11/09/01
12:25pm

Coverage and Reimbursement for CAM

Introduction

Coverage and reimbursement policies on the part of those that pay, provide or insure for health care services have and will continue to play a crucial role in shaping the health care system in this country. Policies regarding the coverage and reimbursement for alternative health care therapies also play a crucial role, both in the future of CAM and the future structure of health care in the United States. Today, coverage of certain CAM therapies is evolving, making these interventions more available as an alternate approach to health care or complementing conventional medicine. The direction of this movement will shape consumer access to CAM services, the utilization of CAM alongside conventional medicine, and the philosophical foundation of the nation's health care system.

Not to minimize the serious magnitude and problems with the uninsured, health care coverage is widely available in this country. Of the civilian, non-elderly population, approximately 71 percent have private health insurance and most of these Americans (about 64 percent) are covered by employer-sponsored benefit programs. [footnote, EBRI] In addition, significant numbers of Americans have health care coverage through government-sponsored programs including Medicare, Medicaid and the military and veterans health care systems for eligible beneficiaries. These sponsoring entities, such as employers, bear most of the cost and are often referred to as the "purchasers" of health care. Employers usually purchase health plan overage or services from a third party or, less commonly, may provide some health services directly. In addition to the role of purchaser, there is a responsibility for the insurance (or financial) risk of offering health care coverage. Insurance risk, in essence, is the potential for shortfalls between revenues (from premiums, copayments, and deductibles) and expenses stemming from utilization of health care services and products – or the difference between anticipated and actual costs of providing health care. Some employers

self-insure against the inherent risk of employee coverage, but many pass this insurance risk on to an insurance company or managed care organization. Government-sponsored programs such as the Medicare program usually bear both the cost and the risk of providing health benefits, with some exceptions such as managed care contracting programs.

Where there is coverage, health care providers are paid by a third party, not by the consumer. This differs from CAM where the cost of services and products is paid largely out-of-pocket by the consumer. This direct financial relationship has some merit – it may well enhance the consumer's interest and participation in his or her treatment. With control over fees and without time-consuming claims payment requirements, many CAM practitioners feel they are more able to individualize services. On the other hand, without insurance coverage, access to CAM services is limited by the consumer's ability to pay. Many consumers are not able to seek out or integrate appropriate CAM treatments unless the therapy is covered under their health plan .

This system of health benefit sponsorship, transference of financial risk, and third party provider payments evolved over the last half century and is now deeply rooted in our society – and our economy. Given the mandate and scope of this Commission, recommendations have been developed to reflect this system.

Coverage and Barriers to Coverage of CAM

Recent surveys of employer-sponsored health plans help illustrate the emerging coverage CAM services. One such survey shows that chiropractic is now commonly covered as a benefit, while other CAM modalities are in an early stage of gaining coverage. In 1998, 49 percent of survey respondents indicated that chiropractic was covered, and by 2000 the number had risen to 70 per cent. Over the same time period, the per cent of survey respondents covering acupuncture rose for 12 per cent to 17 percent, and massage therapy rose from

10 percent to 12 percent. Large employers (those with more than 20,000 employees) were more likely to offer CAM benefits, and Preferred Provider Organizations (PPOs) and indemnity insurers demonstrated higher rates of offering employers products with CAM benefits than HMOs. [footnote, Mercer Foster Higgins National Survey]

Another survey indicates that employers are introducing coverage of CAM primarily in response to employee requests. Other reasons cited include attracting and retaining employees, state mandates, and potentially effective medical benefits. While most respondents believed coverage or discounted CAM programs would be increasing, they cited obstacles including inadequate research, regulatory concerns, lack of knowledge about CAM (and negativity), and the lack of utilization and cost data. [footnote, 1999 survey Census of Certified Employee Benefit Specialists]

Typical models for offering CAM as part of a health plan are:

- ,An additional "rider" to the basic benefit package, often with utilization controls such as copayments, benefit limits (e.g., visit limits, annual limits), or use of a credentialed network of CAM providers.
- A discount program whereby covered employees (or members) pay out-of-pocket but are eligible for discounts off professional CAM fees and CAM products. Discounted fees are usually tied to a pre-approved, credentialed network of CAM practitioners.
- A defined, core benefit that is part of the employee benefit package. Utilization of this benefit is managed by limiting the type of CAM services covered (e.g., only chiropractic, acupuncture, and massage therapy are covered), requiring pre-authorization or primary care physician referral, or setting visit limits, dollar limits, and higher co-payments than for routine physician visits.
- A CAM benefit account, typically an annual dollar amount.

Employers also may offer wellness and health promotion programs, on-site or off-site. These often include smoking cessation, weight control, stress reduction, yoga, etc. Employers are also becoming more interested in educational programs to help employees with chronic diseases manage their conditions. Employers who have introduced these programs often believe they will decrease absenteeism, improve productivity and morale, and result in cost savings, although little research is available to substantiate these perceptions.

[Barrier section is under development]

Fair and Impartial Consideration of Safe, Efficacious CAM Interventions – A General Recommendation

The Commission believes health care interventions proven to be safe and efficacious should be considered for coverage under health benefit programs, regardless of whether the modality is considered conventional, complementary, or alternative medicine. Any medical or health care intervention that has undergone scientific investigation and has been shown to improve health or functioning, or to be effective in treating the chronically or terminally ill, should be given a fair and impartial assessment for inclusion in health plan coverage. The Commission believes that, to accomplish this, the current methods, standards, and processes used with regard to conventional medicine in building evidence and making decisions as to health plan coverage should be extended to CAM. The Commission's intent, in general, is not to treat CAM favorably or differently, but to have stakeholders approach and consider conventional medicine and CAM in a similar manner. The Commission supports an approach that does not prejudice health care coverage toward one philosophy of health care or the other, but give equitable consideration to safe and efficacious interventions for both conventional medicine and CAM.

For some CAM interventions, there is adequate evidence as to safety and efficacy, such as the impact of stress reduction on certain disease conditions. [add footnote] Where there is such evidence, the Commission believes that CAM practices and products should be given fair and equitable consideration for coverage and reimbursement. Likewise, the processes used in deciding coverage policy should be the same as or similar to those used for conventional medical practices and products.

The Commission recognizes that there are challenges to this latter standard, especially achievement of consensus on the adequacy of the evidence given the often ingrained viewpoints within both conventional medicine and CAM. Those who support conventional medical coverage, or who are skeptical about CAM, may be more critical of the research on CAM and hold on longer to beliefs that valid and reliable research is lacking, or certainly inadequate, and thus oppose expanding coverage to many areas of CAM. Those supportive of CAM may be more willing to accept findings of research that still needs further investigation, and may believe that even where there has been an accumulation of solid evidence, even evidence of cost savings, there is bias and opposition to changing the traditional approach – or to adopting coverage of CAM services.

Draft Recommendations: [formerly 50 and 53, revised]

1. The Commission recommends that purchasers and sponsors of health plan coverage consider, and insurance companies and managed care organizations offer, coverage of safe and efficacious CAM interventions in a manner equivalent to that used for conventional medicine. (~~emphasis added for draft only~~

2. The Commission recommends that stakeholders include CAM experts and/or practitioners on coverage advisory bodies, coding work groups,

and in matters relating to coverage of health care generally as well as CAM benefits.

Stakeholders: Federal agencies including the Department of Health and Human Services (in particular, the Centers for Medicare and Medicaid Services), Department of Defense, Veterans Administration, Office of Personnel Management (for the Federal Employees Health Benefits Program); employers and sponsors of health coverage; insurers and managed care organizations.

3. The Commission recommends that all health care organizations involved in or which influence the delivery of health care seek, on a regular basis, information, advice, and consultation from CAM experts.

Stakeholders: Health professional and provider associations, health policy organizations, foundations vested in health care delivery, etc.

4. The Commission recommends that professionals working in complementary and alternative health care seek opportunities to advise and participate in advisory bodies, public or private, that address issues related to coverage, reimbursement, coding, health services research, and CAM-related demonstrations projects.

Stakeholders: CAM practitioners, CAM experts, conventional practitioners and health experts involved in complementary or integrative models of health care.

Medical Effectiveness and CAM

The Commission believes that many CAM interventions enhance health, functioning, and the experience with terminal illness. However, many of these CAM interventions are not covered under a health plan, usually because evidence of medical effectiveness has not been demonstrated through a scientific process. Those responsible for health benefits are concerned that limited health care dollars be spent on care that has been shown safe and efficacious. Purchasers and payers, in the face of ever-rising health care costs and the vicissitudes of the economy, also want value and accountability for their health care investment. Pressures to add new benefits, the addition of state-mandated benefits, as well as the constant stream of new technologies, drugs, and treatment protocols has left these parties cautious about expanding health care benefits. These and other factors have added to the pressure for more evidence of the medical effectiveness of CAM services and products before coverage policy can be developed.

The benefit definitions and policies of insurers (including Medicare) and managed care organizations determine what and when services and products are covered, which practitioners are authorized to perform the services, and how payment will be made. Long-standing, commonly "authorized services" (such as physician visits, outpatient physical therapy, and specific home health services) have contributed to a pervasive bias of the health care system toward the use of conventional medical services. Consequently, access to a health service in a health plan is dependent on coverage policy. Except for chiropractic medicine and growing coverage of acupuncture and massage therapy, much of CAM is not covered or authorized – even where it has been shown to be safe and efficacious. Thus, coverage and reimbursement policies have a significant impact on access to safe and efficacious CAM therapies.

Insurers, managed care organizations, and purchasers of health care (such as employers and federally-sponsored programs) invest significant time, resources, and analyses into developing benefit packages. With the rising cost of health

care and heightened price sensitivity in the market place, the addition of new benefits is a major undertaking. One step in the process is consideration of research and demonstrations on the safety and efficacy of a therapy or product.

For many CAM interventions, insurers, managed care organizations and purchasers do not consider expansion of coverage because clinical research and health services research are limited or nonexistent, and safety and efficacy have not been adequately demonstrated.

The Commission believes that more health services research is needed to establish the safety and clinical efficacy of CAM therapies. Because research dollars are limited, cooperative efforts between the public and private sectors are needed to identify and resolve methodological issues that challenge health services research and to establish research priorities. In addition to safety and efficacy, health services research is needed to evaluate models of CAM, including integrative and collaborative programs, for effectiveness and best practices.

Draft Recommendations:

5. The Commission recommends that the Secretary, Department of Health and Human Services (DHHS), convene public and private stakeholders to develop a multiyear health services research plan that identifies and addresses CAM research and demonstration questions, methodologies, data, priorities, and coordination. 18 months from

   Stakeholders: DHHS, Department of Defense, Veterans Administration, and representatives of the research community, insurance industry, managed care organizations, employers, etc.

6. The Commission recommends that Federal agencies, states, and private organizations 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, including integration and collaboration, within the U.S. health care system.

Stakeholders: DHHS (Agency for Health Research and Quality, National Institutes of Health, Centers for Medicare and Medicaid Services, Health Resources and Services Administration), Department of Defense, Veterans Administration, research and other private foundations, employers, health industry associations, etc.

Cost Effectiveness and CAM

In addition to the issue of proven medical effectiveness, another barrier to coverage and reimbursement for CAM therapies is establishing adequate information on the utilization, costs and overall cost-effectiveness of CAM benefits. Lawmakers, health plans, and employers find that they are ill-equipped to make decisions regarding CAM as continued growth in utilization is documented and pressure increases to make CAM more accessible. The Commission recognizes that costs and cost-effectiveness of health care intervention are important factors in considering changes to coverage policy, and believe that, in the same manner that decision-makers are provided information and analyses on the cost-effectiveness of conventional interventions, so should such information and analyses be available for CAM – especially for CAM interventions used more widely by consumers or where research indicates clinical effectiveness. At the policy level, decision-makers know little about the cost-effectiveness of CAM in treating individuals with a given condition, in preventing illness, or on the health of certain populations. The Commission believes that more information is

needed on the cost-effectiveness of specific CAM interventions for various conditions, different models of CAM practice, the clinical and financial impact of integration with conventional medicine, and the relative costs of CAM treatments versus the costs of conventional medical treatments. Information is needed as to whether CAM interventions reduce utilization of conventional medical services and pharmaceuticals for groups such as those with heart disease, cancer, or with chronic illnesses, the terminally ill, and individuals with chronic pain. In addition, more information is needed about the impact of wellness programs and self-care, or the impact of CAM practices, on questions such as short and long-term health status, workplace productivity, decreasing workmen's compensation costs and disability, or the patterns and costs of health care in the U.S.

At an operational level, the Commission believes that health plans and health researchers need more information for performing cost and actuarial analyses, risk-benefit analyses, and other types of assessments. Common claim forms, such as the HCFA 1500 and the UB-92 are used for some CAM services but not others. Likewise, coding for CAM services is still developing. Common claim forms and coding are essential tools for insurers and managed care plans in gathering and analyzing utilization patterns, setting provider payments, establishing sound premiums, and managing financial risk.

The use of common claims forms and coding is uneven within the field of CAM. Chiropractors typically use standard forms and have billing codes that allow their services to be entered into the statistical data bases necessary to make health benefit policy and pricing decisions for chiropractic benefits. Acupuncture is moving toward the common claims form, as is massage therapy. Other modalities of CAM are progressing more slowly or are not seeking third party reimbursement at this time.

Draft Recommendations:

7. The Commission recommends that Federal, state, and private entities fund health services research on the costs and cost-effectiveness of CAM interventions and wellness programs.

Stakeholders: Department of Health and Human Services, Department of Defense, Veterans Administrations, health care research organizations, foundations, insurance industry, managed care organizations, employers, etc.

8. The Commission recommends that the Secretary, Department of Health and Human Services, conduct a study of the current, nationally-used coding processes, analyze the issues associated with integrating CAM services and products into these systems, and support the development of coding for CAM services and products.

Stakeholders: Department of Health and Human Services, American Medical Association, CAM associations, CAM coding experts, health care research organizations, foundations, insurance industry, managed care organizations, employers, etc.

