@cs.com'; 'tom@toms-of-maine.com'; 'joanm@toms-of-maine.com'
Cc: Groft, Stephen (WHCCAMP); Miller, Maureen (WHCCAMP); 'jsgordon@mindspring.com'; Chang, Michele (WHCCAMP); Fisher, Ken (WHCCAMP); Kaczmarczyk, Joseph (WHCCAMP); Pollen, Geraldine (WHCCAMP); 'jpswyers@starpower.net'
Subject: Group B - Info - Material for the 8/30 Conference Call

Dear **Info Workgroup** (David, Tieraona, George, Julia, and Tom),

Thanks to all of you for getting the workgroup discussion on this topic underway during my absence. Maureen did a wonderful job of putting together an initial working document, and her summary of the 8/13 conference call will help us to keep moving forward in our discussions.

Our next call is scheduled for this Thursday, August 30, from 2:00 - 4:00 pm EST. Since the discussions on the last call were on Issues 1 - 11, we will use this call to address Issues 12-15. Attached is a revised document - please let me know if you have any difficulty opening it. This is the document that we will work from on the Thursday call. To be connected to this call, please dial 1-888-677-5721, passcode 29316.

Looking forward to talking to all of you,

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Info
Workgroup.wpd

Topic: Information Development and Dissemination

Staff Lead: Corinne Axelrod

Facilitator: David Bresler, Tieraona Low Dog

Members: David Bresler, Tieraona Low Dog, Julia Scott, George DeVries, Tom Chappell

Issue 12: Adequacy of the Adverse Event Reporting (AER) System in identifying and addressing safety issues in a timely manner.

Background: The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies mostly on its adverse event reporting system to identify safety problems. The system is entirely voluntary, and events can be reported by both consumers and health professionals. However, the a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with dietary supplements.¹

Recommendations:

A) Strengthen the adverse event reporting system so that serious or clinically significant adverse events² related to dietary supplements can be identified and contained in a timely manner and associated morbidity and mortality can be reduced. This may include requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs), requiring manufacturers to register with the FDA so that the FDA can identify and contact them if an adverse event is reported, developing a data base of manufacturers and product ingredients, etc.

B) Increase outreach activities to health professionals and consumers regarding the importance of reporting adverse events and provide information on how to use the system.

Discussion: In April, 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it “an inadequate safety valve”. This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary supplements and provides numerous recommendations to improve the system. Some of these recommendations are included in the FDA’s 10- year strategic plan. Recommendations to require manufacturer and product registration and mandatory manufacturer reporting of adverse events may require legislative authority, while most recommendations can be implemented administratively with additional funding.

Challenges: May require additional resources or legislation.

¹ - DHHS, OIG, Adverse Event Reporting for Dietary Supplements, April 2001

² - These terms are defined under Medwatch and in the FDA’s Standard Operating Procedures of 1999

Issue 13: Adequacy of packaging and labeling information of dietary supplements in determining ingredients, benefits, appropriate use, and potential risks.

Background: Laboratory testing of dietary supplements has shown that some do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain ingredients other than those listed on the label. If the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences.

Product information on benefits, appropriate use, and potential risks is limited. Under DSHEA, dietary supplements do not need drug approval, but without drug approval status they can only make structure and function claims. As a result, even when there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Also, even when risk information is known such as with interactions between St. John's Wort and some drugs, this information cannot be included in the product.

Recommendation:

A) Implement the FDA's Good Manufacturing Practices (GMP) to help assure quality and consistency of dietary supplements.

B) Increase consumer information of dietary supplements through improved labeling, package inserts, and information at points-of-sale. Information on possible interactions with prescription or OTC drugs, foods, or other health products should be included, as well as possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

Discussion: ConsumerLab testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and phenol levels that they claimed the product contained.³ Testing of 13 SAME products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable level).⁴ Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies⁵. There are numerous other examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. The GMPs developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements.

³ - ConsumerLab.com, September 2000

⁴ - ConsumerLab.com, January 2000

⁵ - FDA

The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to “diagnose, treat, prevent, cure, or mitigate” a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent, and any realized benefits will apply to all manufactures, not just the one who prepared the application.

Challenges: The U.S. Court of Appeals for the District of Columbia, in the matter of *Pearson v. Shalala*, ordered the FDA to clarify its significant scientific agreement (SSA) standard, reevaluate some previously denied claims, and permit health claims that do not meet the SSA standard if a disclaimer can ensure that the claim will not mislead consumers. It is unclear how this will change health claims information.

Issue 14: Quality control of dietary supplements to assure consumer safety

Background: Some dietary supplements have been found to be contaminated with pesticides or infectious organisms such as salmonella..

Recommendation:

A) Implement the FDA’s Good Manufacturing Practices (GMP) to help assure the purity of dietary supplements.

B) Encourage the Department of Health and Human Services to work with the Department of Agriculture and the Environmental Protection Agency to inspect and identify sources of contamination.

C) Encourage the Department of Health and Human Services to work with the World Health Organization and other appropriate international organizations to establish guidelines for to help assure the purity of herbal ingredients.

Discussion: In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. In April, 2001, Solgar Vitamin and Herb Company recalled some dietary supplements due to salmonella contamination of raw materials supplied by American Laboratories. In May 2001, Natural Organics recalled several dietary supplements, also due to salmonella contamination of raw materials supplied by American Laboratories. The University of California, Cooperative Extension, has found toxic levels of mercury in some pills from China⁶. While the extent of contamination of dietary supplements is not known, steps

⁶ - University of California, Cooperative Extension, Environmental Toxicology Newsletter, Vol. 19, No.1, 1999

should be taken to assure that these products are free of contaminants.

Challenges: Increased product costs may result.

Issue 15: Federal oversight to assure public access to and safety of botanical products.

Background: The use of all dietary supplements has grown remarkably since DSHEA was enacted in 1994, and well-trained, highly skilled professionals are needed to provide oversight to assure public safety. Additional expert staff in botanical products are needed to provide appropriate leadership and oversight.

Recommendation:

A) Assure an adequate staff of professionals within the FDA with expertise in botanical products. This could include hiring people with these specific skills, and/or providing training to current staff.

Discussion: Only with staff that is knowledgeable in the field of botanical products can the FDA assure access to botanicals, provide appropriate oversight, and enjoy public support of their efforts.

Challenges: May require additional staff or resources.

Topic: Information Development and Dissemination

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Recommendation:

A) Assure an adequate staff of professionals within the FDA with expertise in botanical products. This could include hiring people with these specific skills, and/or providing training to current staff.

Discussion: Only with staff that is knowledgeable in the field of botanical products can the FDA assure access to botanicals, provide appropriate oversight, and enjoy public support of their efforts.

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⁶ - University of California, Cooperative Extension, Environmental Toxicology Newsletter, Vol. 19, No.1, 1999

TOPIC: CAM Information Development and Dissemination

Staff Lead: Corinne Axelrod (Maureen Miller substitute until 8/20)

Facilitators: Tieraona Low Dog and David Bressler

B . 8/13/01
4-6 p.m.**List of Issues:**

Issue 1: Consumers and the Internet: The Internet should serve as an accurate, reliable, safe, and timely source of information on CAM.

Issue 2. Availability of Consumer Information: The safe use of CAM may be enhanced by a centralized, consumer-friendly source of information.

Issue 3. Protecting Privacy: The privacy of individuals using CAM Internet sites, in particular those with an adverse health conditions, should be protected.

Issue 4. Media Information: Media coverage of and cautions about CAM services and products are often uneven, incomplete, or biased.

Issue 5. Federal Websites. Federal departments that have a role in health care can provide useful and valuable information regarding CAM products and services.

Issue 6. Accessing the Internet : Public resources for Internet guidance and use may not be familiar with CAM information or how to access such information.

Issue 7. Diverse Audiences: The barriers to gaining information about CAM for diverse groups of consumers should be removed *How do we make sure*

Issue 8. International Information: There is a wealth of information in other countries and in other languages regarding CAM therapies that is not generally available to consumers and practitioners in the U.S.

Issue 9: Marketing and Fraud: False and deceptive claims are prevalent on the Internet, creating potential harm to individuals and to the status of legitimate companies providing CAM products and practices.

Issue 10: Protecting the Vulnerable: Some populations, such as the recently arrived Hispanic immigrant population, other immigrants and non-English speaking persons, the elderly, etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television. [Huerta, 3/26/01].

Issue 11: Practitioner Qualifications: People providing CAM therapies can have significant differences in their level and type of training and it is difficult for consumers to understand the differences and make informed choices.

Issue 12: Info on Adverse Events: Minimal information on adverse events associated

*IG report**CAM Central**CAM Central*

with dietary supplements is reported or addressed by government oversight agencies.

USP **Issue 13: Product Quality Control:** Consumers purchasing and ingesting dietary supplements may not be getting the product described on the label, or the product may be adulterated or contaminated.

FDA **Issue 14: Supplement Labeling:** Information about the actions of dietary supplements that may be beneficial to consumers is currently limited and sometimes confusing.

FDA **Issue 15: Consumer Warnings:** Consumers may be unaware of possible risks of using one or more dietary supplements.

Amur **Issue 16: Qualified Professional Oversight:** The science and complex issues involved in the oversight of botanicals requires sufficient, well-trained, highly skilled professionals.

TOPIC: CAM Information Development and Dissemination

Staff Lead: Corinne Axelrod (Maureen Miller substitute until 8/20)

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A. Internet, Radio, Television, and Print Media

Issue 1: Consumer Information: The Internet should serve as an accurate, reliable, safe, and timely source of information on CAM.

Discussion: The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers. The NCCAM website reports receiving over half a million hits per month [Lui, 3/26/01], the Ask Dr. Weil site reports up to 5 million page views per month [Weil, 3/26/01], AlternativeMedicine.com reports 2 million hits per months [Goldberg, 3/26/01], and WebMD reports 4.7 unique visits last December [Detwiler, 3/26/01]. In addition to the many CAM sites, there are numerous general health information sites that include CAM information. Of concern, however, is the unevenness in quality, accuracy, accessibility, and timeliness of CAM information. Some sites maintain high standards on a voluntary basis, while many others contain inaccurate, misleading, or outdated information.

Background:

- Several organizations have developed standards for health sites on the Internet.
 - Hi-Ethics, Inc., a non-profit membership organization, has defined a set of criteria for health information on the Internet that addresses quality, privacy, and disclosure. Membership is \$20,000 annually, although membership will not be required to participate in their upcoming "E-Health Seal" program.
 - Health on the Net, a Swiss -based organization, also has a list of ethical standards for health sites that address issues such as advertising, sponsorship, etc. and does not charge for membership.
 - The Internet Healthcare Coalition charges \$50 per year for membership and has more emphasis on the quality of the information. However, none of their Board of Directors or Advisory Board members listed on their Internet site have any CAM credentials.

Challenges:

- Current efforts to set e-information standards have been voluntary and have not resolved the issues related to CAM information on the Internet.
 - Some of the members of the standard-setting groups are the very

websites that have been used as examples of the problems in CAM-related e-information, e.g., inconsistent quality, accuracy, accessibility, timeliness, etc.

- Most of these programs are focused on ethics related issues such as privacy and financial sponsorship, and not on content, and the one that does address content is composed exclusively of representatives from conventional medicine.
 - These programs have not made an impact on consumers.
- The ability to control the quality of information on the Internet is extremely limited, due to both the nature of the technology and the First Amendment protection of free speech.
 - Public-private partnerships have been a successful model in various areas of health care in the past. A government-sponsored partnership could bring more exposure, credibility, and balance to an effort to establish e-information standards for CAM.
 - There is a need for public education in the use of Internet information as a tool to guide an individual's health care and decision-making. For example, consumers need to be able to evaluate and validate the e-information.

Draft Recommendations:

1. Establish under the aegis of the Department of Health and Human Services a public-private partnership to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM Internet sites, as well as disclosure of any conflicts of interest.
2. Establish an oversight board and develop an ongoing process to review those websites that agree to participate for compliance with these standards. Sites reviewed and found in compliance with the criteria should publicize this achievement and display a logo identified with this level of merit.
3. Conduct a public education campaign that teaches people how to evaluate CAM information on the Internet. [Note: Do we want to add a recommendation to build into high school information technology course curriculum techniques and skills at evaluating Internet information, such as on health care?]

Issue 2. Availability of Consumer Information: The safe use of CAM may be enhanced by a centralized, consumer-friendly source of information.

Discussion: Consumers, who are increasingly using CAM services and products, currently obtain much of their information about CAM through word-of-mouth, magazine and newspaper articles, books, and Internet sites. Currently, most information sources

are unchecked and unmonitored and may not meet appropriate (and needed) standards. On the other hand, accurate and reliable sources of information may not be readily available to many consumers. There is no centralized source of information in the Federal government or the private sector that provides information on CAM topics, other than research findings, such as types of CAM modalities, training and licensure of practitioners, access, costs and reimbursement, wellness, self-care, herbs, botanicals, legislation, disease-specific information, etc. Easily available information about CAM would enhance the health and safety of consumers using or with the intent to use CAM services and products.

Background:

- NCCAM contracts with a clearinghouse to provide information on research findings to the public. NCCAM has invested a substantial amount of time and resources to develop a clearinghouse for CAM information related to research.
- Other agencies, such as the FDA, have clearinghouses for consumer information, but these do not specifically address CAM.
- Neither NCCAM nor any other Federal agency has been authorized to provide more comprehensive information on CAM.

Challenges:

Draft Recommendations:

4. Form a task force to determine and make recommendations as to how the Federal government could provide comprehensive CAM information to the public. This may include:
 - a. Expanding the scope of NCCAM's clearinghouse activities;
 - b. Requiring other agencies such as the FDA, CDC, HRSA, etc. and other Departments such as the Department of Education and the Department of Agriculture to provide CAM information relevant to the mission and activities of those organizations;
 - c. Establishing a centralized source of CAM information in DHHS to coordinate and develop CAM information for the public; etc.
5. Establish a clearinghouse of comprehensive CAM information for public use (based on the previous recommendation).

Issue 3. Protecting Privacy: The privacy of individuals using CAM Internet sites, in particular those with an adverse health conditions, should be protected.

Discussion: Information technology that tracks Internet sites accessed by individuals and other patterns of individual use is emerging and already used in e-commerce. Such technology creates the possibility of expanding markets for profiles about

individuals, including insurance companies and potential employers who, in turn, could use such information to make decisions regarding health insurance coverage, employment, etc. While there is no documented evidence that this is occurring, the possibility exists and steps should be taken to prevent this from becoming a problem.

Background:

- About 60 million American adults have used the Internet for health information [Raine, 3/26/01]. Some studies show that 70% of health seekers search for illness-related information, compared to only 13% for health or wellness related information [Detwiler, 3/26/01].
- Some 85% of health seekers on the Internet say they are concerned about their insurance company finding out such information and changing their insurance status or rates [Raine, 3/26/01].
- [Insert information about the HIPAA legislation and recent regulations, and other pertinent background info.]