Licensure as a Requirement for Coverage and Reimbursement

The Commission recognizes that insurers, managed care organizations, and other health plan sponsors interested in safe, cost-effective CAM interventions may not be able to offer coverage because of the lack of CAM licensure laws or other authority to legally practice within a State. The Commission believes that CAM practitioners qualified to furnish services within their scope of practice, and for which payers will approve payment, should have the ability to practice legally within their State, the same as conventional practitioners.

Coverage and reimbursement for health care services are linked to a provider's ability to legally practice within the State. The legal authority to practice is fundamental to the coverage and reimbursement relationship between providers and purchasers, insurers, and managed care organizations. Laws and processes which establish professional standing within a state not only protect the public, they give assurances that covered health benefits will be provided by qualified practitioners whose services should meet recognized standards of care.

Insurers, managed care organizations, hospitals, clinics, Federal agencies, states, and other sponsors of health plans often are constrained in offering CAM benefits because practitioners do not have authority to practice within the state, i.e., they are not licensed or recognized under a comparable certification program by the State.

Draft Recommendations:

9. The Commission recommends that state governments address the need for legal authority to practice CAM interventions within their state and ~~remove~~ any other obstacle that inhibits coverage of safe and effective CAM services and products.

Determining When to Pay for or Provide CAM

The Commission recognizes that insurers, managed care plans, and publicly financed health benefit programs use necessity and appropriateness standards as parameters for defining coverage and making coverage decisions. Like conventional medicine, CAM needs to develop such standards.

Insurers and HMOs rely heavily on "medical necessity" criteria to define the extent of a benefit, manage utilization, and make claims payment decisions. The

management of health care expenditures and utilization is fundamental to financial stability under managed care and third-party reimbursement systems.

The Commission found that evidence and criteria normally used by health plan sponsors in making coverage determinations is evolving for CAM, but needs continued development with the assistance of CAM experts. Likewise, medical literature increasingly addresses and provides information to guide decisions regarding the necessity or appropriateness of CAM interventions, but needs continued development.

For many CAM services and products, however, criteria for necessity and appropriateness are not well established, are not in a format typically used by payers, or are not readily accessible to payers. In addition, CAM criteria may have an approach different from the disease-based or condition-oriented medical necessity criteria of conventional medicine. CAM services, such as acupuncture, may be used alone as a therapy, or to enhance or support a conventional medical therapy, help prevent the onset or progression of a disease in at-risk individuals, or promote wellness and general disease prevention. Thus, as CAM criteria are developed, payers probably will learn new approaches or will modify current approaches from "medical necessity" to "appropriateness" criteria. The Commission believes that Federal leadership is necessary to initiate, promote, and support innovative efforts.

Draft Recommendations:

10. The Commission recommends that the Secretary, Department of Health and Human Services, convene a meeting of stakeholders to identify issues, discuss approaches, and establish guidance for developing necessity and appropriateness criteria in the field of CAM services and products.

Stakeholders: Insurance companies and associations, managed care organizations and associations, employers, Federal agencies, states, CAM professionals and associations, benefit experts, etc.

11. The Commission recommends that purchasers and payers work cooperatively with CAM professionals to develop criteria for appropriate coverage of CAM.

Stakeholders: Insurers, managed care organizations, employers, Federal agencies, states, benefit experts, etc.

Supporting Coverage and Reimbursement Through Information

The Commission believes that purchasers, insurers, managed care organizations, and other sponsors of health care coverage need access to timely, reliable information about safe, efficacious, and cost-effective CAM practices and products. Such information will help overcome disparities and assist in the fair consideration of CAM practices and products in developing health benefit packages. That is, CAM interventions shown to be safe, efficacious, and cost-effective would be given more equitable consideration for coverage and reimbursement in a health benefits package.

The "players" in developing benefit packages, including health benefits consultants, have well-established methods and processes for analyzing changes in coverage. Purchasers and payers also have inducements to maintain more traditional packages of benefits. Consumers covered under a health plan, for their part, generally are disinclined to give up or have any significant change made to their existing benefits. Once a benefit is added, it is difficult to reduce, replace, or modify the coverage -- and maintain member satisfaction. Purchasers and payers are concerned also about the financial impact of a health benefit not previously offered in the market place, or for which

there is little data. Cost estimates for adding a new health benefit are often too low because of the difficulty in estimating utilization, and the industry's past experience with underestimating the number of users. Purchasers and providers find it difficult to make significant changes to benefit packages without sufficient, high-confidence information.

The paucity of clinical and health services research, as well as publication and dissemination issues, have created an information crisis. Insurers, managed care organizations, public purchasers, and other sponsors are increasingly willing to consider coverage of safe, cost-effective CAM interventions but are challenged in building a valid information base and evaluating available information in order to make coverage policy decisions.

The Commission believes that a Federal initiative is needed to bridge this information gap, and that an out-reach effort will be needed to inform purchasers, such as employers and community health centers, of the availability of this initiative. The Department of Health and Human Services, given its resources focused on CAM research, should consider ways of addressing the information gap, such as creating an electronic or paper resource for consumers, employers, other purchasers, the insurance and managed care industries, and professionals.

Draft Recommendations:

12. The Commission recommends that the Secretary, Department of Health and Human Services provide consumers and professionals with timely, easily accessible information on the results of research related to CAM services and products. that have been scientifically proven to be safe & effective

    Stakeholders: DHHS, researchers, CAM professionals and associations, Federal and state agencies, insurance and managed care industries, etc.

13. The Commission encourages Federal departments to report to Congress, the President, and departments within the Executive Branch on the status of research, coverage, access and availability of CAM services for their respective beneficiaries or through their respective sponsorships.

Stakeholders: Department of Health and Human Services, Department of Defense, Veterans' Administration

14. The Commission recommends all health care and health research organizations integrate CAM topics into their informational and development meetings, such as annual professional meetings, and that the Secretary, Department of Health and Human Services, provide support for the development of such informational programs.

Stakeholders: Employers and other sponsors of health plans, health benefits experts, health care (provider and professional) associations, medical educational institutions, health policy bodies, foundations, etc.

To be added: information on Medicare and other federal programs.

- CAM Central

• Many Resources - 150 References - Overwhelming
• Core Recommendations Reference is Narrow

08Nov01

CAM Information Development and Dissemination

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

Issue 1: Availability 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 health topics. Throughout the Federal government, fact sheets, reports, pamphlets, posters, books, etc. are produced to provide useful and reliable information to the public. These materials provide consumers with an array of information on specific diseases, health care delivery services, research findings, etc. Information is also available though various government internet sites, or though numerous toll-free numbers, many of which are associated with a clearinghouse.

The National Center for Complementary and Alternative Medicine (NCCAM) has a congressional mandate to "establish a clearinghouse to exchange information with the public about alternative medicine.[1]" The NCCAM Clearinghouse has a toll free telephone number and provides fact sheets, information packages, and publications on CAM research and NCCAM's activities. Within the Department of Health and Human Services, CAM- related information is also available from the National Cancer Institute and the Office of Dietary Supplements in the National Institutes of Health, and in the Center for Food Safety and **Applied** Nutrition in the Food and Drug Administration. Other government entities such as the Department of Agriculture and the Federal Trade Commission also have information related to specific CAM topics.

Despite these efforts, information on CAM from the Federal government is inconsistently available and often difficult to locate. 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. Existing materials should be reviewed and, where appropriate, CAM information should be added and new materials developed.

[1] -

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. Particularly for the media, there is no centralized place in the Federal government to quickly get objective and comprehensive information on CAM, which would assist in providing more complete, balanced, and unbiased information to a wide audience.

The Federal government, through the General Services Administration, operates *Firstgov.gov*, a consumer-friendly search engine that searches rapidly every word of every US government document 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, and greater efforts should be made to promote the use of this search engine. For people who do not use the internet, a centralized, toll free telephone number would help to direct callers to the appropriate agency to answer their questions.

Challenges:

Federal entities may be reluctant to include information on CAM in the information they develop for the public for a variety of reasons. These may include limited awareness or acceptance of CAM by Federal staff or leadership, lack of agency policy on the inclusion of CAM information, limited availability of research on many of the CAM products and services people are using, etc.

Recommendations:

1) The Commission recommends that the Secretary, DHHS, establish an inter-departmental task force to identify and eliminate existing gaps in the development and dissemination CAM information in the Federal government.

2) The Commission recommends that existing resources be made more readily available to the public, including the media, to direct callers to the appropriate agency and/or person for specific CAM information.

Issue 2: Availability and adequacy of CAM information for diverse groups of consumers.

Background:

Differences in how people access and utilize information is an important consideration in the development, distribution, and evaluation of CAM information. According to the most recent National Adult Literacy Survey, forty-eight percent of U.S. adults, or close to 100 million Americans, have very limited literacy skills[2] due to lack of

[2] - National Adult Literacy Survey, U.S. Department of Education, National Center for Education Statistics,1992

English skills, reading disabilities, or under-education[3]. In addition to varying literacy skills, differences in accessing and utilizing information can exist among men and women, people of different age groups and income levels, and people with different racial, ethnic, and cultural backgrounds.

Health information materials (print, radio, television, or other media) are often targeted to reach specific audiences, particularly if a population is at higher risk for developed a disease or condition, or has higher utilization of a particular practice or product. Materials may be produced in different languages, and the content, pictures, and style may be altered to more effectively reach the intended population.

Developing CAM materials that are targeted to different racial, ethnic, or cultural groups and people of varying literacy levels is especially important because use of CAM varies among people of different racial, ethnic, and cultural groups[4]. Some populations are particularly susceptible to advertisements of CAM products such as the sale of herbs, tonics, vitamins, and other products that have not been shown to be effective and in some cases, may even be harmful, or services that promise to cure health and other problems not addressed through the conventional health care system or through legitimate CAM providers. This may be due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, distrust or fear, and other similar factors. Not only does this take money away from people with limited resources, but it can also delay treatment of serious or life-threatening conditions. 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.

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. Librarians may also not be aware of other sources of CAM information such as books, periodicals, and newsletters. The National Library of Medicine has begun working directly with public libraries through the American Library Association to train local librarians to use the internet to find health information. This effort could be enhanced to include more training and focus on CAM, and include other resources for CAM information.

Challenges:

Currently available demographic data do not provide adequate information on CAM usage among various population subgroups or the range of methods and patterns in accessing CAM information.

---

[3] - ibid

[4] - Wooton J., Sparber A. Surveys of Complementary and Alternative Medicine; J of Alternative and Complementary Medicine, Vol.7, No.2, 2001, 195-208.

Recommendations:

3) The Commission recommends that adequate resources and support be made:

a) CAM information materials be developed at a level that most of the adult general public can understand and utilize, and

b) national and local community leaders of population subgroups identify strategies and develop materials to enhance the availability of CAM information to the communities they represent and help prevent special populations from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental. Contracts & Grants ↑ sufficient resources

4) The Commission recommends that, in partnership with the National Library of Medicine and the American Library Association, training materials be developed and training be provided to assist librarians in guiding people to find CAM information.

Issue 3: Accuracy and quality of CAM information on the internet.

Background:

According to the most recent Census Bureau estimates, 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.[5] The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers, with an estimated 60 million[6] U.S. adults having used the internet to get health information last year. Most sites are general health information sites that include CAM information, but some sites are specific to CAM.

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.

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 some do not have any qualified CAM

[5] - Census Bureau Report, September 6, 2001

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

practitioners on their review boards. **Publicly available information or evaluation of the efforts of these organizations promoting standards for health sites on the internet is scarce and evidence of any positive impact on the content of these sites is lacking.**

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.

Privacy of information is an issue of great concern to many people. 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 rates[7]. Privacy protections for health information seekers on the internet are limited. In 1998, Congress enacted the Children's Online Privacy Protection Act (COPPA) to prevent the collection of personally identifiable information from young children without their parent's consent. The Federal Trade Commission has filed four civil penalty actions this year to enforce COPPA and has additional cases under investigation. The Health Insurance Portability and Accountability Act of 1996 applies to health plans, health care clearinghouses, and health care providers conducting electronic transaction. It does not provide privacy protection for health information seekers on the internet.

Challenges:

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:

5) The Commission recommends that a public-private partnership be formed to review new and existing websites and develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites, as well as disclosure of sources of support and any conflicts of interest. Sites reviewed and found in compliance with the standards could publicize this achievement and display a logo identified with this level of merit.

6) The Commission recommends that a public education campaign be conducted that teaches people, including students, how to evaluate health care information, including CAM information, on the internet.

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

7) The Commission recommends that Congress protect the privacy of individuals using CAM internet sites by

a) requiring all health information sites, including CAM sites, to disclose if users are tracked and how that information is utilized (including whether that information is sold to third parties), stored; and

b) assessing if current legislation or regulations are adequate to assure the protection of privacy of health information seekers on the internet, including CAM information seekers, and evaluating the need for developing new legislation.

Issue 4: Accuracy of advertising of dietary supplements and other CAM products and practices.

Background:

The Federal Trade Commission (FTC) is responsible for assuring that advertising of dietary supplements and other products is truthful, not misleading, and substantiated so that consumers can make informed decisions about these products. They do this by enforcing laws that prohibit unfair or deceptive acts or practices in print and broadcast advertisements (including the internet), catalogs, and similar direct marketing materials.

Much of the focus has been on dietary supplements, which are used by over 158 million consumers[8]. There are an estimated 1566 businesses that manufacture dietary supplements[9], and sales are reported to have reached $17 billion in 2000[10]. An estimated $700 million was spent in 2000 by dietary supplement companies to advertise their products on television and in print.[11] While much of the advertising of dietary supplements conforms to the standards of the Dietary Supplement Health and Education Act of 1994 (DSHEA), abuses have been identified, particularly on the internet and in advertising materials sent directly to consumers. Legitimate companies that comply with current anti-deception and substantiation standards stand to lose market share and suffer financially as a result of companies using deceptive advertising.