Challenges:

- [Insert information regarding the insurance, managed care, and employers' concerns regarding Internet privacy requirements, e.g., the lack or limits of available security technology.]
- [Insert information regarding the Secretary of DHHS's recent statements that he may modify the HIPAA regulations.]

CAM control to protect
in

Draft Recommendations:

6. Encourage CAM sites to disclose if users are tracked and how that information is used, including whether such information is sold to third parties.
7. Explore the necessity of developing or amending current legislation or regulations to assure the protection of privacy of CAM health information seekers on the Internet.

Issue 4. Media Information: Media coverage of and cautions about CAM services and products are often uneven, incomplete, or biased.

Discussion: Media sources reporting on health matters utilize nationally recognized authorities, such as Federal agencies, professional associations, or a health-specific organization (e.g., Alzheimer disease, diabetes). For CAM, however, the availability of objective, comprehensive information for the media is compromised by the lack of a centralized or singular authority. Even the Federal government is hampered in reporting its efforts and activities because it does not have a central place for the media to contact on CAM [Schardt, 3/26/01].

Background:

- NCCAM is used as a resource by the media, but its legislative mandate is limited primarily to research and the Center is not a comprehensive authority for CAM.

Challenges:

- The news media works on very short timelines and when they have a breaking story related to CAM, they need to have a centralized source in the government to verify the information and provide balance to their stories. This would also include referrals to experts in different areas of CAM
- At this stage, the Federal government may be the appropriate central source of objective, comprehensive information for all aspects of CAM.

Draft Recommendations:.

8. Create a centralized office in the Office of the Secretary, DHHS, for information on CAM, with links to other resources such as the NCCAM. (See Group F)

Issue 5. Federal Websites. Federal departments that have a role in health care can provide useful and valuable information regarding CAM products and services.

Discussion: There are many government agencies that provide information on diseases, conditions, or products and do not include any information on CAM in their fact sheets or Internet sites. In addition, consumers often turn to federal agencies as an information resource to help assure that they are obtaining safe and effective health care services.

Background:

- There has been some discussion to having the government develop a new web site that would list pros and cons of various therapies and interventions, much like a voter pamphlet provides both sides of an issue. While the concept has some merit, it may be more cost-effective and acceptable to have existing government web sites utilize this format to provide balanced information.
- There are numerous types of CAM providers with different levels of training and it is difficult for the public to understand the differences between them and make informed choices. This is due to several factors, including the variability of state scope of practice acts, the lack of definition of some professions (e.g., [Herbalist]), and the use of the same title by people of different levels of training (e.g., professional acupuncturists and physicians can both be called [acupuncturist]).

Challenges:

- Consumers have no easy way of determining the training and quality of people offering CAM services or products.

- To help assure public safety, information should also be available on any disciplinary actions against a practitioner.

Draft Recommendations:

9. Direct all government agencies involved with health to include CAM-related information on their fact sheets and internet sites as appropriate. This could include information on wellness and CAM, CAM preventive and therapeutic measures, information relevant to specific diseases or conditions where appropriate, advise for patients to tell their physicians about any vitamins, herbals or botanicals they may be taking, etc. This information should emphasize CAM as part of the whole person wellness and healing process in concert with conventional care.
10. Encourage government sites that provide CAM information to describe both benefits and cautions where appropriate,
11. Government Internet sites should provide information describing the training and certification requirements of CAM professionals, and link to states to provide information on licensure.
12. Government Internet sites should have links to state licensing and disciplinary information sites.

Issue 6. Internet Access: Public resources for Internet guidance and use may not be familiar with CAM information or how to access such information.

Discussion: While the use of the Internet has proliferated, there are still many people, especially elderly and low-income people, who do not have personal access to the Internet or knowledge of how to use the internet for CAM information. People without home or work access to the Internet often will use publicly available resources to research information.

Background:

- Public libraries exist in most communities and are a source of both Internet access and guidance. However, many librarians lack training on how to access CAM information on the Internet.
- The NLM has begun working directly with public libraries through the ALA to train local librarians to use the Internet to find health information [Kotzin, 3/26/01]. This effort could be enhanced to include more training and more focus on CAM.

Challenges:

Draft Recommendations:

13. In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the Internet.

Issue 7. Diverse Audiences: The barriers to gaining information about CAM for diverse groups of consumers should be removed

Discussion: Much of the information on CAM may be written at a level that is difficult to understand by significant numbers of consumers, many of whom may be using CAM services and products. For persons of diverse racial, ethnic or cultural origins, little or no information about their traditional healing practices may be available. The latter situation could be particularly challenging for conventionally-trained health professionals working with individuals who use such traditional practices.

Background:

- According to the 1992 National Adult Literacy Survey, 48% of U.S. adults, or close to 100 million Americans, have very limited literacy skills [U.S. Dept. of Ed, Natl. Center for Education Statistics, 1992]. Factors that contribute to this are 1) lack of English skills, 2) reading disabilities, and 3) under-education [ibid.]. While the use of CAM among this population is unknown, it is believed that a substantial number use CAM. [Huerta, 3/26/01].

Challenges:

- Even for those without difficulty reading, there is a lack of CAM information that is targeted to specific population groups, despite the numerous indications that there is great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups.

Draft Recommendations:

14. Promote the development of CAM information materials at a reading level that the general public can understand and utilize.
15. Promote the development of CAM information that is targeted to different population groups.

Issue 8. International Information: There is a wealth of information in other countries and in other languages regarding CAM therapies that is not generally available to consumers and practitioners in the U.S.

Discussion: Lack of information on effectiveness of CAM therapies is often cited as reason to not provide or reimburse for these services, but there is a significant amount

of high quality CAM information published in other countries that is not available in English or in the U.S.

Background:

Challenges:

Draft Recommendations:

16. Provide funding to i) identify barriers to identifying and translating relevant articles, reports, and other materials, ii) develop a strategy to overcome these barriers.

B. Advertising, Marketing, and Labeling

Issue 9: Marketing Fraud: False and deceptive claims are prevalent on the Internet, creating potential harm to individuals and to the status of legitimate companies providing CAM products and practices.

Discussion: The Federal Trade Commission (FTC), through a special initiative called Operation Cure.all, is monitoring the Internet for deceptive health claims. Under current resources, the FTC is able to pursue only a small percentage of the fraudulent claims it identifies.

Background:

- The FTC oversees advertising of products and services and brings actions against false and deceptive claims in the marketplace. To address what it calls “an epidemic of health fraud on the Internet” [Rusk, 3/26/01], the FTC established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims on the Internet.
 - Operation Cure.all is not looking exclusively at CAM related health sites, but many of the fraudulent claims are related to CAM products and services, often claiming to cure cancer, AIDS, and other diseases.
 - In one afternoon of internet surveillance, 400 clearly fraudulent health claims were identified. After sending an email warning, 80 of these sites either dropped the questionable claim or took down the site down. Of the 320 that did not respond to the email warning, the FTC was able to take action on only 2.
- Legitimate companies that comply with current anti-deception and substantiation standards can lose market share and suffer financially as a result of companies using deceptive advertising [Taylor, 3/26/01].

Challenges:

- If the perception exists that less than one percent of identified fraudulent claims are pursued, it is likely that there will be even more deceptive CAM advertising.
- Companies that invest their resources to comply with FTC regulations and provide truthful information to the public should not be put at a disadvantage in the marketplace.

Draft Recommendation:

16. Provide additional support to the FTC to identify false and deceptive CAM-related health claims on the Internet and to take appropriate action to minimize the occurrence of these claims/ Provide adequate funding to the FTC to enforce current requirements for substantiation of advertising and marketing claims.
17. Provide education to the public to assist consumers in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

Issue 10: Protecting the Vulnerable: Some populations, such as the recently arrived Hispanic immigrant population, other immigrants and non-English speaking persons, the elderly, etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television. [Huerta, 3/26/01].

Discussion: Due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, and other similar factors, certain populations are particularly susceptible to advertisements of CAM products or services that promise to cure health and other problems not addressed through the conventional health care system or through legitimate CAM providers. This not only takes money away from people who have very little, but also can delay treatment of serious conditions until they become emergencies.

Background:**Challenges:**

- The involvement of community leaders that are trusted by the populations they represent is essential to successfully educate vulnerable consumers and develop strategies to prevent their exploitation.

Draft Recommendations:

17. Provide additional support to the FTC to monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations.
18. Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for

products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Issue 11: Practitioner Qualifications: People providing CAM therapies can have significant differences in their level and type of training and it is difficult for consumers to understand the differences and make informed choices.

numerous
Discussion: People can advertise themselves as a practitioner of a CAM therapy, yet licensing requirements, certification, scope of practice, regulations, and even definitions vary considerably from state to state. An herbalist may have years of training or no training at all. Acupuncture can be practiced in some states by practitioners of other health modalities (e.g. physicians, dentists, podiatrists, etc.) with no additional training, or by someone who has spent several years in acupuncture-specific training. Some practices require licensure, others do not. Information that explains a person's level and scope of training will help consumers to make informed choices in their selection of a practitioner.

Background:

Challenges:

Draft Recommendation:

19. Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.
20. Encourage States and local governments to make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

Issue 12: Info on Adverse Events: Minimal information on adverse events associated with dietary supplements is reported or addressed by government oversight agencies.

Discussion: The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies mostly on its adverse event reporting system to identify safety problems. The system is entirely voluntary, and events can be reported by both consumers or health professionals. However, a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with dietary supplements [DHHS, OIG, Adverse Event Reporting for Dietary Supplements, 4/01].

Background:

- In April, 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it “an inadequate safety valve”. This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary supplements and provides numerous recommendations to improve the system. Some of these recommendations are included in the FDA’s 10-year strategic plan.

Challenges:

- Recommendations to require manufacturer and product registration and mandatory manufacturer reporting of adverse events may require legislative authority, while most recommendations can be implemented administratively with additional funding. The recommendations do not appear to be in conflict with the intent of DSHEA, and would be beneficial in protecting public health and safety.

Draft Recommendation:

21. Strengthen the adverse event reporting system so that serious or clinically significant adverse events related to dietary supplements can be identified and contained in a timely manner, and associated morbidity and mortality can be reduced. This may include requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs), requiring manufacturers to register with the FDA so that the FDA can identify and contact them if an adverse event is reported, and developing a data base of manufacturers and product ingredients, etc. [See Medwatch and FDA Standard Operating Procedures, 1999, for definitions.]
22. Strengthen outreach activities to health professionals and consumers regarding the importance of reporting adverse events and how to use the system.

Issue 13: Product Quality Control: Consumers purchasing and ingesting dietary supplements may not be getting the product described on the label, or the product may be adulterated or contaminated.

Discussion: Some dietary supplements do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain ingredients other than those listed on the label. If the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences, and erode consumer confidence. Adulteration and contamination of products is of equal concern.

Background:

- ConsumerLab testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and phenol levels that they claimed the product contained [ConsumerLab.com, 9/00]. Testing of 13 SAME products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable

Let's look at this a little more

level) [ConsumerLab.com, 1/00].

- Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies [FDA].
- In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. In April, 2001, Solgar Vitamin and Herb Company recalled some dietary supplements due to salmonella contamination of raw materials supplied by American Laboratories. In May 2001, Natural Organics recalled several dietary supplements, also due to salmonella contamination of raw materials supplied by American Laboratories. The University of California, Cooperative Extension, has found toxic levels of mercury in some pills from China [U. of CA, Cooperative Extension, Environmental Toxicology Newsletter, Vol 19, No. 1, 1999].

Challenges:

- There are numerous examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. The Good Manufacturing Practices (GMPs) developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements. The GMPs are currently in OMB.
- While the extent of contamination of dietary supplements is not known, steps should be taken to assure that these products are free of contaminants. (international issues?)

Draft Recommendations:

23. The FDA's Good Manufacturing Practices (GMP) for quality control, standardization, accurate labeling, should be issued and implemented.
24. Support programs in the public and private sections (e.g. U.S. Pharmacopoeia) to assess the quality of dietary supplements and develop standards for certification of composition, quality, consistency, and safety.
25. The Department of Agriculture and the Environmental Protection Agency should work together to inspect and identify sources of contamination.
26. Work with the World Health Organization to establish guidelines for to help assure the purity of herbal ingredients.

Issue 14: Supplement Labeling: Information about the actions of dietary supplements that may be beneficial to consumers is currently limited and sometimes confusing.

Discussion: Under the provisions of DSHEA, dietary supplements can make structure and function claims. Only approved drugs, however, can make claims about preventing, treating, curing, or mitigating a disease. Since drug approval is a labor-intensive process that requires substantial research, time, and money, most manufacturers of dietary supplements do not seek drug status for their products. The unintended effect is that in some instances where there is research supporting a claim by a dietary supplement for preventing, treating, curing, or mitigating a disease, dietary supplement claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA).

Background:

- The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug.
- Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to “diagnose, treat, prevent, cure, or mitigate” a disease.
- The U.S. Court of Appeals for the District of Columbia, in the matter of *Pearson v. Shalala*, ordered the FDA to clarify its significant scientific agreement (SSA) standard, reevaluate some previously denied claims, and permit health claims that do not meet the SSA standard if a disclaimer can ensure that the claim will not mislead consumers. It is too early to assess how this will change health claims information.

Challenges:

- The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent, and any realized benefits will apply to all manufactures, not just the one who prepared the application.
- While consumers need to have accurate and truthful information, they should also have access to available data to assist them in their decision making.

Draft Recommendations:

24. Include package inserts that explain current information on the product, as well as the limitations of that information.

Issue 15: Consumer Warnings: Consumers may be unaware of possible risks of using one or more dietary supplements.

Discussion: Many people have the misconception that so-called “natural” products are inherently safe. While not much is not known about safety, interactions with other drugs or foods, or the effect on various conditions or diseases, consumers should be made explicitly aware that these are all possibilities until proven otherwise. However, even when information becomes known, such as St. John’s Wort decreasing the efficacy of some drugs, that information is not included with the product.

Background:

Challenges:

Recommendations:

25. Include warnings in dietary supplements regarding interactions with other dietary supplements, drugs, OTCs, foods, or other products with which interactions may occur, or with certain health conditions. If this information is not available, the labels should state so.
26. Warnings for pediatric use, use by pregnant or nursing women, and those whose immune system is compromised should be included.

Issue 16: Qualified Professional Oversight: The science and complex issues involved in the oversight of botanicals requires sufficient, well-trained, highly skilled professionals.

Discussion: The use of all dietary supplements, including botanicals, has grown remarkably since DSHEA was enacted in 1994, yet the FDA has not received appropriations commensurate with its new responsibilities. Oversight of the composition, quality, safety, labeling, and adverse events of botanical products should be performed by professionals with expertise in botanical products.