Some advertisements promise to treat or cure a disease or condition without the necessary substantiation to make such a claim. Others provide misleading information that claims to slow down or reverse the aging process and increase longevity, energy, memory, and sexual function. While some products have beneficial effects, others have no effect. In some cases, they can even cause serious unintended effects ranging from the consequences of delayed

[8] -Prevention Magazine's Survey of Consumer Use of Dietary Supplements, 2000, p4

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

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

[11] - Dietary Supplement Market View 2 (10): 1-9; October 2000

treatment to interactions with prescription drugs to increased risk for other conditions. Some have caused illness and death.

A recent Government Accounting Office (GAO) report and Senate hearing[12] highlighted the potential for physical and economic harm by dietary supplements marketed and advertised as anti-aging therapies. In addition to potential medical consequences, the GAO reports that for 20 companies marketing products to seniors that have been the subject of law enforcement activities, the average economic harm to consumers as a whole was about $1.8 million per company[13].

Due to the proliferation of health fraud on the internet, 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. Although the FTC has identified hundreds of internet sites with questionable or clearly fraudulent health claims, and has sent out email advisories to more than 500 of those sites, they have only been able to bring formal action against 16 of those sites since 1997.

In addition to these Internet cases, the FTC has brought 40 enforcement actions **since 1997** against the deceptive marketing of dietary supplements in other media, including radio, television ads and infomercials, newspapers, magazines and direct mail since 1997. The challenged advertising promoted products for such conditions as ADHD (attention deficit hyperactivity disorder), colds and allergies, impotence, diabetes, vascular diseases and obesity.

Challenges:

Recommendations:

8) The Commission recommends that additional support be provided to the Federal Trade Commission to expand efforts to identify false and deceptive CAM- related health claims and take appropriate enforcement action; and increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

Issue 5: Information on training, certification, and other qualifications to enhance consumer knowledge and choice.

[12] - Special Committee on Aging, U.S. Senate, September 10, 2001

[13] - Health Products for Seniors; Anti-Aging Products Pose Potential for Physical and Economic Harm, GAO, Sept 2001

Background:

A person can advertise themself as a practitioner of CAM, yet training, licensing requirements, certification, scope of practice, regulations, and even definitions can vary considerably. For example, naturopathic medicine and naturopathy are practiced by different levels of practitioners, and naturopathic doctors distinguish themselves from naturopathic physicians. Acupuncture can be practiced by a professional acupuncturist who has spent several years in acupuncture-specific training, or by a practitioner of another health modality (e.g., physician, dentist, podiatrist, physical therapist, chiropractor) with little or no additional training. An herbalist may have years of training or no formal training at all. Licensing requirements and scope of practice vary from state to state. Certification can be granted by a Department of Education approved organization, or someone printing certificates.

Navigating through the maze of titles and certificates can be a challenge for consumers, most of whom are unfamiliar with the nuances of a profession. Information that explains a person's level and training should be readily available to help consumers to make informed choices in their selection and use of a practitioner. Also, to help assure public safety, information on State regulations, requirements, and disciplinary actions should be readily available for consumers.

Challenges:

CAM practitioners without any formal training may be reluctant to provide this information. **Also, consumers may not be able to distinguish between a degree or certification obtained from a legitimate organization or a degree or certificate purchased from an organization that awards degrees without requiring its students to meet established educational standards ("diploma mills").**

Credential Geo de Ole

Recommendations:

9) The Commission recommends that States and local governments require all persons providing any kind of health services or products, including CAM, to make information easily available to consumers that explains their level and scope of training so that consumers can make informed choices.

10) The Commission recommends that States and local governments make information on state guidelines, requirements, licensure, certification, and disciplinary actions of health providers, including CAM providers, readily available to the public. Internet

Issue 6: 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 **potentially** significant amount of high quality CAM information published in other countries that is not available in English or in the U.S. As globalization of information increases, the research, findings, and experiences of other countries can provide valuable information on the safety and efficacy of CAM.

Challenges:

Recommendation:

11) 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, scientific materials are made available to researchers, clinicians, policymakers, and others.

Issue 7: Adequacy of information on manufacturing and safety of dietary supplements to assure consumer safety.

Background:

The availability and use of dietary supplements in the United States has grown significantly in the past several years. As a result, public interest related to safety and efficacy of dietary supplements have also increased. While these concerns are analogous to those associated with the safety of food and drugs, dietary supplements are unique in that some are used for nutritional purposes and others for disease prevention and treatment. They are regulated as foods, not drugs and therefore are considered safe for human consumption. Yet problems with composition, purity, adulteration, and contamination have been reported and raise concern about safety.

Laboratory testing of dietary supplements has shown that some do not contain the ingredients or the amount of the ingredients declared on the label. Testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and **polyphenol (or marker compound)** levels that they claimed the product contained [14]. Testing of 13 SAMe (*S-adenosyl-L-methionine*) products showed that 5 had less than half of the amount listed on the labels and one had no detectable level at all[15]. Laboratory testing has also shown that some herbal preparations contain ingredients other than those listed on the label, including undeclared pharmaceuticals such as non-steroidal anti-inflammatories, corticosteroids and diazepam[16].

---

[14] - ConsumerLab.com, Sept 2000
[15] - ConsumerLab.com, January 2000
[16] - DeSmet PAGM. *Drug Safety* 1995; 13: 81-93

Aristolochic acid, a naturally occurring **compound** which has been associated with cancer and renal failure, has been identified in various dietary supplements, prompting recalls of products by several companies[17]. Certain pyrrolizidine alkaloids, which are found in numerous plants used medicinally around the world[18], have been found to be hepatotoxic in animals and humans[19] . Some dietary supplements have been found to be contaminated with heavy metals, microorganisms, and pesticides, and toxic levels of mercury have been reported in some imported herbal products[20]. In April and May 2001, two manufacturers recalled several products as a result of salmonella contamination.

These examples raise concerns as to the adequacy of current regulations to assure the safety of dietary products and to respond quickly when a problem is identified. Under the Dietary Supplement Health Education Act of 1994 (DSHEA), a manufacturer is responsible for determining that the dietary supplements it produces and/or distributes are safe and that claims are substantiated by adequate scientific evidence. However, DSHEA does not require a manufacturer to disclose what information was used to determine the safety of their product. The absence of a requirement to provide data on safety is a potential weakness of the current regulatory system.

Although they are regulated as foods, separate Good Manufacturing Practices (GMP) are being developed for dietary supplements with support from many members of the dietary supplement industry. Implementation of GMPs will focus on manufacturing practices that will help ensure the identity, purity, quality, strength and composition of dietary supplements. The formal publication and implementation of GMPs are still pending.

While implementation of GMPs will address domestically produced products, imported finished products from some countries may not meet the standards set forth by the GMPs. Appropriate government entities, such as the Department of Health and Human Services, the U.S.Department of Agriculture, the Environmental Protection Agency, the US Customs Services, and others 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. Linkages with the World Health Organization and other appropriate international organizations should also be developed to establish guidelines to help assure the **quality** of herbal ingredients and, where possible, set international **guidelines**. These efforts should also include preventing the exploitation of endangered species for the manufacturing of herbal products.

Since 1994, many new dietary supplement products have been introduced onto the US market, yet validated analytical methods have not been developed for many of these supplements, particularly botanicals. Different

---

[17] - FDA -

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

[19] - Hirono I, Mori H, Haga M. Carcinogenic activity of *Symphytum officinale. J Natl Cancer Inst* 1978; 61(3): 865-69.

[20] -

analytic methods are used by different manufacturers, leading to varying test results regarding levels of marker compounds. Government, industry, and scientific organizations have begun developing validated analytical methods for botanical and dietary supplements so that consensus can be reached regarding the chemical and physical standards for composition and quality. These efforts need to be enhanced. Efforts by the Institute of Medicine[21], to develop a framework for reviewing data on the safety of dietary supplement ingredients will also assist in improving safety. The framework includes consideration of many factors such as available scientific literature, known risk factors, and extent of use.

Challenges:

Continual cooperation between government and industry will be needed to assure the safety of dietary supplements.

Recommendations:

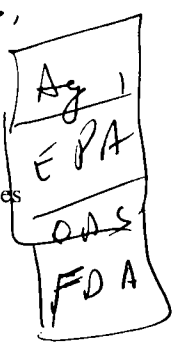
12) The Commission recommends that efforts to assure the development, validation, and dissemination of analytical methods and reference materials for well-characterized products to the public be enhanced and accelerated.

13) The Commission recommends that the Good Manufacturing Practices **for Dietary Supplements** be implemented to help assure the quality and composition of dietary supplements, and that a study be commenced 12 - 18 months after the full implementation of the GMPs by an external organization to evaluate current efforts and provide recommendations for improvement.

14) The Commission recommends that appropriate Federal entities work with

a) manufacturers and importers to monitor the quality of imported and domestic dietary supplements to identify and prevent contaminated or adulterated products from entering the US marketplace; and

b) the World Health Organization and other appropriate international organizations to establish guidelines to help assure the **quality** of herbal ingredients and, where possible, set international standards for consistency.



Issue 8: Adequacy of packaging and labeling information of dietary supplements for consumers and providers.

Background:

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, and product labels must conform to the laws and regulations that govern its intended use. Thus, a vitamin or a botanical that claims to prevent or treat a

[21] - FDA Contract #, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences

disorder must be an approved drug for this information to be included on the label. A product that makes a health claim related to a nutrient-disease relationship, such as "diets high in calcium may reduce the risk of osteoporosis," or " diets low in sodium may reduce **the risk of** high blood pressure" must be approved under the Nutrition Labeling and Education Act of 1990 (NLEA) for this to be on the label. The NLEA allows health claims to be made after an extensive review of the scientific literature has been conducted using the "significant scientific agreement" standard to determine that the nutrient/disease relationship is well established.

The Dietary Supplement Health Education Act of 1994 (DSHEA) allows products that do not make claims of preventing or treating a disorder or a nutrient-disease relationship to be marketed as dietary supplements provided they only include structure and function information on the label. Not having to have drug approval or a health claim has greatly enhanced the availability of dietary supplement products, yet has limited the availability of label information to consumers on benefits, appropriate use, and potential risks.

For example, glucosamine sulfate (*2-amino-2-deoxyglucose*), which has had numerous controlled studies published in peer-reviewed journals suggesting its effectiveness for treating osteoarthritis[22], can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Saw palmetto (*Serenoa repens*) has had numerous positive scientific studies, a positive monograph by the United States Pharmacopeia, and a favorable meta-analysis in the Journal of the American Medical Association[23] for the treatment of benign prostatic hyperplasia, yet there are no incentives for a manufacturer to petition for a health or drug claim because of the cost of research needed to support the petition and the absence of market exclusivity.

When information about potential risks becomes available, such as the potential interaction between St. John's Wort (*Hypericum perforatum*) and certain prescription drugs, this information should be included on the label of both the prescription drug and the dietary supplement. The dietary supplement label should also include contra-indications, known side effects, or warnings of for use for conditions such as during pregnancy and lactation. Like all FDA-regulated products, dietary supplement labeling is required to include all facts that are material in light of consequences that may result from use of the product or representations made about it[24]. However, this has not resulted in material facts being included on the label. The FDA needs to provide additional guidance to manufactures of dietary supplements as to what type of information is considered a material fact, at what point does a body of information become a material fact, how long after information becomes a material fact should it be on a label, etc. Following clearer guidance on this issue, the FDA should monitor and enforce this important provision of information.

---

[22] -

[23] - Wilt TJ, et al. Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. *JAMA*. 1998 Nov 11; 280 (18):1604-9.

The general public has an expectation that products sold in the United States have been deemed safe. Most people don't understand the complexities and implications of existing regulatory guidelines or recent court decisions which have upheld the right of commercial free speech in advertising and labeling of dietary supplements. Since many dietary supplements are purchased without the knowledge or advice of a physician, pharmacist, or other primary care provider, information on benefits, appropriate use, and potential risks should be made easily available to consumers at the time of purchase. **While labeling information is of primary importance, it is one of several mechanisms available to provide essential information to the public, and other options to assure the availability of pertinent information should also be examined.**

In some cases, imported products have labels with information in a language other than English. Since these products may be used by diverse groups of people, product labels should be required to have all information on the label available in English. This does not preclude another language from also being used on the label, but does assure that a majority of consumers, providers, and regulators can also read the label.

The use of dietary supplements has grown significantly since DSHEA was enacted in 1994. Federal and State regulatory agencies need more 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 ensure public safety.

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 issues. Particularly in the rapidly evolving area of botanicals, having staff with adequate expertise is essential in developing mutually supportive relationships with industry and engendering consumer confidence.

Recommendations:

15) The Commission recommends that the availability of consumer information of dietary supplements be increased through improved labeling, package inserts, and information at points-of-sale. **When interactions with prescription or OTC drugs, foods, or other health products, as well as 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 are known, this information should be required on the label, and all information on labels should be in English, even if another language is also included.**

16) The Commission recommends that the FDA and other agencies with regulatory responsibilities be provided with the necessary funds to employ additional professionals with expertise in dietary supplements.

[24] - Section 201(n); Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product

Issue 9: Adequacy of information on adverse events from dietary supplements.

Background:

The majority of dietary supplements are safe for human use, yet, as with any biologically active substance, adverse events can and do occur. Dietary supplement manufactures must determine that their products are safe, but the rigorous pre-marketing testing and review process of pharmaceutical medications is not required for products marketed as dietary supplements. Therefore, monitoring of adverse events is critical to a better understanding of effects and interactions of dietary supplements and to respond quickly if a problem does occur. The FDA monitors adverse events through its Adverse Events Reporting (AER) system.

The AER system is an important mechanism for the early identification of emerging problems with a specific product, or general trends in dietary supplement related morbidity and mortality. However, reporting is voluntary and manufactures and distributors are not required to notify the FDA of adverse reactions reported to them. 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[25]." This report identifies the limitations of the current system in detecting serious adverse events related to dietary supplements and provides recommendations to improve the system.

Severe adverse events[26] related to dietary supplement usage need to be identified and, when necessary, contained in a timely manner to prevent unnecessary morbidity and mortality. Since manufacturers are not required to register themselves nor their dietary supplement products with the FDA before producing or selling them, containment of a potentially dangerous situation might be extremely difficult.
Poison control centers collect nationwide data and reported ten deaths from dietary supplements in 1999. This information needs to be linked with the AER system.