Background:

Challenges:

- There have been recommendations to establish an Office of Botanical Products within FDA, and recommendations to establish an Office of Botanical Products outside of FDA. These recommendations stem largely from real or perceived concerns that the FDA will either not do its job in a timely, effective, or fair manner, or that it will overstep its authority and limit the access and availability of these products.
- Establishing another office within or outside of FDA would not address the lack of sufficient expertise in the government oversight of botanical products. To provide greater leadership in the oversight of botanical products, FDA needs additional funds to hire qualified expertise and train existing staff to meet the increasing and ongoing

demands of assuring both public access to and safety of botanical products.

Draft Recommendations:

27. Assure an adequate staff of professionals within the FDA with expertise in botanical products. This could include hiring people with these specific skills, and/or providing training to current staff.

Information Development and Dissemination

Staff Lead: Corinne Axelrod

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Issue 1: Accuracy, quality, accessibility, and timeliness of CAM information on the internet.

Background:

Over half of all households have computers, 90 percent of all children ages six to 17 have access to computers through their home or school, and 42 percent of all households can log onto the internet.¹ The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers, and about 60 million American adults have used the internet for health information². The NCCAM website reports receiving over half a million hits per month³, Ask Dr.Weil reports up to five million page views per month⁴, AlternativeMedicine.com reports two million hits per months⁵, and WebMD reports 4.7 unique visits last December⁶. Some sites are specific to CAM, and others are general health information sites that include CAM information.

The quality, accuracy, accessibility, and timeliness of the information vary greatly. Some sites provide accurate and current information, while many others contain inaccurate, misleading, or outdated information. The ability to assure the quality of information on the internet is extremely limited, due to both the nature of the technology and the First Amendment protection of free speech.

In a recent study, 85% of health seekers on the internet said they are concerned about their employer or health insurance company tracking their internet site visits and using that information to change their insurance status or rates⁷. Privacy protections for health information

¹ - Census Bureau Report, September 6, 2001

² - Harrison Lee Raine, WHCCAMP testimony, March 26, p195

³ - Irene Lui, WHCCAMP testimony, March 26, 2001, p16

⁴ - Andrew Weil, WHCCAMP testimony, March 26, 2001, p56

⁵ - Burton Goldberg, WHCCAMP testimony, March 26, 2001, p

⁶ - Susan Detwiler, WHCCAMP testimony, March 26, 2001, p210

⁷ - Harrison Raine, WHCCAMP testimony March 26, p201

seekers on the internet should include visits to CAM sites.

Challenges:

Several organizations have developed standards for health sites on the Internet. However, some of the members of the standard-setting groups are the very websites that have been used as examples of the problems in quality, accuracy, accessibility, and timeliness of CAM-related information on the internet. Most of these programs are focused on ethics related issues such as privacy and financial sponsorship, and not on content, and the one that does address content is composed exclusively of representatives from conventional medicine.

Public-private partnerships that include industry groups, consumers, and governments have been successful in developing guidelines and establishing standards for many products and services. A government-sponsored partnership could bring more exposure, credibility, and balance to the effort to improve the quality, accuracy, accessibility, and timeliness of CAM-related information on the internet

Regardless of efforts to develop standards and assure quality, there will always be a need for consumers to evaluate and validate information from the internet. Public education in using the internet as a source of health information can help guide an individual's knowledge and decision-making on their health.

Recommendations:

A) Form a public-private partnership to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest, and establish an oversight board and develop an ongoing process to review those websites that agree to participate for compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.

B) Conduct a public education campaign that teaches people how to evaluate CAM information on the internet. This should include partnerships with schools that use computers to develop students' skills at evaluating internet information on health care.

C) Protect the privacy of individuals using CAM internet sites by encouraging CAM sites to disclose if users are tracked and how that information is utilized, including whether that information is sold to third parties. If necessary, develop or amend current legislation or regulations to assure the protection of privacy of CAM health information seekers on the internet.

Issue 2: Adequacy and accessibility of CAM information from the Federal government.

Background:

Consumers, health professionals, and the media look to the Federal government for authoritative

information on a wide range of CAM topics. Many entities within the Federal government develop informational materials for the public, which are then put on their internet sites, as well as distributed through a clearinghouse. NCCAM has the only CAM-specific clearinghouse.

Currently, there are several Federal agencies within HHS that provide CAM- related information such as NIH (through the NCCAM, NCI, ODS, etc.), FDA (through the CFSN), and others. Information related to CAM is also available through other government agencies, such as the Departments of Agriculture, Department of Labor, Federal Trade Commission, etc. Various methods of providing information are utilized, including mailing of fact sheets and reports; the internet; or toll-free telephone numbers. Government agencies with oversight responsibilities for various aspects of health care often do not include any information on CAM in their materials, resulting in significant gaps in CAM information on diseases, health conditions, practitioners, and products. Even when CAM information is available, it is often difficult for the public to navigate the system to locate the desired information in a timely manner.

Challenges:

The provision of information on licensing and certification requirements is critical, as consumers have no easy way of determining the training and quality of people offering CAM services or products. There are numerous types of CAM providers with different levels of training and it is difficult for the public to understand the differences between them and make informed choices. This is due to several factors, including the variability of State-established Scope of Practice Acts, the lack of definition of some professions (e.g., “Herbalist”), and the use of the same title by people of different levels of training (e.g., professional acupuncturists and physicians can both be called “acupuncturist”). Also, to help assure public safety, information should also be available on any disciplinary actions against a practitioner.

The Federal government, through the General Services Administration, operates *Firstgov.gov*, a consumer-friendly search engine that searches every word of every US government document in a quarter of a second or less and links with relevant non-government sites. For people who use the internet, it is a very fast and easy way to access existing information. However, many people still don’t know of its existence.

Media coverage of CAM services and products is often incomplete, unbalanced, or biased, and there is no centralized place in the Federal government for the media to quickly get objective and comprehensive information on CAM.⁸

Recommendations:

A) Form an inter-agency task force of Federal agencies to: a) identify gaps in CAM information (e.g., information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-

⁸ - David Schardt, WHCCAMP testimony, March 26, p.228

Federal agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.

B) Establish a centralized source of CAM information in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.

Issue 3: Availability and adequacy of CAM information for diverse groups of consumers.

Background:

While the use of the internet has proliferated, there are still many people, especially elderly and low-income people, who do not have personal access to the internet or knowledge of how to use the internet for CAM information. People without home or work access to the internet often will use publicly available resources to research information. Public libraries exist in most communities and are a source of both internet access and guidance. However, many librarians lack training on how to access CAM information on the internet.

According to the 1992 National Adult Literacy Survey, 48% of U.S. adults, or close to 100 million Americans, have very limited literacy skills⁹. Factors that contribute to this are 1) lack of English skills, 2) reading disabilities, and 3) under-education¹⁰. Use of CAM among this population is believed to be substantial¹¹.

There is a lack of CAM information that is targeted to specific population groups, despite the numerous indications that there is great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups.

Challenges:

The NLM has begun working directly with public libraries through the ALA to train local librarians to use the internet to find health information¹². This effort could be enhanced to include more training and focus on CAM.

Federal agencies frequently develop informational materials to reach specific audiences. Materials are produced in many languages, and the content, pictures, and style are often altered to reach the intended population. Developing CAM materials that are targeted to different racial, ethnic, or cultural groups would be a valuable source of authoritative information to various population groups.

⁹ - U.S. Department of Education, National Center for Education Statistics, 1992

¹⁰ - *ibid*

¹¹ - Elmer Huerta, WHCCAMP testimony March 26, p.142, and Frances Brisbane, WHCCAMP testimony, March 27, p191

¹² - Sheldon Kotzin, WHCCAMP testimony March 24, p28

Recommendations:

A) In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the internet.

B) Promote the development of CAM information materials at a reading level that the general public can understand and utilize.

C) Promote the development of CAM information that is targeted to different population groups.

Issue 4: Availability of CAM information from other countries and in other languages.**Background:**

Lack of information on effectiveness of CAM therapies is often cited as reason to not provide or reimburse for these services, but there is a significant amount of high quality CAM information published in other countries that is not available in English or in the U.S.

Challenges:**Recommendation:**

A) Identify barriers to identifying and translating relevant articles, reports, and other materials; develop a strategy to overcome these barriers; assure that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

Issue 5: False and deceptive health claims on the internet.**Background:**

The Federal Trade Commission (FTC) oversees advertising of products and services and brings actions against false and deceptive claims in the marketplace. To address what they call “an epidemic of health fraud on the internet¹³,” the FTC established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims on the internet. Yet, they are only able to pursue a small percentage of the fraudulent claims identified. Some populations, such as the recently arrived immigrants, non-English speaking persons, the elderly, etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television.¹⁴

The prevalence of false and deceptive claims on the Internet are potentially harmful to individuals. Also, legitimate companies that comply with current anti-deception and

¹³ - Michele Rusk, WHCCAMP testimony, March 26, p.276

¹⁴ - Elmer Huerfano, WHCCAMP testimony March 26, p.145

substantiation standards can lose market share and suffer financially as a result of companies using deceptive advertising¹⁵.

Challenges:

Operation Cure.all is not looking exclusively at CAM related health sites, but many of the fraudulent claims are related to CAM products and services, often claiming to cure cancer, AIDS, and other diseases. In one afternoon of internet surveillance, 400 clearly fraudulent health claims were identified. After sending an email warning, 80 of these sites either dropped the questionable claim or took down the site down. Of the 320 that did not respond to the email warning, the FTC was able to take action on only 2. If the perception exists that less than one percent of identified fraudulent claims are pursued, it is likely that there will be even more deceptive CAM advertising.

Due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, and other similar factors, certain populations are particularly susceptible to advertisements of CAM products or services that promise to cure health and other problems not addressed through the conventional health care system or through legitimate CAM providers. This not only takes money away from people who have very little, but also can delay treatment of serious conditions until they become emergencies. The involvement of community leaders that are trusted by the populations they represent is essential to successfully educate vulnerable consumers and develop strategies to prevent their exploitation.

Recommendations:

A) Provide additional support to the FTC to a) identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims; b) monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations; and c) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

B) Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Issue 6: Full disclosure of training, certification, and other qualifications of CAM practitioners so consumers can make informed choices.

Background:

People providing CAM therapies can have significant differences in their level and type of training and it is difficult for consumers to understand the differences and make informed choices. People can advertise themselves as a practitioner of a CAM therapy, yet licensing requirements, certification, scope of practice, regulations, and even definitions vary considerably

¹⁵ - Sara Taylor, WHCCAMP testimony, March 26, p.288

from state to state. An herbalist may have years of training or no training at all. Acupuncture can be practiced in some states by practitioners of other health modalities (e.g., physicians, dentists, podiatrists, etc.) with no additional training, or by someone who has spent several years in acupuncture-specific training. Some practices require licensure, others do not. Information that explains a person's level and scope of training will help consumers to make informed choices in their selection of a practitioner.

Challenges:

Recommendations:

- A) Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.
- B) Encourage States and local governments to make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

Issue 7: Adequacy of the Adverse Event Reporting (AER) System in identifying and addressing safety issues in a timely manner.

Background:

The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies in part on its adverse event reporting (AER) system to identify safety problems. The AER is an important mechanism to provide consumer protection while assuring access to these products, and is an educational tool to aid in ongoing research of safety and efficacy of products. Events can be reported by both consumers and health professionals. However, the system is entirely voluntary, and a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with dietary supplements.¹⁶ Serious or clinically significant adverse events¹⁷ related to dietary supplements need to be identified and contained in a timely manner to prevent unnecessary morbidity and mortality.

Challenges:

In April 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it "an inadequate safety valve." This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary supplements and provides numerous recommendations to improve the system, some of which are included in the FDA's 10- year strategic plan. Most of the recommendations can be implemented administratively with additional funding, while some, such as mandatory manufacturer and product registration and reporting of adverse events may require legislative

¹⁶ - DHHS, OIG, Adverse Event Reporting for Dietary Supplements, April 2001

¹⁷ - These terms are defined under Medwatch and in the FDA's Standard Operating Procedures of 1999

authority.

Recommendations:

A) Strengthen the AER system by: a) encouraging voluntary registration of dietary manufacturers so that the FDA can identify and contact them if an adverse event is reported; b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs); c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients; d) simplifying the system to facilitate increased usage and easier reporting; and e) increasing outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

Issue 8: Adequacy of packaging and labeling information of dietary supplements in determining ingredients, strength, benefits, appropriate use, and potential risks.

Background:

Laboratory testing of dietary supplements has shown that some do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain ingredients other than those listed on the label. If the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences.

Some labels state that an ingredient, or mixture of several ingredients, is standardized (e.g., “the product contains 3% of a standard extract of x,” or “x is a standard extract”), but do not identify the standards against which it is compared. While some dietary supplements have industry-approved standards, many do not have any standards or their standards have not yet been scientifically confirmed. Labels claiming standardization of an ingredient or mixture product are misleading if the standard has not been fully established, and do not provide consumers with adequate information on the strength of the ingredients.

Product information on benefits, appropriate use, and potential risks is limited. Under DSHEA, dietary supplements are regulated as foods and do not have regulatory approval as drugs, and therefore can only make structure and function claims. As a result, even when there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Also, even when risk information is known, such as the interaction between St. John’s Wort and certain drugs, this information is not required be included on the product label. Public understanding of this issue is also compromised by the complexity and implications of both existing regulatory guidelines and recent court decisions which have upheld the right of commercial free speech in advertising and labeling of dietary supplements.

Challenges:

The regulation of dietary supplements and other products such as foods, prescription drugs, over-the-counter drugs, and special dietary foods is determined by the intended use of the product. Product labels must conform to the laws and regulations that govern its intended use. Thus, a vitamin or a botanical that prevents or treats a disorder must be an approved drug for this information to be included on the label. If a product is marketed as a dietary supplement, only structure and function claims can be stated on the label.

The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to “diagnose, treat, prevent, cure, or mitigate” a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent, and any realized benefits will apply to all manufactures, not just the one who prepared the application.

To increase the availability of standards, government and industry has formed a task force to validate analytical methods for botanicals and other dietary supplements. The task force includes the Association of Analytical Chemists (AOAC) International, United States Pharmacopeia (USP), American Herbal Products Association (AHPA), the FDA, NIH, and the National Institute of Standards and Technology (within the Commerce Department), and others. They are developing consensus standards on processing and manufacturing, and chemical and physical standards for composition and quality.

Recommendations:

A) Increase consumer information of dietary supplements through a) improved labeling, package inserts, and information at points-of-sale, b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products, c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

B) Require that claims of standardization be limited to products with industry-approved standards.

Issue 9: Quality control of dietary supplements to assure consumer safety.

Background:

In addition inconsistencies in the amount and purity of the listed ingredients, some dietary supplements have been found to be adulterated with pesticides, microorganisms, heavy metals, or other potentially toxic substances.

Challenges:

Testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and phenol levels that they claimed the product contained.¹⁸ Testing of 13 SAME products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable level).¹⁹ Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies²⁰. There are numerous other examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. The GMPs developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements.

In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. In April 2001, Solgar Vitamin and Herb Company recalled some dietary supplements due to salmonella contamination of raw materials supplied by American Laboratories. In May 2001, Natural Organics recalled several dietary supplements, also due to salmonella contamination of raw materials supplied by American Laboratories. The University of California, Cooperative Extension, has found toxic levels of mercury in some pills from China²¹. While the extent of contamination of dietary supplements is not known, steps should be taken to assure that these products are free of contaminants.

Recommendations:

A) Implement the FDA's Good Manufacturing Practices (GMP) to help assure the purity of dietary supplements.

B) The Department of Health and Human Services, Department of Agriculture, Environmental Protection Agency, US Customs Services, and other appropriate Federal departments and agencies should work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace.

C) The Department of Health and Human Services Department of Agriculture, Environmental Protection Agency, and others should work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

Issue 10: Federal oversight to assure public access to and safety of dietary supplements.

¹⁸ - ConsumerLab.com, September 2000

¹⁹ - ConsumerLab.com, January 2000

²⁰ - FDA

²¹ - University of California, Cooperative Extension, Environmental Toxicology Newsletter, Vol. 19, No.1, 1999

Background:

The use of all dietary supplements has grown significantly since DSHEA was enacted in 1994, and Federal and State regulatory agencies need well-trained, highly skilled professionals with expertise in dietary supplements, particularly in areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products) to assure appropriate oversight and public safety.

Challenges:

In a regulatory agency such as FDA, it is critical that staff with oversight responsibility of specific products be sufficiently knowledgeable of both the regulatory system and the products to effectively balance consumer protection and access issues. Particularly in the rapidly evolving area of botanicals, having staff with adequate expertise is essential in developing good relationships with industry and engendering consumer confidence.

Recommendation:

A) Assure an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

Information Development and Dissemination

Staff Lead: Corinne Axelrod

Members: David Bresler (Facilitator), Tieraona Low Dog (Facilitator), Julia Scott, George DeVries, Tom Chappell

Issue 1: Accuracy, quality, accessibility, and timeliness of CAM information on the internet.

Background:

Over half of all households have computers, 90 percent of all children ages six to 17 have access to computers through their home or school, and 42 percent of all households can log onto the internet.¹ The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers, and about 60 million American adults have used the internet for health information². The NCCAM website reports receiving over half a million hits per month³, Ask Dr. Weil reports up to five million page views per month⁴, AlternativeMedicine.com reports two million hits per month⁵, and WebMD reports 4.7 unique visits last December⁶. Some sites are specific to CAM, and others are general health information sites that include CAM information.

The quality, accuracy, accessibility, and timeliness of the information vary greatly. Some sites provide accurate and current information, while many others contain inaccurate, misleading, or outdated information. The ability to assure the quality of information on the internet is extremely limited, due to both the nature of the technology and the First Amendment protection of free speech.

In a recent study, 85% of health seekers on the internet said they are concerned about their employer or health insurance company tracking their internet site visits and using that information to change their insurance status or rates⁷. Privacy protections for health information

¹ - Census Bureau Report, September 6, 2001

² - Harrison Lee Raine, WHCCAMP testimony, March 26, p195

³ - Irene Lui, WHCCAMP testimony, March 26, 2001, p16

⁴ - Andrew Weil, WHCCAMP testimony, March 26, 2001, p56

⁵ - Burton Goldberg, WHCCAMP testimony, March 26, 2001, p

⁶ - Susan Detwiler, WHCCAMP testimony, March 26, 2001, p210

⁷ - Harrison Raine, WHCCAMP testimony March 26, p201

seekers on the internet should include visits to CAM sites.

Challenges:

Several organizations have developed standards for health sites on the Internet. However, some of the members of the standard-setting groups are the very websites that have been used as examples of the problems in quality, accuracy, accessibility, and timeliness of CAM-related information on the internet. Most of these programs are focused on ethics related issues such as privacy and financial sponsorship, and not on content, and the one that does address content is composed exclusively of representatives from conventional medicine.

Public-private partnerships that include industry groups, consumers, and governments have been successful in developing guidelines and establishing standards for many products and services. A government-sponsored partnership could bring more exposure, credibility, and balance to the effort to improve the quality, accuracy, accessibility, and timeliness of CAM-related information on the internet

Regardless of efforts to develop standards and assure quality, there will always be a need for consumers to evaluate and validate information from the internet. Public education in using the internet as a source of health information can help guide an individual's knowledge and decision-making on their health.

Recommendations:

A) Form a public-private partnership to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest, and establish an oversight board and develop an ongoing process to review those websites that agree to participate for compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.

B) Conduct a public education campaign that teaches people how to evaluate CAM information on the internet. This should include partnerships with schools that use computers to develop students' skills at evaluating internet information on health care.

C) Protect the privacy of individuals using CAM internet sites by encouraging CAM sites to disclose if users are tracked and how that information is utilized, including whether that information is sold to third parties. If necessary, develop or amend current legislation or regulations to assure the protection of privacy of CAM health information seekers on the internet.

Issue 2: Adequacy and accessibility of CAM information from the Federal government.

Background:

Consumers, health professionals, and the media look to the Federal government for authoritative

information on a wide range of CAM topics. Many entities within the Federal government develop informational materials for the public, which are then put on their internet sites, as well as distributed through a clearinghouse. NCCAM has the only CAM-specific clearinghouse.

Currently, there are several Federal agencies within HHS that provide CAM- related information such as NIH (through the NCCAM, NCI, ODS, etc.), FDA (through the CFSN), and others. Information related to CAM is also available through other government agencies, such as the Departments of Agriculture, Department of Labor, Federal Trade Commission, etc. Various methods of providing information are utilized, including mailing of fact sheets and reports; the internet; or toll-free telephone numbers. Government agencies with oversight responsibilities for various aspects of health care often do not include any information on CAM in their materials, resulting in significant gaps in CAM information on diseases, health conditions, practitioners, and products. Even when CAM information is available, it is often difficult for the public to navigate the system to locate the desired information in a timely manner.

Challenges:

The provision of information on licensing and certification requirements is critical, as consumers have no easy way of determining the training and quality of people offering CAM services or products. There are numerous types of CAM providers with different levels of training and it is difficult for the public to understand the differences between them and make informed choices. This is due to several factors, including the variability of State-established Scope of Practice Acts, the lack of definition of some professions (e.g., “Herbalist”), and the use of the same title by people of different levels of training (e.g., professional acupuncturists and physicians can both be called “acupuncturist”). Also, to help assure public safety, information should also be available on any disciplinary actions against a practitioner.

The Federal government, through the General Services Administration, operates *Firstgov.gov*, a consumer-friendly search engine that searches every word of every US government document in a quarter of a second or less and links with relevant non-government sites. For people who use the internet, it is a very fast and easy way to access existing information. However, many people still don’t know of its existence.

Media coverage of CAM services and products is often incomplete, unbalanced, or biased, and there is no centralized place in the Federal government for the media to quickly get objective and comprehensive information on CAM.⁸

Recommendations:

A) Form an inter-agency task force of Federal agencies to: a) identify gaps in CAM information (e.g., information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-Federal

⁸ - David Schardt, WHCCAMP testimony, March 26, p.228

agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.

B) Establish a centralized source of CAM information in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.

NCCAM required to be the Department

Issue 3: Availability and adequacy of CAM information for diverse groups of consumers.

Background:

While the use of the internet has proliferated, there are still many people, especially elderly and low-income people, who do not have personal access to the internet or knowledge of how to use the internet for CAM information. People without home or work access to the internet often will use publicly available resources to research information. Public libraries exist in most communities and are a source of both internet access and guidance. However, many librarians lack training on how to access CAM information on the internet.

According to the 1992 National Adult Literacy Survey, 48% of U.S. adults, or close to 100 million Americans, have very limited literacy skills⁹. Factors that contribute to this are 1) lack of English skills, 2) reading disabilities, and 3) under-education¹⁰. Use of CAM among this population is believed to be substantial¹¹.

There is a lack of CAM information that is targeted to specific population groups, despite the numerous indications that there is great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups.

Challenges:

The NLM has begun working directly with public libraries through the ALA to train local librarians to use the internet to find health information¹². This effort could be enhanced to include more training and focus on CAM.

Federal agencies frequently develop informational materials to reach specific audiences. Materials are produced in many languages, and the content, pictures, and style are often altered to reach the intended population. Developing CAM materials that are targeted to ~~different racial,~~ *diverse* ethnic, or cultural groups would be a valuable source of authoritative information to various population groups.

⁹ - U.S. Department of Education, National Center for Education Statistics, 1992

¹⁰ - *ibid*

¹¹ - Elmer Huerta, WHCCAMP testimony March 26, p.142, and Frances Brisbane, WHCCAMP testimony, March 27, p191

¹² - Sheldon Kotzin, WHCCAMP testimony March 24, p28

Recommendations:

A) In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the internet.

B) Promote the development of CAM information materials at a reading level that the general public can understand and utilize.

C) Promote the development of CAM information that is targeted to ^{diverse} different population groups.

Issue 4: Availability of CAM information from other countries and in other languages.**Background:**

Lack of information on effectiveness of CAM therapies is often cited as reason to not provide or reimburse for these services, but there is a significant amount of high quality CAM information published in other countries that is not available in English or in the U.S.

Challenges:**Recommendation:**

A) Identify barriers to identifying and translating relevant articles, reports, and other materials; develop a strategy to overcome these barriers; assure that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

Issue 5: False and deceptive health claims on the internet.**Background:**

The Federal Trade Commission (FTC) oversees advertising of products and services and brings actions against false and deceptive claims in the marketplace. To address what they call “an epidemic of health fraud on the internet¹³,” the FTC established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims on the internet. Yet, they are only able to pursue a small percentage of the fraudulent claims identified. Some populations, such as the recently arrived immigrants, non-English speaking persons, the elderly, etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television.¹⁴

The prevalence of false and deceptive claims on the Internet are potentially harmful to

¹³ - Michele Rusk, WHCCAMP testimony, March 26, p.276

¹⁴ - Elmer Huerta, WHCCAMP testimony March 26, p.145

individuals. Also, legitimate companies that comply with current anti-deception and substantiation standards can lose market share and suffer financially as a result of companies using deceptive advertising¹⁵.

Challenges:

Operation Cure.all is not looking exclusively at CAM related health sites, but many of the fraudulent claims are related to CAM products and services, often claiming to cure cancer, AIDS, and other diseases. In one afternoon of internet surveillance, 400 clearly fraudulent health claims were identified. After sending an email warning, 80 of these sites either dropped the questionable claim or took down the site down. Of the 320 that did not respond to the email warning, the FTC was able to take action on only 2. If the perception exists that less than one percent of identified fraudulent claims are pursued, it is likely that there will be even more deceptive CAM advertising.

Due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, and other similar factors, certain populations are particularly susceptible to advertisements of CAM products or services that promise to cure health and other problems not addressed through the conventional health care system or through legitimate CAM providers. This not only takes money away from people who have very little, but also can delay treatment of serious conditions until they become emergencies. The involvement of community leaders that are trusted by the populations they represent is essential to successfully educate vulnerable consumers and develop strategies to prevent their exploitation.

Recommendations:

resources
A) Provide additional support to the FTC to a) identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims; b) monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations; and c) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

B) Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Issue 6: Full disclosure of training, certification, and other qualifications of CAM practitioners so consumers can make informed choices.

Background:

People providing CAM therapies can have significant differences in their level and type of

¹⁵ - Sara Taylor, WHCCAMP testimony, March 26, p.288

training and it is difficult for consumers to understand the differences and make informed choices. People can advertise themselves as a practitioner of a CAM therapy, yet licensing requirements, certification, scope of practice, regulations, and even definitions vary considerably from state to state. An herbalist may have years of training or no training at all. Acupuncture can be practiced in some states by practitioners of other health modalities (e.g., physicians, dentists, podiatrists, etc.) with no additional training, or by someone who has spent several years in acupuncture-specific training. Some practices require licensure, others do not. Information that explains a person's level and scope of training will help consumers to make informed choices in their selection of a practitioner.

Challenges:

Recommendations:

A) Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

B) Encourage States and local governments to make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

Issue 7: Adequacy of the Adverse Event Reporting (AER) System in identifying and addressing safety issues in a timely manner.

Background:

The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies in part on its adverse event reporting (AER) system to identify safety problems. The AER is an important mechanism to provide consumer protection while assuring access to these products, and is an educational tool to aid in ongoing research of safety and efficacy of products. Events can be reported by both consumers and health professionals. However, the system is entirely voluntary, and a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with dietary supplements.¹⁶ Serious or clinically significant adverse events¹⁷ related to dietary supplements need to be identified and contained in a timely manner to prevent unnecessary morbidity and mortality.

Challenges:

In April 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it "an inadequate safety valve." This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary

¹⁶ - DHHS, OIG, Adverse Event Reporting for Dietary Supplements, April 2001

¹⁷ - These terms are defined under Medwatch and in the FDA's Standard Operating Procedures of 1999

supplements and provides numerous recommendations to improve the system, some of which are included in the FDA's 10- year strategic plan. Most of the recommendations can be implemented administratively with additional funding, while some, such as mandatory manufacturer and product registration and reporting of adverse events may require legislative authority.

Recommendations:

A) Strengthen the AER system by: a) encouraging voluntary registration of dietary ^{supplements} manufactures so that the FDA can identify and contact them if an adverse event is reported; b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs); c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients; d) simplifying the system to facilitate increased usage and easier reporting; and e) increasing outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

Issue 8: Adequacy of packaging and labeling information of dietary supplements in determining ingredients, strength, benefits, appropriate use, and potential risks.

Background:

Laboratory testing of dietary supplements has shown that some do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain ingredients other than those listed on the label. If the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences.

Some labels state that an ingredient, or mixture of several ingredients, is standardized (e.g., "the product contains 3% of a standard extract of x," or "x is a standard extract"), but do not identify the standards against which it is compared. While some dietary supplements have industry-approved standards, many do not have any standards or their standards have not yet been scientifically confirmed. Labels claiming standardization of an ingredient or mixture product are misleading if the standard has not been fully established, and do not provide consumers with adequate information on the strength of the ingredients.

Product information on benefits, appropriate use, and potential risks is limited. Under DSHEA, dietary supplements are regulated as foods and do not have regulatory approval as drugs, and therefore can only make structure and function claims. As a result, even when there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Also, even when risk information is known, such as the interaction between St. John's Wort and certain drugs, this information is not required be included on the product label. Public understanding of this issue is also compromised by the complexity and implications of both existing regulatory guidelines and recent court decisions

which have upheld the right of commercial free speech in advertising and labeling of dietary supplements.

Challenges:

The regulation of dietary supplements and other products such as foods, prescription drugs, over-the-counter drugs, and special dietary foods is determined by the intended use of the product. Product labels must conform to the laws and regulations that govern its intended use. Thus, a vitamin or a botanical that prevents or treats a disorder must be an approved drug for this information to be included on the label. If a product is marketed as a dietary supplement, only structure and function claims can be stated on the label.

The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to “diagnose, treat, prevent, cure, or mitigate” a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent, and any realized benefits will apply to all manufacturers, not just the one who prepared the application.