Challenges:

Some representatives of the dietary supplement industry are willing to support mandatory registration of manufacturers and products as long as it remains a simple registration and does not evolve into a cumbersome and time-consuming licensing system.

Recommendations:

---

on the Structure or Function of the Body; Final Rule; 65 Federal Register 999-1050, 1/6/2000

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

[26] - Defined under Medwatch and in the FDA's Standard Operating Procedures of 1999

17) The Commission recommends that Congress require dietary supplement manufacturers and suppliers to register their products with the FDA and that the FDA encourage voluntary registration under such a requirement is in effect.

18) The Commission recommends that dietary supplement manufacturers and suppliers be required to maintain a record of adverse events and report serious adverse events to the FDA to facilitate FDA's dissemination of information to other manufacturers and suppliers and the public, **and that the FDA promptly notify manufacturers of any severe and/or clinically significant adverse events reported to the FDA to allow companies the opportunity to provide important information about known safety and product formulation.**

19) The Commission recommends that the FDA simplify the Adverse Event Reporting system to facilitate reporting of adverse events and increased outreach activities to health professionals (including poison control centers, emergency room physicians, CAM practitioners, mid-level marketers) and consumers to underscore the importance of reporting adverse events.

10/9/01

(10)

Status -

Meeting Format - December 6-7

Procedure to contact Agencies & Dept

CAM IAC - 11/19/01

- ~~Strategies~~ Implementation
- Add more Specifics
- to Recs

(Specificity vs Generality of Report)

- Read text leading up to Rec
- Recs - end product & discussions & rationale text substantiate the Recs

1. <Specific Issue> <Goal Subject> -
2. Write Concerns/Questions → Final Report Recs
3. Open Forum
4. Questions to Commission - at meeting / tone content / process

- Goal is to get Agreement on Rec + Text Issues
- Most Controversial at Beginning / Come to Consensus get rid of nuance
- Next meeting will get agreement on Final Report

Janet Kahn

John Weeks
Sheila Quinn
Alan +

Response letter

93% favor Issues + Recommendations

tried to have all commission members present

H
S — 2 Sides of the Aisle
Daschle
Harkin
DeFazio

Apologies — Restricting our Presence at Invitational only meetings

Sheila Quinn: National Standards of Practitioners

Themes:

- Differences of levels of Development of CAM Intervention
- Economic Competition is the major obstacle for integrative medicine approach

NCCAM Growth, Diversification, Maturation
# of Applications
1999 — 23 RO1, R21 >50% of Applications
2000 — >400 Applications

2001 <17½%
2002 — <10% of applications

Reviewers

Risk-Averse Research — Frontier Research
→ Wayne Jonas

Acupuncture — high % of Research $

We are Visiting Federal Stakeholders to Discuss Recommendations

Validate ~~about~~ the direction we are going in

Revised Outline for WHCCAMP Report

Table of Contents

Executive Summary

Part I: Introduction

- Background
- Overview of Commission
- Commission's Charge
- Guiding Principles of the Commission

Part II: Overview of CAM

- Definition and Description of CAM
- History of CAM in the U.S.
- Current Status of CAM in the U.S.

Part III: Wellness

Part IV: Research

Part V: Education and Training

Part VI: Access and Delivery

Part VII: Information Dissemination

Part VIII: Vision for the Future

Glossary:

Appendices:

A. List of Commissioners and Their Affiliation
B. List of Commission and Town Hall Meetings and Presenters
C. ~~Overview of Institute of Medicine Report: Crossing the Quality Chasm~~
~~D. Overview of Healthy People 2010~~
~~E. Overview of DSHEA~~
F. Others?

Index

PART TWO

OVERVIEW OF CAM IN THE UNITED STATES:

DEFINITION AND DESCRIPTION, HISTORY, AND CURRENT STATUS

Defining and Describing CAM

Definition

Complementary and alternative medicine is a heterogeneous group of medical, health care, and healing systems, modalities, products, and practices other than those intrinsic to mainstream healthcare in the United States. CAM includes all such systems and practices and their accompanying theories, explanations, and worldviews that have to do with preventing and treating illness and promoting health and well-being. Although heterogeneous, the major CAM systems have many common characteristics, including a major focus on individualizing treatments, treating whole people and systems, promoting self-care and self-healing, and supporting vitalism and spirituality. Many CAM systems have characteristics also commonly found in some branches of mainstream healthcare, such a focus on good nutrition and preventive medicine. Thus, boundaries between CAM and mainstream medicine as well as between CAM systems are often blurred and constantly shifting and evolving.

Description

Some of the health care systems, practices, and products that are typically classified as CAM in the United States are listed in Table 1, below.

Table 1: Common CAM Therapies and Systems of Medicine Offered in the U.S.*

*Acupuncture	Chiropractic	Naturopathic Medicine
*Acupressure	(Sacral) Cranial Osteopathy	Nutritional Therapy
Alexander Technique	Environmental Medicine	*Qigong
Applied Kinesiology	*Herbal Medicine	Reflexology
Anthroposophic Medicine	Homeopathy	Relaxation and Visualization
Aromatherapy	Hypnosis	Reiki
Autogentic Training	Imagery	Shiatsu
Ayurvedic Medicine	Massage and Bodywork	Spiritual Healing
Bioelectromagnetics	*Meditation	Therapeutic Touch
Energy Medicine	*Mexican-American Medicine	Traditional Chinese Medicine
Feldenkrais	Native American Medicine	*Yoga

*Many CAM therapies and practices are derived from complex systems of healthcare and healing and are typically delivered within the context of the overall care rather than as a stand-alone therapy, although they may be delivered as stand-alone treatments by those who are not trained in the particular system of medicine.

Adapted from Zollman C, Vickers A. What is complementary medicine? BMJ 1999;319:693-696

Common Characteristics of CAM Systems

Despite their diversity, there are a number of similarities among the major CAM systems listed in Table 1. These similarities include a focus on:

a) Clinical observation - Many of these practices have evolved out of clinical experience, from small groups who use the intervention (e.g. neural therapy, polarity) to widely used, elaborately detailed systems such as Traditional Chinese Medicine.

b) Whole systems - CAM systems tend to emphasize a complete or combination systems approach that includes multiple simultaneous interventions with individualization, or variation, of those interventions during the course of treatment. They often assume that the entire system is required as a package independent of the isolated effects of its individual components (e.g., the use of whole plant extracts rather than isolated active ingredients). For example, a chiropractor, in addition to providing a spinal adjustment, may also offer

advice on diet and exercise, provide guidance on breathing and relaxation, and prescribe nutritional supplements.

c) Stimulating Self-Healing Processes - CAM systems tend to emphasize the stimulation or support of natural healing processes, referred to as *vis medicatrix naturae* (the healing power of nature) and seek to enhance those processes in order to accelerate the natural course of recovery, rather than mask or suppress the symptoms of the disease. (e.g. nutritional & diet therapy for rheumatic diseases rather than immuno-suppressants.). Even CAM modalities that are not directly evolved from traditional systems of medicine, have adopted the philosophy that the body's self-healing mechanism can be speeded up, sometimes to an astonishing degree, by the proper stimuli. Thus, many CAM practitioners employ therapies designed to stimulate the patient's constitution to fight on its own behalf, on the assumption that this emphasis on enhancing the natural healing process is the most appropriate foundation of any medical therapy (House of Lords, 2000).

d) Promoting Self Care - CAM systems tend to emphasize a practitioner-patient partnership in looking at options. There is also an emphasis on promoting self responsibility and promoting interventions that incorporate quality of life, patient preferences, and patient satisfaction into the therapeutic and diagnostic decision-making processes.

e) Vitalism - Many CAM systems emphasize the need to achieve balance of energy in order to promote a higher, or optimal, level of functioning above the mere absence of illness. Restoring harmony and promoting optimal functioning is a major focus of many CAM systems, including Ayurvedic Medicine, Native American Medicine, Homeopathic Medicine, Traditional Chinese Medicine, Naturopathic Medicine, and Chiropractic.

f) Spiritualism - Most of the traditional healing systems—Traditional Chinese Medicine, Indian Ayurvedic Medicine, and Native American Medicine—are based on the assumption that humans are connected to one another, to the earth, and the spiritual world in many more ways than science has yet uncovered. Disease, in these systems of medicine, is an imbalance within our bodies as well as between the way we live and the natural, social, and spiritual world (Gordon, 1996).

Many of the systems of medicine and therapies listed in Table I have become associated with CAM because they have been marginalized or underutilized by conventional, or mainstream, health care as critical ingredients to the delivery of high-quality health care. The marginalization has occurred for a variety of reasons, including:

a) a lack of an understanding or acceptance of the explanatory model or models underlying the system (e.g., homeopathy, chiropractic) by mainstream health care professionals. While mainstream clinicians tend to formulate theories and then deduce therapies from them; CAM healers tend to reverse this process, that is, develop explanatory theories based on clinical observations of responses to treatment. The dedication of some CAM systems of health care to simplistic, all-inclusive theories gives them the appearance of sectarian fanaticism in mainstream medicine's eyes (Whorton, 1999).

b) The origin of the system from cultures outside of the U.S. or from indigenous cultures (e.g., Ayurvedic Medicine, Traditional Chinese Medicine, Native American Medicine). Because these systems often rely on low technology (e.g., herbs) or self-help approaches, they are often seen as primitive and unscientific.

c) the lack of sufficient data on safety, efficacy, or potential mechanism of action to support its use for treating specific illnesses (e.g., vitamin therapy).

d) the inability to easily integrate the system into the mainstream healthcare model (see discussion below).

e) the widespread belief that the healthcare or healing system is not practical or feasible for most people, even though there is scientific consensus that it is therapeutic (e.g. environmental medicine, therapeutic diets).

It should be emphasized that because CAM is so diverse any attempt to define or describe it is likely to be deficient or flawed from one or more perspectives. Health care systems, practices, or products that are not widely available and/or are difficult to access in one part of the United States may be readily available and quite easy to access in another.

To truly understand the complexities of this definition and description of CAM, however, it is necessary to understand its origins, its evolution, and its current status in this country. These are the subjects of the remainder of this section.

History: The Fall and Rise of CAM in the United States.

Before the early 19th Century, medicine in the United States was an eclectic mix of co-existing systems of medicine. In colonial and post-colonial America, there were literally dozens of competing medical philosophies, including those derived from European, Asian, African, and Native American cultures.

During this time, there were only a few hundred graduates of American and European medical schools (i.e. M.D.s) practicing in the United States and only the upper classes were able to afford their services. The vast majority of primary medical care in this country, therefore, was provided by botanical healers and midwives, supplemented by barber-surgeons, apothecaries, and a host of other lay healers offering a variety of herbs and nostrums for a range of illnesses (Starr, 1982).

This landscape began to change, however, in the early 1800's. As the number of elite medical-school-trained physicians began to increase—from only a few hundred in 1800 to nearly 7,000 in 1830—they began organizing into professional societies. Many of these societies were established not only to extend the benefits of science to the masses but also to extend the base of potential revenues for their members (Kaptchuk & Eisenberg, 2001). One of their first major activities of many of these societies was to begin discredit what they deemed as "irregular" medicine.

[Put paragraph in here on methods used to descredit irregulars]

This movement to drive irregulars out of the market-place quickly backfired, as an organized wave of populist resistance emerged from a number of these medical traditions, including Thomsonians (botanical healing), Grahamites (health food), homeopaths (microdiluted medicines), hydropaths (water therapy), and mesmerists (energy medicine). The irregulars and their followers saw these elite-trained medical professions as the bulwark of the privileged class and were able to successfully label their efforts as "anti-democratic" snobbery. (Kaptchuk & Eisenberg, 2001).

The battle lines had clearly been drawn, however. Over the next several decades, regular (M.D.) and irregular (non-M.D.) systems of health care engaged in fierce public quarrels. For example, the founder of homeopathy, Samual Hahnemann (1755-1842), lambasted regular medicine for shortening "the lives of ten times as many human beings as the most destructive wars and render[ing] many millions of patients more diseased and wretched than they were originally" (Hahnemann, 1852, p. 738). Hahnemann charges were not without merits, as regular physicians' commonly use harmful therapies that did more harm than good. One of these was *calomel*, a purgative composed primarily of mercurous cholide. It was used to treat a variety of ailments and produced severe side effects--including ulceration of the mouth; a profuse, thick salivation; tooth loss; and necrosis of the jawbone--which were often significantly worse than the original ailment. (Whorton, 1999).

Regular medicine, which was championed by Oliver Wendell Holmes of Harvard Medical School and others, countered Hahnemann's criticisms of their treatments by charging that homeopathy was "a mingled mass of perverse ingenuity, of tinsel erudition, of imbecile credulity, and of artful misrepresentation" (Holmes, 1842, p. ??) and "a confused mass of rubbish" (Hooker, 1949, p. 136). Other systems of irregular medicine were afforded the same level of disrespect (Whorton, 1999). It was common for orthodox health care professionals to refer to ~~stereotype~~ all irregulars as "quacks," "charlatans," or "snake-oil salesmen." (ref?)

A Century of Decline

From the mid-1800s to the mid-1900s, irregular health systems saw themselves being systematically forced out of the mainstream. In 1847, the American Medical Association (AMA) was founded to erect a formal barrier between regular medicine and all other systems of health care. The AMA quickly established a "consultation clause," which made it unethical for AMA members to consult with irregular healers. For the rest of the nineteenth century, this consultation clause was used to oppose the admission of irregular practitioners to local and state medical societies, the staffs of public hospitals and the military medical corps, and the faculties of publicly funded medical schools (Whorton, 1999). The AMA's Committee on Quackery internally policed its members for any signs of collaboration with irregular health care practitioners (Faner et al, 1992)

It was also during this time that AMA began sponsoring and lobbying for state licensing laws, which had been passed in many states in the early part of the 19th century but had been repealed after strong protests from advocates of irregular medicine. By the late 1800s, however, the AMA succeeded in getting most states to begin re-implementing licensing laws, but only for regular medicine. This movement was helped dramatically by the validation of the germ theory (i.e., germs are responsible for many contagious diseases), which significantly renewed public respect for the power of allopathic medicine.