To increase the availability of standards, government and industry has formed a task force to validate analytical methods for botanicals and other dietary supplements. The task force includes the Association of Analytical Chemists (AOAC) International, United States Pharmacopeia (USP), American Herbal Products Association (AHPA), the FDA, NIH, and the National Institute of Standards and Technology (within the Commerce Department), and others. They are developing consensus standards on processing and manufacturing, and chemical and physical standards for composition and quality.

Recommendations:

A) Increase consumer information of dietary supplements through a) improved labeling, package inserts, and information at points-of-sale, b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products, c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

B) Require that claims of standardization be limited to products with industry-approved standards.

Issue 9: Quality control of dietary supplements to assure consumer safety.

Background:

In addition inconsistencies in the amount and purity of the listed ingredients, some dietary supplements have been found to be adulterated with pesticides, microorganisms, heavy metals, or other potentially toxic substances.

Challenges:

Testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and phenol levels that they claimed the product contained.¹⁸ Testing of 13 SAME products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable level).¹⁹ Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies²⁰. There are numerous other examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. The GMPs developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements.

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Recommendations:

A) Implement the FDA's Good Manufacturing Practices (GMP) to help assure the purity of dietary supplements.

B) The Department of Health and Human Services, Department of Agriculture, Environmental Protection Agency, US Customs Services, and other appropriate Federal departments and agencies should work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace.

C) The Department of Health and Human Services Department of Agriculture, Environmental Protection Agency, and others should work with the World Health Organization and other

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appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

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Background:

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Challenges:

In a regulatory agency such as FDA, it is critical that staff with oversight responsibility of specific products be sufficiently knowledgeable of both the regulatory system and the products to effectively balance consumer protection and access issues. Particularly in the rapidly evolving area of botanicals, having staff with adequate expertise is essential in developing good relationships with industry and engendering consumer confidence.

Recommendation:

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⁵ - Burton Goldberg, WHCCAMP testimony, March 26, 2001, p

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information to change their insurance status or rates⁷. Privacy protections for health information seekers on the internet should include visits to CAM sites.

Challenges:

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D) Protect the privacy of individuals using CAM internet sites by encouraging CAM sites to disclose if users are tracked and how that information is utilized, including whether that information is sold to third parties. If necessary, develop or amend current legislation or regulations to assure the protection of privacy of CAM health information seekers on the internet.

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Recommendations:

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B) Establish a centralized source of CAM information in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.

Issue 3: Availability and adequacy of CAM information for diverse groups of consumers.**Background:**

While the use of the internet has proliferated, there are still many people, especially elderly and low-income people, who do not have personal access to the internet or knowledge of how to use the internet for CAM information. People without home or work access to the internet often will use publicly available resources to research information. Public libraries exist in most communities and are a source of both internet access and guidance. However, many librarians lack training on how to access CAM information on the internet.

According to the 1992 National Adult Literacy Survey, 48% of U.S. adults, or close to 100 million Americans, have very limited literacy skills⁹. Factors that contribute to this are 1) lack of English skills, 2) reading disabilities, and 3) under-education¹⁰. Use of CAM among this population is believed to be substantial¹¹.

There is a lack of CAM information that is targeted to specific population groups, despite the numerous indications that there is great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups.

Challenges:

The NLM has begun working directly with public libraries through the ALA to train local librarians to use the internet to find health information¹². This effort could be enhanced to

⁹ - U.S. Department of Education, National Center for Education Statistics, 1992

¹⁰ - *ibid*

¹¹ - Elmer Huerta, WHCCAMP testimony March 26, p.142, and Frances Brisbane, WHCCAMP testimony, March 27, p191

¹² - Sheldon Kotzin, WHCCAMP testimony March 24, p28

include more training and focus on CAM.

Federal agencies frequently develop informational materials to reach specific audiences. Materials are produced in many languages, and the content, pictures, and style are often altered to reach the intended population. Developing CAM materials that are targeted to different racial, ethnic, or cultural groups would be a valuable source of authoritative information to various population groups.

Recommendations:

A) In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the internet.

B) Promote the development of CAM information materials at a reading level that the general public can understand and utilize.

C) Promote the development of CAM information that is targeted to different population groups.

Issue 4: Availability of CAM information from other countries and in other languages.

Background:

Lack of information on effectiveness of CAM therapies is often cited as reason to not provide or reimburse for these services, but there is a significant amount of high quality CAM information published in other countries that is not available in English or in the U.S.

Challenges:

Recommendation:

A) Identify barriers to identifying and translating relevant articles, reports, and other materials; develop a strategy to overcome these barriers; assure that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

Issue 5: False and deceptive health claims on the internet.

Background:

The Federal Trade Commission (FTC) oversees advertising of products and services and brings actions against false and deceptive claims in the marketplace. To address what they call “an epidemic of health fraud on the internet¹³,” the FTC established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims on the internet. Yet, they are

¹³ - Michele Rusk, WHCCAMP testimony, March 26, p.276

only able to pursue a small percentage of the fraudulent claims identified.

The prevalence of false and deceptive claims on the Internet are potentially harmful to individuals. Also, legitimate companies that comply with current anti-deception and substantiation standards can lose market share and suffer financially as a result of companies using deceptive advertising¹⁴.

Challenges:

Operation Cure.all is not looking exclusively at CAM related health sites, but many of the fraudulent claims are related to CAM products and services, often claiming to cure cancer, AIDS, and other diseases. In one afternoon of internet surveillance, 400 clearly fraudulent health claims were identified. After sending an email warning, 80 of these sites either dropped the questionable claim or took down the site down. Of the 320 that did not respond to the email warning, the FTC was able to take action on only 2. If the perception exists that less than one percent of identified fraudulent claims are pursued, it is likely that there will be even more deceptive CAM advertising.

Recommendations:

A) Provide additional support to the FTC to identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims.

B) Increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

Issue 6: False or deceptive advertising targeted toward vulnerable populations.

Background:

Some populations, such as the recently arrived immigrants, non-English speaking persons, the elderly, etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television.¹⁵

Challenges:

Due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, and other similar factors, certain populations are particularly susceptible to advertisements of CAM products or services that promise to cure health and other problems not addressed through the conventional health care system or through legitimate CAM providers. This not only takes money away from people who have very little, but also can delay treatment of serious conditions until they become emergencies.

The involvement of community leaders that are trusted by the populations they represent is

¹⁴ - Sara Taylor, WHCCAMP testimony, March 26, p.288

¹⁵ - Elmer Huerta, WHCCAMP testimony March 26, p.145

essential to successfully educate vulnerable consumers and develop strategies to prevent their exploitation.

Recommendations:

A) Provide additional support to the FTC to monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations.

B) Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Issue 7: Full disclosure of training, certification, and other qualifications of CAM practitioners so consumers can make informed choices.

Background:

People providing CAM therapies can have significant differences in their level and type of training and it is difficult for consumers to understand the differences and make informed choices. People can advertise themselves as a practitioner of a CAM therapy, yet licensing requirements, certification, scope of practice, regulations, and even definitions vary considerably from state to state. An herbalist may have years of training or no training at all. Acupuncture can be practiced in some states by practitioners of other health modalities (e.g., physicians, dentists, podiatrists, etc.) with no additional training, or by someone who has spent several years in acupuncture-specific training. Some practices require licensure, others do not. Information that explains a person's level and scope of training will help consumers to make informed choices in their selection of a practitioner.

Challenges:

Recommendations:

A) Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

B) Encourage States and local governments to make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

Issue 8: Adequacy of the Adverse Event Reporting (AER) System in identifying and addressing safety issues in a timely manner.

Background:

The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to

take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies in part on its adverse event reporting (AER) system to identify safety problems. The AER is an important mechanism to provide consumer protection while assuring access to these products, and is an educational tool to aid in ongoing research of safety and efficacy of products. Events can be reported by both consumers and health professionals. However, the system is entirely voluntary, and a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with dietary supplements.¹⁶ Serious or clinically significant adverse events¹⁷ related to dietary supplements need to be identified and contained in a timely manner to prevent unnecessary morbidity and mortality.

Challenges:

In April 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it “an inadequate safety valve.” This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary supplements and provides numerous recommendations to improve the system, some of which are included in the FDA’s 10- year strategic plan. Most of the recommendations can be implemented administratively with additional funding, while some, such as mandatory manufacturer and product registration and reporting of adverse events may require legislative authority.

Recommendations:

A) Strengthen the AER system by: a) encouraging voluntary registration of dietary manufactures so that the FDA can identify and contact them if an adverse event is reported, b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs), c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients, and d) simplifying the system to facilitate increased usage and easier reporting.

B) Increase outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

Issue 9: Adequacy of packaging and labeling information of dietary supplements in determining ingredients, strength, benefits, appropriate use, and potential risks.

Background:

Laboratory testing of dietary supplements has shown that some do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain

¹⁶ - DHHS, OIG, Adverse Event Reporting for Dietary Supplements, April 2001

¹⁷ - These terms are defined under Medwatch and in the FDA’s Standard Operating Procedures of 1999

ingredients other than those listed on the label. If the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences.

Some labels state that an ingredient, or mixture of several ingredients, is standardized (e.g., “the product contains 3% of a standard extract of x,” or “x is a standard extract”), but do not identify the standards against which it is compared. While some dietary supplements have industry-approved standards, many do not have any standards or their standards have not yet been scientifically confirmed. Labels claiming standardization of an ingredient or mixture product are misleading if the standard has not been fully established, and do not provide consumers with adequate information on the strength of the ingredients.

Product information on benefits, appropriate use, and potential risks is limited. Under DSHEA, dietary supplements are regulated as foods and do not have regulatory approval as drugs, and therefore can only make structure and function claims. As a result, even when there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Also, even when risk information is known, such as the interaction between St. John’s Wort and certain drugs, this information is not required be included on the product label. Public understanding of this issue is also compromised by the complexity and implications of both existing regulatory guidelines and recent court decisions which have upheld the right of commercial free speech in advertising and labeling of dietary supplements.

Challenges:

The regulation of dietary supplements and other products such as foods, prescription drugs, over-the counter drugs, and special dietary foods is determined by the intended use of the product. Product labels must conform to the laws and regulations that govern its intended use. Thus, a vitamin or a botanical that prevents or treats a disorder must be an approved drug for this information to be included on the label. If a product is marketed as a dietary supplement, only structure and function claims can be stated on the label.

The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to “diagnose, treat, prevent, cure, or mitigate” a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent, and any realized benefits will apply to all manufactures, not just the one who prepared the application.

To increase the availability of standards, government and industry has formed a task force to

validate analytical methods for botanicals and other dietary supplements. The task force includes the Association of Analytical Chemists (AOAC) International, United States Pharmacopeia (USP), American Herbal Products Association (AHPA), the FDA, NIH, and the National Institute of Standards and Technology (within the Commerce Department), and others. They are developing consensus standards on processing and manufacturing, and chemical and physical standards for composition and quality.

Recommendations:

A) Implement the FDA's Good Manufacturing Practices (GMP) to help assure quality and consistency of dietary supplements.

B) Increase consumer information of dietary supplements through a) improved labeling, package inserts, and information at points-of-sale, b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products, c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

C) Require that claims of standardization be limited to products with industry-approved standards.

Issue 10: Quality control of dietary supplements to assure consumer safety.

Background:

In addition inconsistencies in the amount and purity of the listed ingredients, some dietary supplements have been found to be adulterated with pesticides, microorganisms, heavy metals, or other potentially toxic substances.

Challenges:

Testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and phenol levels that they claimed the product contained.¹⁸ Testing of 13 SAME products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable level).¹⁹ Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies²⁰. There are numerous other examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. The GMPs developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements.

¹⁸ - ConsumerLab.com, September 2000

¹⁹ - ConsumerLab.com, January 2000

²⁰ - FDA

In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. In April 2001, Solgar Vitamin and Herb Company recalled some dietary supplements due to salmonella contamination of raw materials supplied by American Laboratories. In May 2001, Natural Organics recalled several dietary supplements, also due to salmonella contamination of raw materials supplied by American Laboratories. The University of California, Cooperative Extension, has found toxic levels of mercury in some pills from China²¹. While the extent of contamination of dietary supplements is not known, steps should be taken to assure that these products are free of contaminants.

Recommendations:

A) Implement the FDA's Good Manufacturing Practices (GMP) to help assure the purity of dietary supplements.

B) The Department of Health and Human Services, Department of Agriculture, Environmental Protection Agency, US Customs Services, and other appropriate Federal departments and agencies should work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace.

C) The Department of Health and Human Services Department of Agriculture, Environmental Protection Agency, and others should work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

Issue 11: Federal oversight to assure public access to and safety of dietary supplements.

Background:

The use of all dietary supplements has grown significantly since DSHEA was enacted in 1994, and Federal and State regulatory agencies need well-trained, highly skilled professionals with expertise in dietary supplements, particularly in areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products) to assure appropriate oversight and public safety.

Challenges:

In a regulatory agency such as FDA, it is critical that staff with oversight responsibility of specific products be sufficiently knowledgeable of both the regulatory system and the products to effectively balance consumer protection and access issues. Particularly in the rapidly evolving area of botanicals, having staff with adequate expertise is essential in developing good relationships with industry and engendering consumer confidence.

²¹ - University of California, Cooperative Extension, Environmental Toxicology Newsletter, Vol. 19, No.1, 1999

Recommendation:

A) Assure an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

Information Development and Dissemination - Recommendations

- 1) Form a public-private partnership to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest.
- 2) Establish an oversight board and develop an ongoing process to review those websites that agree to participate for compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.
- 3) Conduct a public education campaign that teaches people how to evaluate CAM information on the internet. This should include partnerships with schools that use computers to develop students' skills at evaluating internet information on health care.
- 4) Protect the privacy of individuals using CAM internet sites by encouraging CAM sites to disclose if users are tracked and how that information is utilized, including whether that information is sold to third parties. If necessary, develop or amend current legislation or regulations to assure the protection of privacy of CAM health information seekers on the internet.
- 5) Form an inter-agency task force of Federal agencies to: a) identify gaps in CAM information (e.g., information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-Federal agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.
- 6) Establish a centralized source of CAM information in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.
- 7) In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the internet.
- 8) Promote the development of CAM information materials at a reading level that the general public can understand and utilize.
- 9) Promote the development of CAM information that is targeted to different population groups.
- 10) Identify barriers to identifying and translating relevant articles, reports, and other materials; develop a strategy to overcome these barriers; assure that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

- 11) Provide additional support to the FTC to identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims.
- 12) Increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.
- 13) Provide additional support to the FTC to monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations.
- 14) Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.
- 15) Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.
- 16) Encourage States and local governments to make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.
- 17) Strengthen the AER system by: a) encouraging voluntary registration of dietary manufactures so that the FDA can identify and contact them if an adverse event is reported, b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs), c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients, and d) simplifying the system to facilitate increased usage and easier reporting.
- 18) Increase outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.
- 19) Implement the FDA's Good Manufacturing Practices (GMP) to help assure quality and consistency of dietary supplements.
- 20) Increase consumer information of dietary supplements through a) improved labeling, package inserts, and information at points-of-sale, b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products, c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.
- 21) Require that claims of standardization be limited to products with industry-approved standards.
- 22) Implement the FDA's Good Manufacturing Practices (GMP) to help assure the purity of dietary supplements.

23) The Department of Health and Human Services, Department of Agriculture, Environmental Protection Agency, US Customs Services, and other appropriate Federal departments and agencies should work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace.

24) The Department of Health and Human Services Department of Agriculture, Environmental Protection Agency, and others should work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

25) Assure an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

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Information Development and Dissemination

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DeVries,

Issue 1: Accuracy, quality, accessibility, and timeliness of CAM information on the internet.

Background: Over half of all households have computers, 90 percent of all children ages 6 to 17 have access to computers through their home or school, and 42 percent of all households can log onto the internet.¹ The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers, and about 60 million American adults have used the internet for health information². The NCCAM website reports receiving over half a million hits per month³, Ask Dr. Weil reports up to 5 million page views per month⁴, AlternativeMedicine.com reports 2 million hits per month⁵, and WebMD reports 4.7 unique visits last December⁶. Some sites are specific to CAM, and others are general health information sites that include CAM information.

The quality, accuracy, accessibility, and timeliness of the information varies greatly. Some sites provide accurate and current information, while many others contain inaccurate, misleading, or outdated information. The ability to assure the quality of information on the internet is extremely limited, due to both the nature of the technology and the First Amendment protection of free speech.

In a recent study, 85% of health seekers on the internet said they are concerned about their employer or health insurance company tracking their internet site visits and using that information to change their insurance status or rates⁷. Privacy protections for health information seekers on the internet should include visits to CAM sites.

Recommendations:

A) Form a public-private partnership to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest.

B) Establish an oversight board and develop an ongoing process to review those websites that agree to participate for compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.

C) Conduct a public education campaign that teaches people how to evaluate CAM information on the internet. This should include partnerships with schools that use computers to develop student's skills at evaluating internet information on health care.

¹ - Census Bureau Report, September 6, 2001

² - Harrison Lee Raine, WHCCAMP testimony, March 26, p195

³ - Irene Lui, WHCCAMP testimony, March 26, 2001, p16

⁴ - Andrew Weil, WHCCAMP testimony, March 26, 2001, p56

⁵ - Burton Goldberg, WHCCAMP testimony, March 26, 2001, p

⁶ - Susan Detwiler, WHCCAMP testimony, March 26, 2001, p210

⁷ - Harrison Raine, WHCCAMP testimony March 26, p201

D) Protect the privacy of individuals using CAM internet sites by encouraging CAM sites to disclose if users are tracked and how that information is utilized, including whether that information is sold to third parties. If necessary, develop or amend current legislation or regulations to assure the protection of privacy of CAM health information seekers on the internet.

mainly **Discussion/Challenges:** Several organizations have developed standards for health sites on the Internet. However, some of the members of the standard-setting groups are the very websites that have been used as examples of the problems in quality, accuracy, accessibility, and timeliness of CAM-related information on the internet. Most of these programs are focused on ethics related issues such as privacy and financial sponsorship, and not on content, and the one that does address content is composed exclusively of representatives from conventional medicine.

Public-private partnerships that include industry groups, consumers, and government have been successful in developing guidelines and establishing standards for many products and services. A government-sponsored partnership could bring more exposure, credibility, and balance to the effort to improve the quality, accuracy, accessibility, and timeliness of CAM-related information on the internet

Regardless of efforts to develop standards and assure quality, there will always be a need for consumers to evaluate and validate information from the internet. Public education in using the internet as a source of health information can help guide an individual's knowledge and decision-making on their health.

Issue 2: Adequacy and accessibility of CAM information from the Federal government.

Background: Consumers, health professionals, and the media look to the Federal government for authoritative information on a wide range of CAM topics. Many entities within the Federal government develop informational materials for the public, which are then put on their internet sites, as well as distributed through a clearinghouse. NCCAM has the only CAM-specific clearinghouse.

Currently, there are several Federal agencies within HHS that provide CAM-related information such as NIH (through the NCCAM, NCI, ODS, etc.), FDA (through the CFSN), and others. Information related to CAM is also available through other government agencies, such as the Departments of Agriculture, Department of Labor, Federal Trade Commission, etc. Various methods of providing information are utilized, including mailing of fact sheets and reports; the internet; or toll-free telephone numbers. Government agencies with oversight responsibilities for various aspects of health care often do not include any information on CAM in their materials, resulting in significant gaps in CAM information on diseases, health conditions, practitioners, and products. Even when CAM information is available, it is often difficult for the public to navigate the system to locate the desired information in a timely manner.

Recommendations:

A) Form an inter-agency task force of Federal agencies to: a) identify gaps in CAM information (e.g. information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-Federal agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.

NCCAM has a legislative mandate to create & manage
B) Establish a centralized source of CAM information in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person. *? delete*

legislative mandate **Discussion/Challenges:** The provision of information on licensing and certification requirements is critical, as consumers have no easy way of determining the training and quality of people offering CAM services or products. There are numerous types of CAM providers with different levels of training and it is difficult for the public to understand the differences between them and make informed choices. This is due to several factors, including the variability of State-established Scope of Practice Acts, the lack of definition of some professions (e.g. "Herbalist"), and the use of the same title by people of different levels of training (e.g. professional acupuncturists and physicians)

can both be called “acupuncturist”). Also, to help assure public safety, information should also be available on any disciplinary actions against a practitioner.

The Federal government, through the General Services Administration, operates *Firstgov.gov*, a consumer-friendly search engine that searches every word of every US government document in a quarter of a second or less and links with relevant non-government sites. For people who use the internet, it is a very fast and easy way to access existing information. However, many people still don't know of it's existence.

Media coverage of CAM services and products is often incomplete, unbalanced, or biased, and there is no centralized place in the Federal government for the media to quickly get objective and comprehensive information on CAM.⁸

Issue 3: Availability and adequacy of CAM information for diverse groups of consumers.

Background: While the use of the internet has proliferated, there are still many people, especially elderly and low-income people, who do not have personal access to the internet or knowledge of how to use the internet for CAM information. People without home or work access to the internet often will use publicly available resources to research information. Public libraries exist in most communities and are a source of both internet access and guidance. However, many librarians lack training on how to access CAM information on the internet.

According to the 1992 National Adult Literacy Survey, 48% of U.S. adults, or close to 100 million Americans, have very limited literacy skills⁹. **Factors that contribute to this are 1) lack of English skills, 2) reading disabilities, and 3) under-education¹⁰. Use of CAM among this population is believed to be substantial.¹¹.**

There is a lack of CAM information that is targeted to specific population groups, despite the numerous indications that there is great variability in CAM therapies and usage among people of ~~different~~ racial, ethnic, or cultural groups. *Elmer Huerta*

Recommendations:

A) In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the internet.

B) Promote the development of CAM information materials at a reading level that the general public can understand and utilize.

C) Promote the development of CAM information that is targeted to ~~different~~ *diverse* population groups.

Discussion/Challenges: The NLM has begun working directly with public libraries through the ALA to train local librarians to use the internet to find health information¹². **This effort could be enhanced to include more training and focus on CAM.**

Federal agencies frequently develop informational materials to reach specific audiences. Materials are produced in many languages, and the content, pictures, and style are often altered to reach the intended

⁸ - David Schardt, WHCCAMP testimony, March 26, p.228

⁹ - U.S. Department of Education, National Center for Education Statistics, 1992

¹⁰ - *ibid*

¹¹ - Elmer Huerta, WHCCAMP testimony March 26, p.142, and Frances Brisbane, WHCCAMP testimony, March 27, p.191

¹² - Sheldon Kotzin, WHCCAMP testimony March 24, p.28

population. Developing CAM materials that are targeted to different racial, ethnic, or cultural groups would be a valuable source of authoritative information to various population groups.

Issue 4: Availability of CAM information from other countries and in other languages.

Background: Lack of information on effectiveness of CAM therapies is often cited as reason to not provide or reimburse for these services, but there is a significant amount of high quality CAM information published in other countries that is not available in English or in the U.S.

Recommendation:

A) Identify barriers to identifying and translating relevant articles, reports, and other materials; develop a strategy to overcome these barriers; assure that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

Discussion/Challenges:

Issue 5: False and deceptive health claims on the internet.

Background: The Federal Trade Commission (FTC) oversees advertising of products and services and brings actions against false and deceptive claims in the marketplace. To address what they call “an epidemic of health fraud on the internet”¹³, the FTC established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims on the internet. Yet, they are only able to pursue a small percentage of the fraudulent claims identified.

The prevalence of false and deceptive claims on the Internet are potentially harmful to individuals. Also, legitimate companies that comply with current anti-deception and substantiation standards can lose market share and suffer financially as a result of companies using deceptive advertising¹⁴.

Recommendations:

A) Provide additional support to the FTC to identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims.

B) Increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

Discussion/Challenges: Operation Cure.all is not looking exclusively at CAM related health sites, but many of the fraudulent claims are related to CAM products and services, often claiming to cure cancer, AIDS, and other diseases. In one afternoon of internet surveillance, 400 clearly fraudulent health claims were identified. After sending an email warning, 80 of these sites either dropped the questionable claim or took down the site down. Of the 320 that did not respond to the email warning, the FTC was able to take action on only 2. If the perception exists that less than one percent of identified fraudulent claims are pursued, it is likely that there will be even more deceptive CAM advertising.

Issue 6: False or deceptive advertising targeted towards vulnerable populations.

Background: Some populations, such as the recently arrived immigrants, non-English speaking persons, the elderly,

¹³ - Michele Rusk, WHCCAMP testimony, March 26, p.276

¹⁴ - Sara Taylor, WHCCAMP testimony, March 26, p.288

etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television.¹⁵

Recommendations:

A) Provide additional support to the FTC to monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations.

B) Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Discussion/Challenges: Due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, and other similar factors, certain populations are particularly susceptible to advertisements of CAM products or services that promise to cure health and other problems not addressed through the conventional health care system or through legitimate CAM providers. This not only takes money away from people who have very little, but also can delay treatment of serious conditions until they become emergencies.

The involvement of community leaders that are trusted by the populations they represent is essential to successfully educate vulnerable consumers and develop strategies to prevent their exploitation.

Issue 7: Full disclosure of training, certification, and other qualifications of CAM practitioners so consumers can make informed choices.

Background: People providing CAM therapies can have significant differences in their level and type of training and it is difficult for consumers to understand the differences and make informed choices. People can advertise themselves as a practitioner of a CAM therapy, yet licensing requirements, certification, scope of practice, regulations, and even definitions vary considerably from state to state. An herbalist may have years of training or no training at all. Acupuncture can be practiced in some states by practitioners of other health modalities (e.g. physicians, dentists, podiatrists, etc.) with no additional training, or by someone who has spent several years in acupuncture-specific training. Some practices require licensure, others do not. Information that explains a person's level and scope of training will help consumers to make informed choices in their selection of a practitioner.

Recommendations:

A) Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

B) Encourage States and local governments to make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

Discussion/Challenges:

Efforts are needed by organizations to establish credentialing programs, etc.

Issue 8: Adequacy of the Adverse Event Reporting (AER) System in identifying and addressing safety issues in a timely manner.

Background: The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies in part on its adverse event reporting (AER) system to identify safety problems. The AER is an important mechanism to provide consumer protection while assuring access to these products, and is an educational tool to aid in ongoing research of safety and efficacy of products. Events can be reported by both consumers and health professionals. However, the system is entirely voluntary, and a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with

¹⁵ - Elmer Huerta, WHCCAMP testimony March 26, p.145

dietary supplements.¹⁶ **Serious or clinically significant adverse events¹⁷ related to dietary supplements need to be identified and contained in a timely manner to prevent unnecessary morbidity and mortality.**

Recommendations:

A) Strengthen the AER system by: a) encouraging voluntary registration of dietary ^{supplement} manufacturers^R so that the FDA can identify and contact them if an adverse event is reported, b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs), c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients, and d) simplifying the system to facilitate increased usage and easier reporting.

B) Increase outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

Discussion/Challenges: In April, 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it “an inadequate safety valve”. This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary supplements and provides numerous recommendations to improve the system, some of which are included in the FDA’s 10- year strategic plan. Most of the recommendations can be implemented administratively with additional funding, while some, such as mandatory manufacturer and product registration and reporting of adverse events may require legislative authority.

Issue 9: Adequacy of packaging and labeling information of dietary supplements in determining ingredients, strength, benefits, appropriate use, and potential risks.

Background: Laboratory testing of dietary supplements has shown that some do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain ingredients other than those listed on the label. If the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences.

Some labels state that an ingredient, or mixture of several ingredients, is standardized (e.g. “the product contains 3% of a standard extract of x”, or “x is a standard extract”), but do not identify the standards against which it is compared. While some dietary supplements have industry-approved standards, many do not have any standards or their standards have not yet been scientifically confirmed. Labels claiming standardization of an ingredient or mixture product are misleading if the standard has not been fully established, and do not provide consumers with adequate information on the strength of the ingredients.

Product information on benefits, appropriate use, and potential risks is limited. Under DSHEA, dietary supplements are regulated as foods and do not have regulatory approval as drugs, and therefore can only make structure and function claims. As a result, even when there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Also, even when risk information is known, such as the interaction between St. John’s Wort and certain drugs, this information is not required be included on the product label. Public understanding of this issue is also compromised by the complexity and implications of both existing regulatory guidelines and recent court decisions which have upheld the right of commercial free speech in advertising and labeling of dietary supplements.

Recommendations:

A) Implement the FDA’s Good Manufacturing Practices (GMP) to help assure quality and consistency of dietary

¹⁶ - DHHS, OIG, Adverse Event Reporting for Dietary Supplements, April 2001

¹⁷ - These terms are defined under Medwatch and in the FDA’s Standard Operating Procedures of 1999

supplements.

B) Increase consumer information of dietary supplements through a) improved labeling, package inserts, and information at points-of-sale, b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products, c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

C) Require that claims of standardization be limited to products with industry-approved standards.

Discussion/Challenges: The regulation of dietary supplements and other products such as foods, prescription drugs, over-the counter drugs, and special dietary foods is determined by the intended use of the product. Product labels must conform to the laws and regulations that govern its intended use. Thus, a vitamin or a botanical that prevents or treats a disorder must be an approved drug for this information to be included on the label. If a product is marketed as a dietary supplement, only structure and function claims can be stated on the label.

The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to “diagnose, treat, prevent, cure, or mitigate” a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent, and any realized benefits will apply to all manufactures, not just the one who prepared the application.