In response to the increasing political might of regular, or orthodox, medicine, as it was now called, many "unorthodox" health care systems began aligning themselves with social and religious activists, whom they saw as kindred victims of systematic political oppression (Kaptchuk & Eisenberg, 2001). For example, when the American Vegetarian Society met in 1855, they invited as speakers Susan B. Anthony, a leading advocate for women's rights, Horace Greeley, a leading antislavery and spiritualist proponent, and an assortment of advocates for sexual emancipation and working class rights (Nissenbaum, 1980).

Some unorthodox health care system reluctantly decided to emulate the AMA and campaign for their own separate licensing laws. Although several of these health care systems eventually succeeded, their progress was painstakingly slow in comparison to orthodox health care (Shyrock, 1967). ~~Osteopaths~~ Doctors of Osteopathy (D.O.), for example, were licensed in 15 states by 1901. However, it took another 71 years--until 1972--for osteopaths to be fully licensed in every state. ~~Chiropractic~~ Doctors of Chiropractic (D.C.) did not win its first licensing battle until 1913. Although another 21 states passed chiropractic licensing laws in the following decade, it took another 50 years—until 1973--for chiropractors to be licensed in all states. Naturopathic medicine doctors have had an even greater struggle, with only 12 states presently issuing naturopathic doctor (N.D.) licenses (**ref?**)

While they campaigned for licensing laws, the leaders of some unorthodox health care systems faced criminal prosecution for practicing medicine without a license. For example, Benedict Lust, the founder of ~~Naturopathy~~, was jailed in 1899 and Daniel David Palmer, the discoverer of chiropractic ~~manipulation~~ adjustment, was jailed seven years later, in 1906 (Kirchfeld & Boyle, 1994; Gielow, 1981). Sometimes the prosecution was instigated from other unorthodox systems of health care rather than from orthodox medicine. For example, in 19??? osteopaths succeeded in getting chiropractors prosecuted for practicing osteopathy without a license (Gevitz, 1982)

The first half of the 20th century marked the low point for unorthodox systems of health care in this country. The Pure Food and Drug Act of 1906, which established the

U.S. Food and Drug Administration, set the stage of the first successful prosecution of a purvey of unorthodox remedies just two years later, in 1908 (McGinnis, 1991). Another major setback for unorthodox healthcare came a few years later, when the Carnegie Foundation funded Abraham Flexnor, an educator and founder of the Institute for Advanced Study in Princeton, N.J., to survey the state of medical education in the United States and Canada. This survey, which uncovered deplorable education standards at nearly all American medical schools, was an acute embarrassment to the orthodox medical profession when it was released. It gave none of them a clean bill of health and served to crystallize an educational reform movement in this country that was already under way. After its release in 1910, many substandard medical institutions, orthodox and unorthodox, were driven out of business or forced to implement significantly more rigorous training programs (Whorton, 1999)

Like orthodox medical schools, Flexnor found unorthodox medical schools to be "hopelessly meager," "utterly wretched," "intolerably foul," and "absurdly" inadequate (Flexnor, 1910, pp. 197, 214, 253). Schools for many unorthodox healing systems either ceased to exist or barely hung on to their existance (Starr, 1982) Homeopathic colleges, for example, dropped from 22 schools in 1900 to only 2 by 1923 (Kaufman, 1969). The only exceptions were osteopathy, which lost only one school in the 20 years following the Flexnor report, and chiropractic schools, which actually gained schools following Flexnor's report.

The tide of public sentiment against unorthodox, or unconventional, health care, as it was now called, increased further when sulfa drugs and then antibiotics were introduced in the 1930s and 1940s. These developments suggested to the public that orthodox, or mainstream, medicine was truly the medicine of the future and that unconventional health care systems and their therapies were relics of the past (Whorton, 1999). This negative sentiment persisted and was even institutionalized for the next quarter of a century. Indeed, until 1961, the AMA labeled osteopathy and chiropractic as "unscientific cults" and deemed it "unethical" for physicians to associate professionally

with osteopathic doctors or chiropractors (Judicial Council of the AMA, 1961, p. 177, 776).

The Road Back to Respectability: From Quackery to CAM

For a variety of reasons, the second half of the 20th century witnessed a steady rebound for many unconventional systems of healthcare. There were several developments, in particular, that dramatically reversed the downward fortunes of many unconventional healthcare practitioners. One of the most dramatic reversals came from an unsuspected source: the AMA itself.

Indeed, in the mid-1960s, the AMA suddenly stopped opposing the admission of osteopaths into orthodox residency programs, and even began allowing them to become AMA members. Around the same time, osteopathic physicians were included in the Medicare reimbursement system when that act was passed. In a matter of just a few years, they had gone from being a labeled "quacks" or "cults" to being accepted into the mainstream health care.

In the early 1970s, the tide began to turn for chiropractic as well. Chiropractors, initially denied the ability to participate in Medicare because it was deemed that their "theory and practice are not based upon the basic knowledge related to health, disease, and health care which has been widely accepted by the scientific community" (Cohen, 1969, pp. 142), succeeded in winning the inclusion of their services under the Medicare system in 1974 (Moore, 1993). Just two years later, in 1976, chiropractors filed an anti-trust suite against the AMA, the American Hospital Association, and several other medical organizations and societies, which they eventually won a decade later.

Based on the success of osteopaths and chiropractors, other unconventional systems of medicine began clamoring for increased recognition and rights. Their cause was aided significantly by President Richard Nixon's historic visit to China in 197?, which cast a national spot light on the ancient healing systems of that country: Traditional

Chinese Medicine (TCM). One TCM practice in particular—acupuncture—captured a good deal of public interest in this country (ref?). This sudden interest in acupuncture not only opened the door for other ancient healing systems of the East, including Ayurveda (the traditional system of medicine of India), but also for the other unorthodox systems of medicine in this country that had seen a steady decline over the previous century (Whorton, 1999).

The 1970s was also a time in which conventional medicine began to significantly alter its views on health and illness. There had long been a theoretical discipline within conventional healthcare, called psychosomatic medicine, which emphasized the connection between negative mental states, such as anxiety, and illness. By the late 1970s, such theories were becoming validated by sophisticated laboratory techniques, which began to document not only that negative mental states could negatively impact the immune system and physical functioning but that positive mental states could actually protect against illness (Kiecolt-Glaser & Glaser, 1989). This newfound understanding that the mind has an ever-present role to play in physical functioning, led to the formal development of several new disciplines within conventional medicine, including psychoneuroimmunology and mind-body medicine (Whorton, 1999).

A better understanding of the mind-body connection also opened the door for conventional health care professionals to begin looking into some of the claims being made by practitioners and advocates of unconventional healthcare. In particular, the concept of the "mind as a healer," which was an integral part of many of the home-grown and imported unorthodox heath care systems in the United States, began to be viewed with a greater degree of scientific curiosity by conventional medical community rather than outright skepticism. This aspect of many unorthodox systems of health care also was particularly appealing to a growing segment of the American public, many who enthusiastically embraced these new, seemingly powerful ways of comprehending the non-physical components of health and wholeness (Whorton, 1999).

In the 1980s, as interest in and use of unconventional healthcare practices began rising dramatically in the United States (see Section I), the terminology used to describe these practices and products began to evolve. Rather than focus on what these other health care systems were not (i.e., unorthodox, unconventional, unscientific, etc.), this terminology began to focus more on what they were and how they were used.

Because it was perceived that many of these systems of health care were being used as alternatives to conventional health care, the term "alternative medicine" was widely adopted in the United States and Europe (Furnham and Smith, 1988; Murray and Shepherd, 1988). This perception, however, was largely dispelled by research in the late 1980's and early 1990's, which found that people were typically using the two systems of health care—conventional and unconventional—simultaneously and essentially to complement one another. In fact, research demonstrated that people used alternative health care systems and therapies because they wanted to utilize a range of therapeutic options, both alternative and conventional (Lerner & Kennedy, 1992)

As a result, the term "complementary medicine" was widely adopted not long afterwards to describe this "other" system of medicine (Ernst, 1995; Joyce, 1994). Yet, even this terminology was unsatisfactory for many because it did not take into account findings that although many alternative therapies were being used to complement conventional medical care, some were being used *instead* of conventional medical care (Astin, 1998). Thus, the phrase "complementary and alternative medicine," or CAM, has recently been adopted to acknowledge this dichotomy.

Current Status of CAM in the U.S.

There is little doubt that a number of health care systems, modalities, and products that are commonly considered CAM are becoming more accepted not only by the public but by mainstream health care as well. Astin and colleagues (1998), for example, conducted a comprehensive review of 25 surveys of physician practices and beliefs with regard to five of the more prominent CAM therapies—acupuncture, chiropractic, homeopathy,

herbal medicine, and massage--and found that about half of the surveyed physicians in these studies believed in the efficacy of these CAM therapies. Surprisingly, a significant proportion were both making referrals to CAM practitioners as well as offering some of the CAM treatments in their own practice.

It is not just individual doctors who have become more receptive to CAM. Indeed, over the past few years hospitals, major academic medical centers, managed care companies, and insurance carriers, have become increasingly interested in incorporating aspects of CAM into their systems. According to the American Hospital Association, for example, nearly 15.5% of America's community hospitals offered CAM services in 2000, up from about 11.1% in 1999 (AHA News, 2001). Furthermore, Pelletier and colleagues (1997) reported that a small but growing number of major medical centers are offering CAM services. This study also found that a similar small but significant number of insurance companies are currently offering or are considering offering coverage for CAM services.

Recently, CAM has also made major inroads into mainstream medical education. A 1997-1998 survey of all 125 U.S. medical schools found that almost two thirds of those schools) that participated (117) in the survey offered elective courses in CAM or included CAM topics in required courses (Wetzel et al., 1998). Of the 123 courses reported in the survey, approximately two-thirds (68%) were stand-alone elective courses and the remaining constituted parts of required medical school courses. Common topics included chiropractic, acupuncture, homeopathy, herbal therapies, and mind-body techniques. Another sign that CAM is increasingly being emphasized in medical school curricula is the recent call from the American Association of Medical Colleges (AAMC) for the incorporation of knowledge about the link between spirituality and health—something that is heavily emphasized in many CAM systems of medicine-- into medical school curricula (AAMC, 1999). AAMC sees the inclusion of spirituality in the medical school curriculum as a key to promoting patient-centered health care as well as treating all aspects of the patient.

CAM and Integrative Medicine

As CAM gains an increasing foothold in the mainstream health care landscape, a number of mainstream academic heath care centers are exploring models of "integrating" CAM with modern health care practices. The ultimate goal of this integrative health care movement is to merge mainstream and CAM practices into a new, more comprehensive, compassionate, and effective model of care that includes both the precision and power of mainstream medicine and the wisdom of other healing traditions (Gordon, 1996). The underlying philosophy is to shift medicine toward healing rather than merely treating symptoms, to promote strengthened doctor-patient relationships, and increase the emphasis on mind and spirit in addition to body. According to some proponents, such an integrated system of health care would have a strong evidence base but also would be sensitive to consumer demand. (Weil, 2000).

One of the integrative models of health care that is being pilot tested at a small but growing number of mainstream medical institutions is to have mainstream and CAM practitioners working side-by-side, collaborating both in the diagnosis and treatment of patient conditions (Muscat, 2000). Although promising, this model of integration and others faces significant obstacles, including communications, certification and training, regulatory, and insurance reimbursement barriers that must first be overcome.

Communications Barriers

Mainstream and CAM health care practitioners often have entirely different worldviews regarding health and disease and, thus, employ a completely different vocabulary and grammar. Most mainstream practitioners have little understanding of CAM diagnostic terms, such as Qi (the Chinese term for vital energy) or doshas (the Ayurvedic term for mind-body type). Sometimes familiar terms are used but with a different meaning: acupuncturists may talk of "taking the pulse," but they will be assessing characteristics such as "wiriness" or "slipperiness," which have no Western equivalent. It is important not to interpret terms used in CAM too literally and to

understand that they are sometimes used metaphorically or as a shorthand for signs, symptoms, and syndromes that are not recognized in conventional medicine.

By the same token, few CAM practitioners have a thorough understanding the theories and terms associated with mainstream health care. Indeed, few CAM disciplines have significant exposure to fields such as pathophysiology, epidemiology, molecular biology, and other sciences that conventional physicians receive training in during the medical school apprenticeships. In such a climate, basic communication, much less collaboration, is difficult if not impossible (Caspi et al, 2000).

Conflicts in integration also are likely to arise because CAM and mainstream practitioners often have very different methods of assessing and diagnosing patients. A TCM practitioner may describe a patient's condition as deficiency in "liver Qi." A homeopath may describe the same condition as a "pulsatilla constitution." Whereas, the mainstream physician may describe the patients illness as "a peptic ulcer." Confusingly, there is little correlation between the different diagnostic systems: some patients with deficient liver Qi do not have ulcers, and some ulcer patients do not have deficient liver Qi but another traditional Chinese diagnosis. This could potentially cause significant problems if a CAM practitioner and mainstream doctor, working side by side, were both trying to diagnose and treat the same patient (House of Lords, 2000).

It is because of such communications barriers that many CAM systems are wary of the concept of integration. They believe that their absorption into the mainstream may result in the loss of their independence and identity (Whorton, 1999). Although grateful and relieved that the mainstream health care community is beginning embracing their ideas, approaches, and techniques, some would prefer to remain completely separate from mainstream medicine.

Licensing and Regulation Barriers

Another obstacle to integration is the difficulty of licensing and regulating CAM practitioners. Although some of these CAM systems lend themselves easily to certification, licensing, and regulation, others do not. There is a great diversity of education, training, and standards of practice among CAM practitioners, ranging from highly educated and organized to self-taught and unregulated. There are at least six categories of CAM practitioners based on their education, training, and regulation. These include:

1. Professional CAM practitioners with a cohesive healing philosophy, defined practice standards, accredited education, state licensing, documented safety, and at least some research substantiation. Examples include chiropractors, naturopathic physicians, and Traditional Chinese Medicine practitioners.