To increase the availability of standards, government and industry have formed a task force to validate analytical methods for botanicals and other dietary supplements. The task force includes the Association of Analytical Chemists (AOAC) International, United States Pharmacopeia (USP), American Herbal Products Association (AHPA), the FDA, NIH, and the National Institute of Standards and Technology (within the Commerce Department), and others. They are developing consensus standards on processing and manufacturing, and chemical and physical standards for composition and quality.

Issue 10: Quality control of dietary supplements to assure consumer safety.

Background: In addition inconsistencies in the amount and purity of the listed ingredients, some dietary supplements have been found to be adulterated with pesticides, microorganisms, heavy metals, or other potentially toxic substances.

Recommendations:

A) Implement the FDA’s Good Manufacturing Practices (GMP) to help assure the purity of dietary supplements.

B) The Department of Health and Human Services, Department of Agriculture, Environmental Protection Agency, US Customs Services, and other appropriate Federal departments and agencies should work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace.

C) The Department of Health and Human Services, Department of Agriculture, Environmental Protection Agency, and others should work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

Discussion/Challenges: Testing of 25 echinacea products found that only 14 (56%) had the amount and type of

echinacea and phenol levels that they claimed the product contained.¹⁸ Testing of 13 SAME products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable level).¹⁹ Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies²⁰. There are numerous other examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. The GMPs developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements.

In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. In April, 2001, Solgar Vitamin and Herb Company recalled some dietary supplements due to salmonella contamination of raw materials supplied by American Laboratories. In May 2001, Natural Organics recalled several dietary supplements, also due to salmonella contamination of raw materials supplied by American Laboratories. The University of California, Cooperative Extension, has found toxic levels of mercury in some pills from China²¹. While the extent of contamination of dietary supplements is not known, steps should be taken to assure that these products are free of contaminants.

Issue 11: Federal oversight to assure public access to and safety of dietary supplements.

Background: The use of all dietary supplements has grown significantly since DSHEA was enacted in 1994, and Federal and State regulatory agencies need well-trained, highly skilled professionals with expertise in dietary supplements, particularly in areas other than vitamins and minerals (e.g. plant, animal, synthetic, and microbial products) to assure appropriate oversight and public safety.

Recommendation:

A) Assure an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g. plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

Discussion/Challenges: In a regulatory agency such as FDA, it is critical that staff with oversight responsibility of specific products be sufficiently knowledgeable of both the regulatory system and the products to effectively balance consumer protection and access issues. Particularly in the rapidly evolving area of botanicals, having staff with adequate expertise is essential in developing good relationships with industry and engendering consumer confidence.

¹⁸ - ConsumerLab.com, September 2000

¹⁹ - ConsumerLab.com, January 2000

²⁰ - FDA

²¹ - University of California, Cooperative Extension, Environmental Toxicology Newsletter, Vol. 19, No.1, 1999

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White Paper on Licensing

1-18

CAM Information Development and Dissemination

Recommendations:

- 1) The Commission recommends that a) a public-private partnership be formed to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest; and b) an ongoing process be developed to review participating websites to determine compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.
- 2) The Commission recommends that a) a public education campaign be conducted that teaches people how to evaluate CAM information on the internet; and b) partnerships be formed with schools that use computers to develop students' skills at evaluating internet information on health care.
- 3) The Commission recommends that the privacy of individuals using CAM internet sites be protected by a) encouraging CAM sites to disclose if users are tracked and how that information is utilized (including whether that information is sold to third parties), and b) assessing if current legislation or regulations are adequate to assure the protection of privacy of CAM health information seekers on the internet, and if not, amending or developing new legislation.
- 4) The Commission recommends that an inter-agency task force of Federal agencies be formed to: a) identify gaps in CAM information (e.g., information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-Federal agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.
- 5) The Commission recommends that a centralized source of CAM information be established in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.
- 6) The Commission recommends that, in partnership with the National Library of Medicine and the American Library Association, training materials be developed to assist librarians in guiding people to find CAM information on the internet.
- 7) The Commission recommends that a) CAM information materials be developed at a reading level that the general public can understand and utilize, and b) CAM information be developed that is targeted to different population groups.
- 8) The Commission recommends that barriers to identifying and translating relevant articles, reports, and other materials be identified; strategies be developed to overcome these barriers; and that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.

9) The Commission recommends that additional support be provided to the FTC to a) identify false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims; b) monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations; and c) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

10) The Commission recommends that national and local leaders of communities of special populations be brought together to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

11) The Commission recommends that health professionals be required to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

12) The Commission recommends that States and local governments make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

13) The Commission recommends that the AER system be strengthened by: a) encouraging voluntary registration of dietary manufactures so that the FDA can identify and contact them if an adverse event is reported; b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs); c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients; d) simplifying the system to facilitate increased usage and easier reporting; and e) increasing outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

14) The Commission recommends that the availability of consumer information of dietary supplements be increased through a) improved labeling, package inserts, and information at points-of-sale; b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products; and c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

15) The Commission recommends that claims of standardization be limited to products with industry-approved standards.

16) The Commission recommends that the FDA's Good Manufacturing Practices (GMP) be implemented to help assure the purity of dietary supplements.

17) The Commission recommends that a) the DHHS, USDA, Environmental Protection Agency (EPA), US Customs Services, and other appropriate Federal departments and agencies work with

manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated or adulterated products from entering the US marketplace; and b) DHHS, USDA, EPA, and others work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

18) The Commission recommends that there be an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

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19. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

20. The Commission recommends including trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

21. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

21.a. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

21.b. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

21.c. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support

mechanisms for high-risk, high-impact studies to expand our understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.

21.d. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.

21.e. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources for National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions.

21.f. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices who have received the same rigorous research training in basic, clinical, or health services research.

21.g. Continue to support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

21.h. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships.

21.i. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk.

21.j. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

21.k. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

21.L. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

22. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.

22.a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

22.b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

22.c. Request recommendations from the National Science Foundation on how to study, in a credible manner, the high-risk, emerging scientific ideas associated with CAM research.

23. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities.

24. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

25. The Commission recommends that public and private resources be provided to support systematic reviews of CAM research literature.

25.a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

25.b. Produce and maintain up-to-date summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force.

25.c. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

26. The Commission recommends that appropriate access to funding and other resources for CAM faculty, curricula, and program development at accredited institutions and by licensed professions should be made possible by amending Titles VII and VIII of the PHS Act to

authorize Health Resources and Services Administration, Bureau of Health Professions to provide this type of support.

27. The Commission recommends that joint research and educational programs involving CAM practitioners and conventional practitioners should be established and financial support for these programs should be identified.

28. The Commission recommends that national educational standards for CAM modalities, therapies, and practices should be established by professional and educational institution organizations linked with the proposed Federal CAM Coordinating Office.

29. The Commission recommends that a basic curriculum in conventional health care and medical sciences for CAM students and practitioners should be developed to facilitate recognition of limits of clinical expertise and potential complications of interventions and appropriate referrals to conventional health care providers.

30. The Commission recommends that collaboration between CAM and conventional health care institutions should be encouraged and funded.

31. The Commission recommends that Traditional healers who practice within a community which provides traditions and oversight should be provided appropriate access to educational funding and allowed to continue to practice without State censure, providing:

- a. Their clients are fully informed of their training (or lack thereof)
- b. They do not mislead their clients by use of titles of licensed professions
- c. They have not been censured by their community.

32. The Commission recommends that CAM students should be eligible for State and where appropriate national fiscal support based on service to designated areas. Eligibility would apply to loans, loan forgiveness, and scholarships. The next reauthorization of Titles VII and VIII of the Public Service Act should be amended to include enabling legislation making CAM students eligible.

33. The Commission recommends that a basic curriculum which surveys the CAM modalities and ensures basic skills in collaborating with or supervising CAM professionals should be developed for conventional health care professionals in professional schools, postgraduate training programs, and continuing education programs to increase knowledge and understanding of CAM in order to enhance and protect the public's health.

34. The Commission recommends that curricula in CAM fundamentals and principles should be developed at conventional health care professional schools in conjunction with CAM experts and CAM institutions.

35. The Commission recommends that conventional health care providers interested in practicing a CAM modality or system of healing should obtain the necessary education in postgraduate or continuing education programs or at accredited CAM institutions.

37. The Commission recommends that combined or joint continuing education and residency programs which include different types of CAM practitioners and conventional health care providers should be developed to improve their mutual understanding and enhance their collaborative interaction.

50. The Commission recommends that a public-private body (DHHS; DOD; VA; representatives of the research community, insurance industry, and managed care organizations, employers, etc.) be convened to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, methodologies, data, priorities, and coordination. The Commission recommends that DHHS work within the partnership to target public and private resources on research priorities, maintain public-private coordination, and build cooperation.

51. The Commission recommends that public entities (AHRQ, NIH, CMS/formerly HCFA, HRSA, DOD, VA, etc.) and private organizations (research and other private foundations, employers, industry associations, etc.) fund and jointly fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, as well as the efficacy of various models for providing CAM services (integration, collaboration, etc.) within the U.S. health care system. The Commission encourages funding bodies to cooperate with the priorities established in Recommendation 1.

52. The Commission encourages health care purchasers including insurers, managed care organizations, Federal and State agencies, and other health plan sponsors to develop and maintain a process, as conducted for conventional therapies, for incorporating safe and efficacious CAM interventions into health benefit packages.

53. The Commission encourages

- Federal agencies that provide health benefits (CMS, DOD, VA, etc.) to include CAM practitioners on coverage advisory bodies, coding work groups, and related working bodies.
- Insurers and managed care organizations to include CAM experts on coverage advisory bodies, and related working groups.
- Professional associations, health policy institutions, and foundations to consider advice, consultation, and information from CAM practitioners and other CAM experts.
- CAM practitioners to seek out opportunities to advise and participate in bodies, public or private, that address issues related to coverage, reimbursement, coding, health services research, and CAM-related demonstrations projects.

54. The Commission recommends that public and private entities (DHHS; DOD; VA; research organizations, foundations, insurance industry, managed care organizations, employers, etc.), as with conventional medicine, fund or jointly fund health services research on the cost-effectiveness of CAM interventions, including the specific interventions for various conditions,

and the impact of CAM on health care costs. The Commission recommends funding to study the clinical and cost-effectiveness of various models of providing CAM services, and comparisons of the costs and outcomes of CAM therapies and conventional medical therapies for the same conditions. Studies on the costs and benefits of CAM practices, wellness programs, and self-care on health status are encouraged.

55. The Commission recommends that purchasers, insurers, managed care organizations, and other health plan sponsors consider coverage of CAM interventions shown to be safe and cost-effective.

56. The Commission recommends Federal agencies responsible for healthcare coverage and services investigate and report to their respective administrators on how safe, cost-effective CAM therapies may be integrated into federal programs.

57. The Commission recommends that DHHS, working in partnership with representative from the private sector (including professional and industry associations for CAM and conventional medicine, the American Medical Association, insurers, managed care organizations, and researchers), conduct a study of current coding processes and CAM, consider the issues associated with appropriate coding for CAM, and report to the Secretary of DHHS.

58. In order to increase access to and coverage of CAM therapies shown to be safe and cost-effective, the Commission encourages State governments to grant legal authority to practice to those CAM professions seeking licensure, or equivalent stature, within the State.

59. The Commission encourages DHHS to support private sector efforts to develop model CAM necessity and appropriateness criteria for CAM services shown to be safe and effective.

60. The Commission encourages insurers, managed care organizations, and benefit experts to work cooperatively with CAM professions to develop criteria for appropriate coverage of CAM benefits.

61. The Commission recommends that DHHS sponsor, or co-sponsor with external partners, an easily accessible, continuously updated website that provides information on CAM practices and products proven to be safe, clinically efficacious, and cost effective. The Commission believes that information should be provided for both consumer and professional use. The Commission encourages an out-reach effort be made to inform purchasers, such as employers and community health centers, of the availability of this website.

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72. The Commission recommends that DHHS, in consultation with the American Hospital Association and others, including CAM professionals and consumers, identify strategies to incorporate CAM in wellness, prevention, and self-care in the nation's hospitals.

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77. The Commission recommends that DHHS identify Federal programs (e.g. Head Start, Meals on Wheels, Women Infants and Children, State Children's Health Insurance Program, etc.) that could benefit from the addition of CAM in wellness, prevention, or self-care, and develop strategies to incorporate these into the programs as appropriate.

78. CAM

Recommendations:

1. The Commission recommends that a) a public-private partnership be formed to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of any conflicts of interest; and b) an ongoing process be developed to review participating websites to determine compliance with these standards. Sites reviewed and found in compliance with the criteria could publicize this achievement and display a logo identified with this level of merit.
2. The Commission recommends that a) a public education campaign be conducted that teaches people how to evaluate CAM information on the internet; and b) partnerships be formed with schools that use computers to develop students' skills at evaluating internet information on health care.
3. The Commission recommends that the privacy of individuals using CAM internet sites be protected by a) encouraging CAM sites to disclose if users are tracked and how that information is utilized (including whether that information is sold to third parties), and b) assessing if current legislation or regulations are adequate to assure the protection of privacy of CAM health information seekers on the internet, and if not, amending or developing new legislation.
4. The Commission recommends that an inter-agency task force of Federal agencies be formed to: a) identify gaps in CAM information (e.g., information on training and licensure requirements of practitioners, access and reimbursement, wellness, self-care, clinical applications, etc.) and develop strategies to reduce the gaps; and b) improve internet linkages of CAM information between Federal and non-Federal agencies and organizations and promote the use of *Firstgov.gov* for people seeking information on the internet.
5. The Commission recommends that a centralized source of CAM information be established in DHHS for the public, including the media, with a toll-free telephone number that would provide information or refer the caller to the appropriate agency and person.
6. The Commission recommends that, in partnership with the National Library of Medicine and the American Library Association, training materials be developed to assist librarians in guiding people to find CAM information on the internet.
7. The Commission recommends that a) CAM information materials be developed at a reading level that the general public can understand and utilize, and b) CAM information be developed that is targeted to different population groups.
8. The Commission recommends that barriers to identifying and translating relevant articles, reports, and other materials be identified; strategies be developed to overcome these barriers; and that relevant and high quality materials are made available to researchers, clinicians, policymakers, and others.
9. The Commission recommends that additional support be provided to the FTC to a) identify

false and deceptive CAM- related health claims on the internet and to take appropriate action to minimize the occurrence of these claims; b) monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations; and c) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

10. The Commission recommends that national and local leaders of communities of special populations be brought together to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

11. The Commission recommends that health professionals be required to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

12. The Commission recommends that States and local governments make information on state guidelines, requirements, licensure, and certification of CAM providers readily available to the public.

13. The Commission recommends that the AER system be strengthened by: a) encouraging voluntary registration of dietary manufactures so that the FDA can identify and contact them if an adverse event is reported; b) requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs); c) mandating registration of manufacturers and developing a data base of manufacturers and product ingredients; d) simplifying the system to facilitate increased usage and easier reporting; and e) increasing outreach activities to health professionals (including poison control centers and emergency room physicians) and consumers regarding the importance of reporting adverse events, and provide information on how to use the system.

14. The Commission recommends that the availability of consumer information of dietary supplements be increased through a) improved labeling, package inserts, and information at points-of-sale; b) inclusion of information on possible interactions with prescription or OTC drugs, foods, or other health products; and c) inclusion of information on possible risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

15. The Commission recommends that claims of standardization be limited to products with industry-approved standards.

16. The Commission recommends that the FDA's Good Manufacturing Practices (GMP) be implemented to help assure the purity of dietary supplements.

17. The Commission recommends that a) the DHHS, USDA, Environmental Protection Agency (EPA), US Customs Services, and other appropriate Federal departments and agencies work with manufacturers and importers to monitor the quality of imported and domestic dietary

supplements and identify and prevent contaminated or adulterated products from entering the US marketplace; and b) DHHS, USDA, EPA, and others work with the World Health Organization and other appropriate international organizations to establish guidelines to help assure the purity of herbal ingredients and, where possible, set international standards for consistency.

18. The Commission recommends that there be an adequate staff of professionals within the FDA and NIH (Office of Dietary Supplements, NCCAM) with expertise in dietary supplements, especially areas other than vitamins and minerals (e.g., plant, animal, synthetic, and microbial products). This could include hiring people with these specific skills, and/or providing training to current staff, and may require increased staffing levels and/or funding.

19. The Commission recommends strengthening and building on the emerging dialogue between conventional medicine and CAM by developing ways to enhance communication, cooperation, and collaboration among conventional and CAM researchers, clinicians, and practitioners; research centers, programs, and institutions; professional leadership organizations; Federal and state research and health agencies; and the public, private, and nonprofit sectors.

20. The Commission recommends including trained and licensed CAM professionals on research, journal, and regulatory advisory and review committees in both the public and private sectors, and adapt as appropriate, any regulations that might impede such representation.

21. The Commission recommends that all Federal agencies with research or related health responsibilities increase, as relevant to their missions, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms of action, and health services research to improve CAM use within the health care system.

21.a. Encourage NIH/IC's and other Federal agencies, as appropriate, to develop programs to evaluate practice-based data for potential research support, and communicate the availability of such initiatives in a proactive manner to practitioners who believe they have promising data on non-approved treatments. Provide training to the practitioners in collecting well developed, objective data and in human subject protection guidelines. The inclusion of CAM professional expertise should be part of the solicitation process.

21.b. Fund clinical research on promising and/or frequently used CAM products that would be unlikely to receive a patent and therefore not likely to attract private research dollars. Develop incentives to stimulate private sector investment on the safety and efficacy of CAM products and on projects to standardize the composition of CAM products, either separately or collaboratively.

21.c. Encourage Federal, private and nonprofit support for CAM research in emerging areas of scientific study, such as the examination of: (1) wellness separate from disease; (2) the role of mind, body, and spirituality in health; and (3) complete biological systems and interacting biological systems, including biofields and energy medicine. Support

mechanisms for high-risk, high-impact studies to expand our understanding of health and disease. Provide resources to NIGMS/NIH to support basic science in CAM.

21.d. Support research on why people use CAM, how they determine its effectiveness, and what they find satisfying about CAM in comparison to conventional medicine, and parallel this research with the public impact on the emerging integrated health care system.

21.e. Provide increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional and CAM sites to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Provide resources for National Center for Research Resources/NIH to fund Clinical Research Centers focused on CAM in accredited conventional and CAM institutions.

21.f. Support research training on CAM questions by all Federal health agencies with research training programs, with a special effort to develop a core of CAM and conventional researchers well trained in CAM practices who have received the same rigorous research training in basic, clinical, or health services research.

21.g. Continue to support career development awards to enable investigators focusing on CAM to develop into independent investigators, and mid-career awards to provide support for the time required to mentor new CAM investigators.

21.h. Solicit a study to evaluate methods to stimulate private sector research investment in CAM patents, products, and NDA development, and projects to standardize the composition of CAM products, either separately or in partnership. Consider incentives, such as tax incentives and resolving intellectual property with patent and technology transfer mechanisms, and by developing public-private partnerships.

21.i. Solicit a study of FDA methods for reviewing and approving CAM products, devices and practices, using a step-wise approach for increasing data with increasing risk.

21.j. Use mechanisms such as the NIH Small Business Innovative Research program and the Small Business Technology Transfer Research program to offer the private sector opportunities for research support.

21.k. Encourage the creation of novel funding mechanisms by the private and/or nonprofit sectors to augment in partnership with Federal agencies, or separately, support for CAM research, including research infrastructure and the training of interdisciplinary research teams.

21.L. Request a study from the Institute of Medicine on the prioritization process for CAM research including how to maintain rigor while obtaining input from a variety of stakeholders.

22. The Commission recognizes that it is essential that all biomedical research meet the highest standards of quality and recommends that the standards of research quality for CAM be the same as for conventional biomedical research—neither lower nor higher.

22.a. Develop programs to bring together a variety of disciplines to find innovative research approaches for solving difficult questions in focused CAM areas (example: NCI/SPORE program).

22.b. Encourage public, private, or foundation supported multidisciplinary conferences and workshops to increase opportunities for CAM and conventional practitioners, clinicians, and researchers to exchange ideas and to discuss methodological approaches to studying CAM questions.

22.c. Request recommendations from the National Science Foundation on how to study, in a credible manner, the high-risk, emerging scientific ideas associated with CAM research.

23. The Commission recommends ensuring public participation in the shaping and prioritizing the CAM research agenda. Include public input on advisory committees, institutional review board reviews and institutional research teams, methods to disseminate research results, and the shaping of regulatory and health services activities.

24. The Commission recommends that CAM research results be submitted to the most rigorous peer-reviewed journals. Include both CAM and conventional medical expertise on journal review boards when reviewing CAM manuscripts.

25. The Commission recommends that public and private resources be provided to support systematic reviews of CAM research literature.

25.a. Continue support the Agency for Healthcare Research and Quality's Evidence-based Practice Center systematic reviews on CAM treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria.

25.b. Produce and maintain up-to-date summaries of current evidence on safety and efficacy of CAM practices and products similar to the U.S. Preventive Task Force.

25.c. Develop non-technical, understandable summaries of all systematic reviews of the literature, include them in NLM's MedlinePlus database, accessible directly and through public libraries and other publicly available information services.

26. The Commission recommends that appropriate access to funding and other resources for CAM faculty, curricula, and program development at accredited institutions and by licensed professions should be made possible by amending Titles VII and VIII of the PHS Act to

authorize Health Resources and Services Administration, Bureau of Health Professions to provide this type of support.

27. The Commission recommends that joint research and educational programs involving CAM practitioners and conventional practitioners should be established and financial support for these programs should be identified.

28. The Commission recommends that national educational standards for CAM modalities, therapies, and practices should be established by professional and educational institution organizations linked with the proposed Federal CAM Coordinating Office.

29. The Commission recommends that a basic curriculum in conventional health care and medical sciences for CAM students and practitioners should be developed to facilitate recognition of limits of clinical expertise and potential complications of interventions and appropriate referrals to conventional health care providers.

30. The Commission recommends that collaboration between CAM and conventional health care institutions should be encouraged and funded.

31. The Commission recommends that Traditional healers who practice within a community which provides traditions and oversight should be provided appropriate access to educational funding and allowed to continue to practice without State censure, providing:

- a. Their clients are fully informed of their training (or lack thereof)
- b. They do not mislead their clients by use of titles of licensed professions
- c. They have not been censured by their community.

32. The Commission recommends that CAM students should be eligible for State and where appropriate national fiscal support based on service to designated areas. Eligibility would apply to loans, loan forgiveness, and scholarships. The next reauthorization of Titles VII and VIII of the Public Service Act should be amended to include enabling legislation making CAM students eligible.

33. The Commission recommends that a basic curriculum which surveys the CAM modalities and ensures basic skills in collaborating with or supervising CAM professionals should be developed for conventional health care professionals in professional schools, postgraduate training programs, and continuing education programs to increase knowledge and understanding of CAM in order to enhance and protect the public's health.

34. The Commission recommends that curricula in CAM fundamentals and principles should be developed at conventional health care professional schools in conjunction with CAM experts and CAM institutions.

35. The Commission recommends that conventional health care providers interested in practicing a CAM modality or system of healing should obtain the necessary education in postgraduate or continuing education programs or at accredited CAM institutions.

36. The Commission recommends that opportunities and funding for postgraduate and continuing education resembling that of conventional health care providers should be developed for CAM practitioners providing primary care to enhance the competency and quality of healthcare.

37. The Commission recommends that combined or joint continuing education and residency programs which include different types of CAM practitioners and conventional health care providers should be developed to improve their mutual understanding and enhance their collaborative interaction.

RECOMMENDATIONS 38 - 49 on Access and Delivery Will Be Sent under Separate Cover

50. The Commission recommends that a public-private body (DHHS; DOD; VA; representatives of the research community, insurance industry, and managed care organizations, employers, etc.) be convened to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, methodologies, data, priorities, and coordination. The Commission recommends that DHHS work within the partnership to target public and private resources on research priorities, maintain public-private coordination, and build cooperation.

51. The Commission recommends that public entities (AHRQ, NIH, CMS/formerly HCFA, HRSA, DOD, VA, etc.) and private organizations (research and other private foundations, employers, industry associations, etc.) fund and jointly fund health services research and demonstrations on the safety and clinical effectiveness of CAM practices and products, as well as the efficacy of various models for providing CAM services (integration, collaboration, etc.) within the U.S. health care system. The Commission encourages funding bodies to cooperate with the priorities established in Recommendation 1.

52. The Commission encourages health care purchasers including insurers, managed care organizations, Federal and State agencies, and other health plan sponsors to develop and maintain a process, as conducted for conventional therapies, for incorporating safe and efficacious CAM interventions into health benefit packages.

53. The Commission encourages

- Federal agencies that provide health benefits (CMS, DOD, VA, etc.) to include CAM practitioners on coverage advisory bodies, coding work groups, and related working bodies.
- Insurers and managed care organizations to include CAM experts on coverage advisory bodies, and related working groups.
- Professional associations, health policy institutions, and foundations to consider advice, consultation, and information from CAM practitioners and other CAM experts.
- CAM practitioners to seek out opportunities to advise and participate in bodies, public or private, that address issues related to coverage, reimbursement, coding,

health services research, and CAM-related demonstrations projects.

54. The Commission recommends that public and private entities (DHHS; DOD; VA; research organizations, foundations, insurance industry, managed care organizations, employers, etc.), as with conventional medicine, fund or jointly fund health services research on the cost-effectiveness of CAM interventions, including the specific interventions for various conditions, and the impact of CAM on health care costs. The Commission recommends funding to study the clinical and cost-effectiveness of various models of providing CAM services, and comparisons of the costs and outcomes of CAM therapies and conventional medical therapies for the same conditions. Studies on the costs and benefits of CAM practices, wellness programs, and self-care on health status are encouraged.

55. The Commission recommends that purchasers, insurers, managed care organizations, and other health plan sponsors consider coverage of CAM interventions shown to be safe and cost-effective.

56. The Commission recommends Federal agencies responsible for healthcare coverage and services investigate and report to their respective administrators on how safe, cost-effective CAM therapies may be integrated into federal programs.

57. The Commission recommends that DHHS, working in partnership with representative from the private sector (including professional and industry associations for CAM and conventional medicine, the American Medical Association, insurers, managed care organizations, and researchers), conduct a study of current coding processes and CAM, consider the issues associated with appropriate coding for CAM, and report to the Secretary of DHHS.

58. In order to increase access to and coverage of CAM therapies shown to be safe and cost-effective, the Commission encourages State governments to grant legal authority to practice to those CAM professions seeking licensure, or equivalent stature, within the State.

59. The Commission encourages DHHS to support private sector efforts to develop model CAM necessity and appropriateness criteria for CAM services shown to be safe and effective.

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78. The Commission recommends that The President, Secretary of the Department of Health and Human Services, or Congress should create an Office at the highest possible and most appropriate level with sufficient staff and budget to perform functions that include, but are not limited to, coordination of Federal CAM activities; Federal CAM policy liaison with conventional health care and CAM professionals, organizations, institutions, and commercial ventures; planning and convening conferences, workshops, and necessary advisory groups, centralized Federal media point of contact; and facilitation of implementation of the WHCCAMP recommendations.



FOR CONSUMERS AND PRACTITIONERS
NATIONAL CENTER FOR COMPLEMENTARY & ALTERNATIVE MEDICINE
NCCAM Clearinghouse

Purpose	List of Available Publications
Focal Point for Information	Customer Service Commitment
Access to the Clearinghouse	NIH Resources

Purpose

The **National Center for Complementary and Alternative Medicine (NCCAM) Clearinghouse** is an information service of the NCCAM — serving as the public's point of contact and access to information about the NCCAM's programs, conferences, and research activities.

In accordance with the NCCAM's congressional mandate, "to establish a clearinghouse to exchange information with the public about alternative medicine," the NCCAM established a clearinghouse in the Fall of 1996, with the goal of serving as a site where complementary and alternative health care information is collected, developed, and disseminated to the public.

Focal Point for Information

As the focal point for information resulting from the NCCAM's programmatic and research activities, the Clearinghouse develops and disseminates fact sheets, information packages, and publications to enhance public understanding about complementary and alternative medicine research supported by the National Institutes of Health (NIH). The NCCAM's public information is currently free of charge. However, due to printing and duplication costs, only a limited number of copies can be requested.

Access to the Clearinghouse

Located in Gaithersburg, Maryland, the Clearinghouse responds to inquiries for information by telephone, TTY, fax, or mail:

Toll Free Telephone Number: 1-888-644-6226
Toll Free TTY (hearing impaired): 1-866-464-3615

The Clearinghouse's toll-free number is answered by trained Information Specialists*** from Monday through Friday, from 8:30 a.m. - 5:00 p.m. Eastern Time. Information Specialists can answer inquiries in both English or Spanish. Information Specialists strive to assist as many callers as possible; however, due to the high call volume that they receive daily, there may be a slight delay in reaching an Information Specialist. In the event of a delay, callers have the option of continuing to hold or leaving their name and a call back telephone number where they can be reached.

After normal business hours, callers have the option of receiving fact sheets and other information via fax. Call 1-888-644-6226 to access our **Fax-on-Demand** service.

treatment methods, and NIH sponsored research on a specific condition.

For information about a wide range of diseases or medical conditions, consult the [NIH Homepage](#) for the relevant link to the NIH Institute, Center, or Division that can assist you further.

*** Disclaimer Regarding Medical Information and Advice

Clearinghouse Information Specialists are trained to assist callers, and provide other sources of information. However, because Information Specialists **are not health care professionals**, the information they provide **cannot substitute** for the medical expertise and advice that resides with your primary health care provider. Information Specialists do not provide medical advice to patients, nor provide referrals to alternative health care practitioners.

The NCCAM **encourages all patients to consult their primary health care provider** to discuss both the advantages and risks of complementary and alternative medical treatments.

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