2. Physicians who practice wholistic medicine (i.e., they practice mainstream medicine along with those therapies that are considered complementary to mainstream medicine) but do not consider themselves to be CAM practitioners per se.

3. Dually trained physicians who use conventionally accepted medical practices along with clearly "alternative" therapies and practices that are highly controversial or not widely accepted by mainstream healthcare practitioners and institutions.

4. Emerging professions consisting of lay and self-trained practitioners, such as lay homeopaths and herbalists. Some of these emerging professions are working to establish standards for minimum education and training.

5. Community healers who receive training through centuries-old traditions. They tend to practice solely within their community, which provides informal oversight and regulation. Examples include Native American healers and Mexican-American curanderos.

6. Self proclaimed or minimally educated healers who practice without apparent standards or community oversight.

These variations in education, training, and self-regulation impact access to and delivery of CAM systems by limiting the ability of their practitioners to practice lawfully and obtain malpractice insurance. As previously mentioned, although chiropractic is licensed in all 50 states, many others are not. Acupuncturists are licensed or certified in only 32 states and the District of Columbia, and massage is licensed or certified in only 25 states. Naturopaths are only licensed or certified in 12 states, and only three states separately license homeopaths, although a number of states include homeopathy within the scope of practice of naturopaths, acupuncturists, and chiropractors. For all of the other myriad of CAM systems and approaches, there are no separate licensing and certification standards (Berman, 1999). Since insurance companies tend to cover only CAM therapies that are provided by a licensed practitioner, CAM providers that are not licensed in all 50 states find it extremely difficult to gaining access to the insurance reimbursement system (see below).

Reimbursement Barriers

Pelletier and colleagues (1997) found that insurance carriers that do cover CAM services are not doing so to enhance wellness and prevent disease. Rather, CAM therapies are covered only if treatment is deemed medically necessary for a specific diagnosis. Reimbursement is given only for a certain number of visits and/or dollar limit and typically only to licensed or certified CAM practitioners. Thus, lack of data proving not only efficacy for a specific condition but also cost-effectiveness compared to standard therapies is a significant barrier for CAM practitioners attempting to gain reimbursement for their services.

This creates a significant problem for many CAM providers attempting to gain insurance coverage for their patients because some CAM therapies are predominantly used as preventive medicine, and therefore cannot be easily evaluated by a disease treatment oriented system. In addition, many CAM practitioners emphasize unique, individualized treatments for each of their patients, which makes it extremely difficult to develop standards of practice guidelines (Colgate, 1995). Thus, the integration of many of these CAM approaches into mainstream health care would necessitate either a change in the CAM approach or the current mainstream health care model. ~~Such changes are easier said than done~~.

Research Barriers

Related to all of ~~the other~~ barriers discussed above is the need for more and better research on CAM. This includes not only clinical research, but also basic science and health services research.

[Put a paragraph in here on what types of clinical studies are needed. e.g., preventive medicine, etc]

[Put paragraph in here on why basic science studies are needed]

Cost effectiveness analyses are needed on individual clinically efficacious treatments as well as on combinations of mainstream and CAM treatments. Additionally, such research could compare the success of integrated CAM and mainstream approaches versus mainstream or CAM care only.

Until such research studies are conducted, the impetus for mainstream health care system to collaborate with CAM providers as well as to provide licensure and certification for CAM and reimburse for their services will be muted.

Information Dissemination Barriers

Obtaining reliable, up-to-date information on CAM has and continues to be a significant barrier for both the general public and the mainstream health care community. The quality, accuracy, accessibility, and timeliness of the information on CAM from current sources vary greatly. 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. There also is a great need ~~not~~ for campaigns not only that teach people how to find and evaluate CAM information, but also for hospitals, health care providers, and insurance companies who are interested in CAM. The provision of information on licensing and certification requirements also is critical, as 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.

Summary

As we learn more about how the various systems, approaches, and products that are commonly referred to as CAM are applied, used, and perceived, the terminology used to define and describe them will undoubtedly continue to evolve. Based on the recent history of CAM in this country, ~~it is probably safe to say that~~ interest in and public use of CAM is likely to continue to grow in this country in the foreseeable future. Such consumer interest will likely continue to put pressure on the mainstream health care system to incorporate aspects of CAM as well as to adapt and modify itself to do so. How quickly that process occurs, however, depends on developing innovative strategies for overcoming a number of significant barriers. Providing recommendations ~~for~~ developing such strategies ~~is a major reason this Commission was created.~~

References

Astin JA. Why patients use alternative medicine: results of a national study JAMA 1998;279: 1548-53.

Astin JA, Marie A, Pelletier KR, Hansen E, Haskell WL. A review of the incorporation of complementary and alternative medicine by mainstream physicians. Arch Intern Med. 1998;158(21):2303-10.

Berman, AF. Complementary and alternative medicine needs and evidence base before regulation. *West J Med* 1999;171:149-150.

Caspi O, Bell IR, Rychner D, Gaudet TW, Weil AT. The Tower of Babel: communication and medicine. *Arch Intern Med* 2000; 160:3193-3195.

Colgate MA. Gaining insurance coverage for alternative therapies. *J Health Care Market* 1995:5:24-28.

Eisenberg DM, Kessler RC, Foster C, et al. Unconventional medicine in the United States. New Engl J Med 1993:328:246-52.

Ernst E. Complementary medicine: common misconceptions. J R Soc Med. 1995;88(5):244-7. Review.

Faner AW, Carson JG, Zwicky JF. *Guide to the American Medical Association Historical Health Fraud and Alternative Medicine Collection*. Chicago: American Medical Association, 1992.

Flexnor A. *Medical Education in the United States and Canada*. New York, NY: Carnegie Foundation for the Advancement of Teaching, 1910.

Furnham A, Smith C. Choosing alternative medicine: a comparison of the beliefs of patients visiting a general practitioner and a homoeopath. Soc Sci Med. 1988;26(7):685-9.

Gevetz N. *The D.O.'s. Osteopathic Medicine in America*. Baltimore, MD: Johns Hopkins University Press, 1982.

Gielow V. *Old Dad Chiro*. Davenport, IA: Bawden, 1981.

Gordon J. *Manifesto for a New Medicine*. New York, NY: Addison-Wesley Publishing Company, 1996.

Hannemann S. *The Lesser Writings of Samuel Hannemann*. New York, NY: Radke, 1852.

Holmes OW. *Homeopathy and Its Kindred Delusions*. Boston, MA: WD Ticknor, 1842.

Hooker W. *Physician and Patient*. New York, NY: Baker and Scribner, 1849.

House of Lords. *Science and Technology – Sixth Report*. Science and Technology Committee Publications, 2000.

Joyce CR . Placebo and complementary medicine. *Lancet*. 1994;344(8932):1279-81.

Kaptchuk TJ, Eisenberg DM. Varieties of healing: Medical pluralism in the United States. *Ann Intern Med* 2001;135:189-195.

Kaufman M. *Homeopathy in America. The Rise and Fall of Medical Heresy*. Baltimore, MD: Johns Hopkins University Press, 1969.

Kirchfeld F, Boyle W. Nature Doctors. Pioneers in Naturopathic Medicine. Portland, OR: Medicina Biologica, 1994.

McGinnis LS. Alternative therapies, 1990: An overview. *Cancer* 1991; 67:1788-1792.

Murray J, Shepherd S. Alternative or additional medicine? A new dilemma for the doctor. J R Coll Gen Pract. 1988 Nov;38(316):511-4.

Muscat M.Beth Israel's Center for Health and Healing: Realizing the goal of fully integrative care. Altern Ther Health Med. 2000;6(5):100-1.

Pelletier KR, Marie A, Krasner M, Haskell WL. Current trends in the integration and reimbursement of complementary and alternative medicine by managed care, insurance companies, and hospital providers. Am J Health Promot 1997;12:112-122.

Nissenbaum S. Sex, Diet, and Debility in Jacksonian America: Sylvester Graham and Health Reform. Westport, CT: Greenwood Press, 1980.

Skyrock R. Medical Licensing in America, 1650-1965. Baltimore, MD: Johns Hopkins University Press, 1967.

Starr P. *The Social Transformation of American Medicine.* New York, NY: Basic Books, Inc., 1982

Zolman C, Vickers A. ABC of complementary medicine: What is complementary medicine? BMJ 1999; 319:693-696.

Weil A. The significance of integrative medicine for the future of medical education. American Journal of Medicine 2000; 108:441-443.

Wetzel MS, Eisenberg DM, Kaptchuck TJ. Courses involving complementary and alternative medicine at US medical schools. JAMA 1998; 280:784-787.

Whorton JC. The history of complementary and alternative medicine. In Jonas WB (ed.).

11/5/01

Walk Through the Questions - Gen... Anything else missing

COORDINATION OF RESEARCH DRAFT: 11/1

Introduction

To be developed. Brief review of the growth of CAM research, its value, and its promise for future research. Include references to public and private activities (Kronenberg, Eisenberg, Fishman, Berman, etc.) and future directions. Possibly move some general text on NCCAM and other IC's and agencies to this section.

1 AHRQ, VA, DOD,
2 Survey of All Federal Agencies
Past Summary
(3) Private Sector Development - Herb GLAXO, Whitehall
Medtronic Templeton, + othe Fr...

Dialogue, Partnerships, and Public Input

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

Insert having representative sit on an advisory Boards is not adequate, need training program for public participants for CAM Rsch - How to be good public representative for all phases of Research

Renew + design → Evaluation

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

The Commission views partnerships and cooperation as being at the very heart of the challenge to increase the quality CAM research and the acceptance of research

applications that may be outside the mainstream. The building of working relationships among professionals from both conventional medical and CAM disciplines is essential to progress in studying CAM practices and products. The absence of these relationships impedes progress in building knowledge about CAM.

The growing influence of the public on the health care system and considerable public interest in why people are turning to CAM is becoming increasingly evident, pointing to the need to ensure public participation in shaping the CAM research agenda. Requirements and opportunities for public participation currently exist, such as the NIH Director's Council of Public Representatives, as well as Institute and Center advisory councils, boards, and committees, and FDA and IRB advisory committees. During testimony, the Commission heard often about the value of integrating conventional and CAM approaches. In a random household telephone survey, of 831 respondents who saw a medical doctor and used CAM therapies in the previous year, 79 percent perceived the combination to be superior to either one alone. Of 411 respondents who saw both a medical doctor and a CAM provider, 70 percent saw the medical doctor before or concurrent with their visit to a CAM provider.*(citation–AIM)*

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

To be most effective, CAM and conventional researchers, clinicians, and practitioners,

and the leadership of CAM and conventional research centers, programs, accredited institutions, and professional organizations have to participate in the dialogue and form meaningful working relationships. Federal and state research and health agencies, the private and nonprofit sectors, and the public are also integral to this cooperative environment. Raising the quality of CAM research, research infrastructure and training, and the publication of CAM research results depend on increased interaction, as appropriate, between trained and properly qualified CAM and conventional medical professionals on research, journal, and regulatory advisory and/or review committees, as well as in discussions on CAM-related research policy issues.

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

Existing conference support mechanisms, such as the NIH conference grant, are available. In addition, the idea was put forth during testimony that interested nonprofit

organizations might pool resources to support, independently or collaboratively with the public and/or private sectors, interdisciplinary conferences on CAM research, as well as to support CAM research, research infrastructure and training, and information dissemination..

Draft Recommendations

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

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

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

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

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

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

historical case studies + empirical observations

Research Support

The Commission believes that research provides the accurate information needed to increase the public's knowledge about CAM, and for educating and training CAM and conventional health care professionals, regulating the quality and use of CAM products and devices, and improving access to safe and effective practices and products and coverage for them. The point was made and reiterated during testimony, that clinical, basic, and health services research are all essential and any of these types of research absent the others is insufficient for achieving safe and effective CAM use within an improved health care system. *(citation--Eisenberg 5/01)*

Multiple research approaches that are pertinent and relevant to the question being asked all contribute in valuable ways to developing evidence of safety and efficacy, improving our understanding of CAM in the evolving health care system, and formulating accurate information for practitioners and the public. Among these approaches are randomized controlled clinical trials, non-randomized and observational research, ~~anecdotal~~ reports, case studies, evaluations of practice-based data, epidemiologic and surveillance studies,

empirical observations, &

behavioral and quality-of-life studies, qualitative research, cost-effectiveness studies, population and utilization studies, studies on health care delivery, demonstration projects and other health services aspects of CAM.

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

Beyond safety and efficacy, CAM research may offer exciting areas for scientific inquiry and the Commission recognizes the potential of CAM research to contribute to emerging areas of scientific study beyond isolated treatments for conditions or diseases. Many people who testified noted the emphasis CAM places on wellness separate from disease and expressed admiration for the attention many CAM practitioners give to self care, life-style, quality of life, the recognition that mind, body, and spirituality play a combined role in health, disease, and healing, and on the patient-practitioner interaction. Therefore, in addition to the primary task of examining CAM practices and products which, if found to be safe and effective, may be identified as complementary or alternative to conventional care for a condition, disorder, or disease, CAM may also contribute

innovative ideas to emerging areas of scientific study that could expand our understanding of health, disease, and healing.

The CAM research spectrum is broad. It includes areas that are almost indistinguishable from conventional medicine except for application, such as exercise/diet/lifestyle therapies, herbal/nutritional supplements, behavioral/mind-body methods; and the effects of culture on health and treatment. It includes areas that receive less attention but are of interest to conventional science, such as increasing our understanding of complete biological systems and how they interact; the ability of the body to heal itself; and electromagnetic fields. It also includes areas that challenge biological/scientific concepts and assumptions depending on the context in which they are presented, such as energy medicine, biofields, and Qigong. Answers to some of these questions may be found in the study of Ayurvedic Medicine, Traditional Chinese Medicine, Tibetan Medicine, Native American Medicine, African Medicine, Naturopathy, and other systems of healing that involve a complexity of elements. Applying rigorous scientific methods to the exploration of these areas may require merging whole system concepts with modern reductionist expertise and the input of CAM practitioners working with experts in a wide variety of fields, including but not limited to physics, cell and molecular biology, physiology, chemistry, neurology, psychology, and engineering.

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

standardization/non-standardization, individualization/generalization, blinding, randomization, the placebo effect, and compound mixtures, need to be resolved within the context of the study design.

The adaptation of methodology and design, the Commission notes, is also required in conventional clinical research. Science has always followed its quests for knowledge by developing new ways to answer difficult questions and the Commissioners believe that pluralism in research design allows scientists to develop innovative methods to examine complex CAM questions. The NIH Specialized Center Awards, such as the Specialized Center of Research (SCOR) or the Special Program of Research Excellence (SPORE) promotes ~~bidirectional~~ interdisciplinary exchange in order to address difficult research questions. The James A. Shannon Director's Award, is a limited grant mechanism for developing, testing, and defining research techniques and the feasibility of innovative, creative, research approaches.

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

To help implement the process, the Commission would like to see NIH Institutes and Centers and other Federal agencies, as appropriate, develop programs to evaluate

need to be studied on the value of the system being ~~studied~~ used

practice-based data for potential research support, communicate the availability of such initiatives in a proactive manner to CAM and conventionally-trained practitioners and, if the project receives funding, include the practitioner as part of the research team. The programs may also offer training in data collection and the scientific method, and ethical guidelines and human subject protection. An example of such a program is the best case series program of the OCCAM/NCI.

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

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

Draft Recommendations

7. The Commission recommends that all Federal agencies with research or related health responsibilities increase CAM activities relevant to their biomedical or health services missions in a more proactive manner, including NCCAM, OCCAM Strategic Planning Center at CDC.

8. The Commission recommends the creation of process by which practitioners can successfully move to clinical investigation of a non-approved treatment while maintaining their ethical and professional responsibilities toward the public.

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

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

11. The Commission recommends that the Federal government provide incentives to stimulate private sector research investment in CAM products and NDA development, and on ~~improving~~ developing analytical methods for producing better quality CAM products.

12. The Commission recommends that the Federal and private sectors provide support for workshops to discuss research needs for regulatory review and approval

of CAM products and devices.

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

14. The Commission recommends that NCCAM conduct a review assisted by the National Science Foundation or the Institute of Medicine on methods to study in a credible manner, emerging areas of scientific investigation associated with CAM.

Research Training and Infrastructure

The Commission fully appreciates the crucial role that a strong research infrastructure plays in the conduct of quality CAM research and the training skilled researchers. Sustained, adequate funding is essential to building and maintaining long-term research capacity for training clinical investigators, health services researchers, and those who study the underlying mechanisms of CAM products, practices and concepts. A government-wide effort involving NIH, NSF, DOD, the VA and others would strengthen the funding and strategic planning to develop or enhance CAM research sites and training programs.

Research sites supported publically, privately, or by foundations need to be strategically located and structured to conduct basic, clinical, and health services research, train researchers and clinical experts, and deliver integrated care services. Each site depends on

a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. (*Examples: center grants supported by NCCAM, NCI, NICHD [Pediatric Pharmacology Research Units], and others; NCRR/GCRCs, and university examples)* The Commission would like to see CAM research sites developed at public, private and accredited CAM institutions with CAM-trained professionals serving on faculty and/or as consultants and experienced researchers serving as mentors. Cooperation between CAM and conventional medical researchers or institutions and joint research grant applications can contribute to successful research funding.

The same rigorous training is a requirement for and needs to be available to both CAM and conventional medical researchers. CAM researchers need training in the fundamental elements required to conduct quality clinical, basic, or health services research. The elements of scientific research include a strong grounding in the research process and methodology, unbiased data collection, all aspects of protocol design, IRB and other regulatory requirements, and grant application and submission processes. CAM research training should teach multiple outcome measures, including social and biopsychological measures of health, and offer experience working as part of a multdisciplinary research team to allow broader paradigms of health and healing. CAM research trainees need experienced mentors and incentives may have to be developed to attract them. Research centers offer excellent opportunities to exchange experiences on how best to educate researchers in CAM practices and how to introduce CAM practitioners to the research culture.

[Move to Introduction] The Commission recognizes the work of NCCAM and (*other organizations)* in developing a core of CAM and conventional medical researchers investigating CAM questions, who receive the same rigorous research training in basic, clinical, or health services research. The Commission also notes the Institute's support of

career development awards that enable investigators focusing on CAM to develop into independent investigators and mid-career awards to provide the time required to mentor new CAM investigators.

Draft Recommendations

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

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

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

CAM Research Results: Systematic Reviews and Evaluations

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

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

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

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

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

Draft Recommendations

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

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

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

Attachments:

List of Agencies

Budget Tables and Charts

Wayne Jonas' Triangle

Groft, Stephen (NCCAM)

From: Jim Swyers [jpswyers@starpower.net]
Sent: Wednesday, October 24, 2001 4:41 AM
To: WBJonas@aol.com
Cc: Tom@toms-of-maine.com; Groft, Stephen (NCCAM)
Subject: Re: Guiding principles

Wayne,

Actually, when I looked at the tally again, Choice got 15 points which ties it with Prevention (I scored the votes for choice incorrectly and missed one tally at the end). If you combine all of the votes for Education and Empowerment/ Education, you get a final score of only 7 points. So, the revised priority list is:

No. 1: Wholeness (70 points)

No. 2: Evidence of Safety and Efficacy (59 points)

No. 3: Health and Healing (54 points)

No. 4: Individuality (22 points)

No 5: Choice (15 points)

No. 6: Prevention (15 points)

No. 7: Partnerships (13 points)

No. 8: Education and Empowerment (7 points)

No. 9: Self Healing (4 points)

No 10: Public Involvement (no votes)

WBJonas@aol.com wrote:

> Thanks Jim. Does this mean that consumer choice and education and
> empowerment got the same score and tied for place?
>
> wj
>
> In a message dated 10/22/01 12:10:10 PM, jpswyers@starpower.net writes:
>
> << Tom and Wayne,
>
> Below is a priority rating for the guiding principles that was voted on
> by the Commission. Wayne asked that I prioritize all 10, even though we
> only asked for votes on the top 5. You'll note that I combined "Choice"
> with "Education and Empowerment." I did this because one of the
> Commissioner's combined them this way (see official tally at the end).
> Also, this allowed me to keep the two guiding principles that received
> no votes in the list. It may be important to keep them, but I'll leave
> that up to you. Wayne has offered to take another stab at rewriting the
> Guiding Principles section, which will now be included in the overall
> introduction of the report. Wayne, since I'm planning to finish the
> history and definitions section (part 2 of the report) first, you have a
> little extra time to get that done.
>
> Speaking of part 2, I am hoping to finish it by the end of this week

> and send it to you both to review. If you can get your comments back by
> the 30th, I will send it on to the rest of the work group no later than
> November 1st. I would then like to schedule a conference call for
> either the 5th or 7-9th of November. Let me know ASAP if you are
> available any of these days. Thanks and take care.
>
> Commission's Rating of Guiding Principles
>
> Rating System
>
> 5 points for first place vote, 4 points for second place, 3 points for
> third place, 2 points for fourth place, and 1 point for fifth place.
>
> No. 1: Wholeness (70 points)
>
> No. 2: Evidence of Safety and Efficacy (59 points)
>
> No. 3: Health and Healing (54 points)
>
> No. 4: Individuality (22 points)
>
> No. 5: Prevention (15 points)
>
> No. 6: Partnerships (13 points)
>
> No. 7: Education, Choice, and Empowerment (9 points)
>
> No. 8: Self Healing (4 points)
>
> No 9: Public Involvement (no votes)
>
> No 10: Dissemination (no votes)
>
> Official Vote Tally:
>
> #1: Wholeness (11); Evidence of Safety and Efficacy (6); Health and
> healing (1)
>
> #2: Self Healing (1); Evidence of Safety and Efficacy (2); Health and
> Healing (9); Wholeness (2); Prevention (1); Partnerships (1);
>
> #3: Health and Healing (3); Evidence of Safety and Efficacy (6);
> Prevention (1); Wholeness (1); Individuality (5); Partnerships (1)
>
> #4: Partnerships (2); Choice (5); Individuality (3); Health and Healing
> (2); Evidence of Safety and Efficacy (1); Individuality (2); Safety (1);
> Wholeness (1); Education (1); Wholeness (1)
>
> #5: Prevention (4); Education and Empowerment (3); Customization
> [Individualization], Choice, and Rights (1); Education (1); Partnerships
> (2); Evidence of Safety and Efficacy (1); Prevention, Wellness, and
> Health Promotion (1); Choice (4);
>
> <!doctype html public "-//w3c//dtd html 4.0 transitional//en">
>
> Tom and Wayne,
> Below is a priority rating for the guiding principles that was voted
> on by the Commission. Wayne asked that I prioritize all 10, even though
> we only asked for votes on the top 5. You'll note that I combined "Choice"
> with "Education and Empowerment." I did this because one of the
> Commissioner's
> combined them this way (see official tally at the end). Also, this allowed
> me to keep the two guiding principles that received no votes in the list.
> It may be important to keep them, but I'll leave that up to you. Wayne
> has offered to take another stab at rewriting the Guiding Principles section,
> which will now be included in the overall introduction of the report.
> Wayne, since I'm planning to finish the history and definitions section

> (part 2 of the report) first, you have a little extra time to get that
> done.
> Speaking of part 2, I am hoping to finish it by the end of this
> week and send it to you both to review. If you can get your comments back
> by the 30th, I will send it on to the rest of the work group no later than
> November 1st. I would then like to schedule a conference call for
> either the 5th or 7-9th of November. Let me know ASAP if you are
> available any of these days. Thanks and take care.
>
>
> Commission's Rating of Guiding Principles
>
>
> Rating System
> 5 points for first place vote, 4 points for second place, 3 points for
> third place, 2 points for fourth place, and 1 point for fifth place.
>
>
> No. 1: Wholeness (70 points)
> No. 2: Evidence of Safety and Efficacy (59 points)
>
>
>
> No. 3: Health and Healing (54 points)
>
>
>
> No. 4: Individuality (22 points)
> No. 5: Prevention (15 points)
>
>
>
> No. 6: Partnerships (13 points)
> No. 7: Education, Choice, and Empowerment (9 points)
>
>
>
> No. 8: Self Healing (4 points)
> No 9: Public Involvement (no votes)
> No 10: Dissemination (no votes)
>
>
> Official Vote Tally:
> #1: Wholeness (11); Evidence of Safety and Efficacy (6); Health and
> healing (1)
> #2: Self Healing (1); Evidence of Safety and Efficacy (2);
> Health and Healing (9); Wholeness (2); Prevention (1); Partnerships (1);
>
>
> #3: Health and Healing (3); Evidence of Safety and Efficacy (6); Prevention
> (1); Wholeness (1); Individuality (5); Partnerships (1)
> #4: Partnerships (2); Choice (5); Individuality (3); Health and
> Healing (2); Evidence of Safety and Efficacy (1); Individuality (2); Safety
> (1); Wholeness (1); Education (1); Wholeness (1)
> #5: Prevention (4); Education and Empowerment (2); Customization
> [Individualization], Choice, and Rights (1); Education (1); Partnerships
> (2); Evidence of Safety and Efficacy (1); Prevention, Wellness, and Health
> Promotion (1); Choice (4); Education and Empowerment (1)
>
>
>
> ---------- Headers ----------
> Return-Path: <jpswyers@starpower.net>
> Received: from rly-st08.mail.aol.com (rly-st08.mail.aol.com [172.31.34.3])
> by air-yb04.mail.aol.com (v81.9) with ESMTP id MAILINYB45-1022121010; Mon, 22
> Oct 2001 12:10:10 -0400
> Received: from rly-yd05.mx.aol.com (rly-yd05.mail.aol.com [172.18.150.5])

```
>       by rly-st08.mail.aol.com (8.8.8/8.8.8/AOL-5.0.0)
>       with ESMTP id MAA20941 for <wbjonas@aol.com>;
>       Mon, 22 Oct 2001 12:06:57 -0400 (EDT)
> Received: from  smtp-hub.mrf.mail.rcn.net (smtp-hub.mrf.mail.rcn.net
> [207.172.4.107]) by rly-yd05.mx.aol.com (v81.9) with ESMTP id
> MAILRELAYINYD55-1022120613; Mon, 22 Oct 2001 12:06:13 -0400
> Received: from smtp02.mrf.mail.rcn.net ([207.172.4.61])
>     by smtp-hub.mrf.mail.rcn.net with esmtp (Exim 3.33 #10)
>     id 15vhaf-0007Cs-00; Mon, 22 Oct 2001 12:06:13 -0400
> Received: from 208-59-175-121.c3-0.slvr-ubr2.lnh-slvr.md.cable.rcn.com
> ([208.59.175.121] helo=starpower.net)
>     by smtp02.mrf.mail.rcn.net with esmtp (Exim 3.33 #10)
>     id 15vhae-00051A-00; Mon, 22 Oct 2001 12:06:12 -0400
> Message-ID: <3BD3FDFA.F4DC9487@starpower.net>
> Date: Mon, 22 Oct 2001 08:07:38 -0300
> From: Jim Swyers <jpswyers@starpower.net>
> Organization: JPSE, Inc.
> X-Mailer: Mozilla 4.74 [en] (Win98; U)
> X-Accept-Language: en
> MIME-Version: 1.0
> To: "Jonas, Wayne" <wjonas@siib.org>, "Jonas, Wayne" <WBJonas@aol.com>,
>         "Chappell, Tom" <Tom@toms-of-maine.com>
> CC: "Groft, Stephen (NCCAM)" <grofts@od31em1.od.nih.gov>
> Subject: Guiding principles
> Content-Type: multipart/alternative;
>  boundary="------------7A8ECF70073DA0753296A749"
>
>  >>
```

Outline for Introduction to WHCCAMP Report

Background:

- Briefly describe consumer-driven CAM phenomena in U.S.
- Discuss high usage among specific populations (chronic pain, cancer, HIV, etc.)
- Discuss emerging data supporting use of CAM for some of these conditions
- Discuss how wellness benefits of CAM offer potentially significant public health benefits (nutrition, stress reduction, exercise, etc.). [cite mortality data and spirituality studies]
- Discuss potential safety issues involved in CAM use and how they may be exacerbated by communications gap between physicians and their patients about use of CAM (e.g., herb-drug interactions)
- Discuss briefly barriers to both to integrating CAM practitioners, approaches, practices and products into the mainstream as well as to educating people about the appropriate use of these CAM therapies (see chapter 2 for a more detailed discussion of barriers)
- Discuss how formation of Commission is designed to address these barriers

Overview of the Commission

- Discuss President's Executive Order
- Discuss general makeup of the Commission (see Appendix for detailed roster)
- Discuss in detail process Commission used to gather evidence and testimony (see Appendix for details of meetings, town halls, site visits, and individuals who provided information and testimony).
- Discuss process for tackling issues and developing draft recommendations and final recommendations (e.g., work groups, etc.)

Guiding Principles of the Commission in Developing Recommendations

- List and discuss 10 Guiding Principles

    1. Wholeness
    2. Evidence of Safety and Efficacy

3. Health and Healing
4. Individuality
5. Choice
6. Prevention
7. Partnerships
8. Education and Empowerment
9. Self Healing
10. Public Involvement

- Discuss guiding principles overlap/complement other major public health initiatives
    - IOM report,
    - Healthy People 2010
    - Etc.

Overview of the Report

- Brief discussion of its content and structure
- Brief discussion of how it can best be utilized

Groft, Stephen (NCCAM)

From: Jim Swyers [jpswyers@starpower.net]
Sent: Monday, November 05, 2001 3:47 PM
To: Chappell, Tom; Chow, Effie; Jonas, Wayne; Pizzorno, Joe; Paz, Conchita; Veronica Gutierrez (E-mail)
Cc: Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); Groft, Steve; Kaczmarczyk, Joseph (NCCAM); Gordon, Jim; Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Definition section

Part II, Draft #4 11-01 JPS.do...

Dear Work Group H members.

This is to remind you that our next conference call is scheduled for this Thursday, November 8, from 2:00 to 3:00 Eastern. To be connected to this call please dial 888-928-9528 and reference passcode 38644 (call leader: Jim Swyers)

I have attached the revised definitions section. As requested at our last meeting, I have moved the definition and description of CAM to the beginning of this section.
Following that, I have written an overview of the history of CAM in this country. You'll note that I've tried to simplify the narrative as much as possible by telling the history in fairly linear format.

The historical overview is followed by a discussion CAM's current status in this country. I've tried to make the point that although it is gaining in recognition and acceptance, there are still significant barriers to overcome before widespread collaboration and/or integration can occur.

Please note that the Guiding principles have been taken out of this section and will be moved to the overall introduction of the report. The introduction will provide an overview of the Commission and overall mission, which will now be followed by the Commission's guiding principles (see below for new prioritization). I am writing that section now. Wayne will be revising the language for the guiding principles based on the comments we heard at the October meeting. You will receive that section with the rest of the report in a couple of weeks.

If you cannot make the call, please feel free to call me and I will represent your viewpoint on the call. I look forward to all of your comments. Take care.

Jim Swyers

P.S.: Based on the prioritization that Wayne asked the Commission to vote on, here is the way the 10 Guiding principles ranked.

No. 1: Wholeness (70 points)

No. 2: Evidence of Safety and Efficacy (59 points)

No. 3: Health and Healing (54 points)

No. 4: Individuality (22 points)

No 5: Choice (15 points)

No. 6: Prevention (15 points)

No. 7: Partnerships (13 points)

No. 8: Education and Empowerment (7 points)

No. 9: Self Healing (4 points)

No 10: Public Involvement (no points)

11/21/01

CDER – Material time & Effort

"Significant Scientific Agreement"
CFSAN - Labeling document

Manufacturer
201(N) Safety DSHEA
10 year Plan – Full funding ⇒

Pre market costs less than Post Marketing
Pre Market Post Marketing
< 5×

Authoritative Health Claim = Significant Scientific Agreement

Issue X: Use of food stamps to purchase dietary supplements.

Background:
Data from national surveys show that between 41 and 48 percent of the U.S. population reported vitamin and mineral use. Among Food Stamp Program (FSP) participants, usage is estimated at approximately 30 percent[1].

In the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Congress specified that the Secretary of Agriculture, consulting with appropriate outside experts, conduct a study on the use of food stamps to purchase nutritional (i.e. vitamin and mineral) supplements. Currently, the FSP allows only the purchase of food products and seeds for gardening. An expert panel was convened in November 1998 and recommended further studies on the food consumption patterns of FSP participants to determine nutritional status; the effects of dietary supplement consumption on dietary behavior; the cost-effectiveness of supplement use; and the effect of dietary supplements on the occurrence or progression of chronic disease. They further recommended that if FSP participants were allowed to use food stamps to purchase dietary supplements before these studies were made, that these purchases be limited to nutritional supplements rather than all dietary supplements, and that these nutritional supplements be further limited to single or multiple vitamin-mineral products that do not exceed the nutrient recommendations of the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences. They also recommended that educational efforts to guide FSP in the use of nutritional supplements be initiated.

In September, 1999, the Department of Agriculture released "The Use of Food Stamps to Purchase Vitamin and Mineral Supplements"[2]. In an accompanying letter from then Secretary Dan Glickman to the Senate, the Department of Agriculture recommended that current policy remain unchanged. The reasons stated are 1) the FSP is designed to meet general, not special, dietary needs based on a low-cost nutritious food-based diet; 2) educating low-income consumers to make educational choices about vitamin and mineral supplements would be "an enormous challenge with uncertain prospects for success"; 3) existing data shows no unique nutrient gaps among program participants and that FSP participants generally consume more nutrients than low-income non-participants; and 4) the cost of supplements is low and FSP participants can purchase them with cash. The Department of Agriculture further states that expanding the FSP to include vitamin and mineral purchases would create administrative and enforcement challenges which would strain limited resources and threaten program integrity. Their concern is that it would be difficult for stores to distinguish between approved vitamin and mineral supplements and the growing array of herbal, botanical, and other dietary supplements, and that this would create pressure to expand the categories of stores allowed to accept food stamps.
An issue not addressed in these reports is the right of FSP participants to choose to use their food stamps in a way that is consistent with U.S. dietary standards and is consistent with the food purchasing behavior of non-FSP participants. FSP participants have free choice in the purchase of foods, but do not have freedom of choice and access in regards to dietary supplements.

Challenges:
The Department of Agriculture does not support changing their policies to allow purchase of dietary supplements with food stamps.

Recommendations:
1) The Commission recommends that the Department of Agriculture change their administrative policies to allow Food Stamp Program Participants to use their food stamps to purchase single or multiple vitamin-mineral products that do not exceed the nutrient recommendations of the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences. To address the concern over confusion over which products are acceptable for purchase with food stamps, the Department of Agriculture could develop a list of acceptable products, and limit their purchase to the stores already eligible to accept food stamps.

2) The Commission recommends that Congress request a report in 3 years on the impact of allowing FSP

---

[1] - Continuing Survey of Food Intakes by Individuals, U.S. Department of Agriculture, Agricultural Research Service, 1999
[2] - The Use of Food Stamps to Purchase Vitamin and Mineral Supplements, U.S. Department of Agriculture, Food and Nutrition Service, Sept 1999

participants to use food stamps to purchase the specified vitamin-mineral products, including the effects of dietary supplement consumption on dietary behavior, and include recommendations for future actions

Health Services Research– Working Draft

Definitions

Institute of Medicine (IOM): HSR is a multidisciplinary field of inquiry, both basic and applied, that examines access to, and the use, costs, quality, delivery, organization, financing, and outcomes of health care services to produce new knowledge about the structure, processes, and effects of health services for individuals and populations.

Agency for Health Research and Quality (AHRQ, formerly AHCPR): HSR is a field of inquiry that examines the impact of the organization, financing and manage- ment of health care services on the delivery, cost, access to, and outcomes of such services.

Involved Disciplines – bio/medicine, nursing and other health professions, biostatistics, epidemiology, sociology, law, economics, political science, management, operations research, psychology, social work

Stakeholders – policy makers, puchasers/payers, federal and state agencies, public and private organizations, managers, clinicians and health practitioners, lawyers, consumers

HSR and research-related activities (including demonstrations):

- ➤access to health care (including special populations)
- ➤delivery and management (including models of care such as managed care)
- ➤utilization patterns
- ➤workforce assessment (including numbers, type, competency, distribution)
- ➤quality of health care (including quality assessment and improvement)
- ➤outcomes evaluation (what works/comparisons of approaches and modalities)
- ➤Clinical practice (best practice) guidelines
- ➤cost-effectiveness of safe and effective modalities
- ➤Payment and financing models
- ➤Health information, statistics, and epidemiology
- ➤Health technology assessment
- ➤Health policy/economics

IOM's Definition of Health Technology Assessment: any evaluation of the cost, efficacy, cost-effectiveness, patterns of use, and the ethical, economic, and social consequences of the use of a medical technology.

AHRQ's Definition of Clinical Practice Guidelines: a set of directions or principles to assist the health care practitioner with patient care decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances.

Definitions (from "Glossary of Terms Commonly Used in Health Care", a publication of the Academy for Health Services Research and Health Policy)

Licensure – A permission granted to and individual or organization by a competent authority, usually public, to engage lawfully in a practice, occupation, or activity. Licensure is the process by which the license is granted. It is usually granted on the basis of examination and/or proof of education rather than on measures of performance. A license is usually permanent but may be conditioned on annual payment of a fee, proof of continuing education, or proof of competence.

Certification -- The process by which a governmental or nongovernmental agency or association evaluates and recognizes an individual, institution, or educational program as meeting predetermined standards. One so recognized is said to be "certified." It is essentially synonymous with accreditation, except that certification is usually applied to individuals, and accreditation to institutions. Certification programs are generally nongovernmental and do not exclude the uncertified from practice as do licensure programs.

Credentialing – The recognition of professional or technical competence. The credentialing process may include registration, certification, licensure, professional association membership, or the award of a degree in the field. Certification and licensure affect the supply of health personnel by controlling entry into practice and influence the stability of the labor force by affecting geographic distribution, mobility, and retention of workers. Credentialing also determines the quality of personnel by providing standards for evaluating competence and by defining the scope of functions and how personnel may be used.

Accreditation – A process whereby a program of study or an institution is recognized by an external body as meeting certain predetermined standards. For facilities, accreditation standards are usually defined in terms of physical plant, governing body, administration, and medical and other staff. Accreditation is often carried out by organizations created for the purpose of assuring the public of the quality of the accredited institution or program. The State and Federal government can recognize accreditation in lieu of, or as the basis for licensure or other mandatory approvals. Public or private payment programs often require accreditation as a condition of payment for covered services. Accreditation may either be permanent or may be given for a specified period of time.

Groft, Stephen (WHCCAMP)

From: Kulkarni, Kathy [Kathy.Kulkarni@mail.house.gov]
Sent: Friday, October 05, 2001 3:45 PM
To: Groft, Stephen (NCCAM)
Subject: RE: WHCCAMP Background Material

Steve,

I sincerely apologize for Congressman's Pallone's inability to attend your meetings in Bethesda. He was really looking forward to it, but unfortunately could not attend due to the voting schedule on the House floor today.

Please find attached the testimony he was planning on delivering. I would like to submit it for the Commission's records. Would you kindly let me know if this is possible - my boss would really appreciate it.

Thank again for your flexibility and willingness to have Congressman Pallone participate. I hope we can plan to have him at the December meetings.

Thanks,
Kathy
202-225-4671

<<01.hlth.dietsupps.whccam.testimony.doc>>

From: Groft, Stephen (WHCCAMP)[SMTP:grofts@od31em1.od.nih.gov]
Sent: Monday, October 01, 2001 4:44 PM
To: Kulkarni, Kathy
Subject: WHCCAMP Background Material

<<File: AgendaOct4-62001FINL.wpd>><<File: recommendationsallPubOct4-6.wpd>><<File: FinalIntProgressReptsg#24.91801.rtf>>

Kathy,

Thank you for the call and interest. I have attached the Interim progress report issued last Friday. Also you will find a draft agenda and a list of Draft recommendations that will be discussed at the meeting. We expect the agenda to change very little but the Draft recommendations will change considerably after the discussion held this week. If you have trouble opening any of these documents, please send me a quick note back.

Best wishes and my direct number is 301-435-6199.

Steve Groft

<<AgendaOct4-62001FINL.wpd>> <<recommendationsallPubOct4-6.wpd>> <<FinalIntProgressReptsg#24.91801.rtf>>

Rep. Frank Pallone, Jr.

Testimony before the White House Commission on Complementary and Alternative Medicine Policy

October 5, 2001

Good morning, Mr. Chairman and Commissioners. Thank you for the unique opportunity to testify before you on several complementary and alternative medicine (CAM) issues of concern to me.

As a Member of Congress and senior Democratic Member of the House Commerce Subcommittee on Health, I have always been interested in Complementary and Alternative healthcare issues. The debate regarding dietary supplements and their use in CAM practice are constantly resonated in my district and home state of New Jersey. It was about 10 years ago that I first heard from my constituents about dietary supplements and how important these supplements are to personal healthcare. I worked closely with former Congressman Bill Richardson when he led the effort to pass the Dietary Supplement Health and Education Act of 1994 (DSHEA) in the House of Representatives and when this commission was being created in the Balanced Budget Act of 1998, I supported its creation. I am happy to be making a contribution to the CAM arena.

Before I share with you my particular concerns on dietary supplement issues, I would like to note that I believe you, as a Commission, are doing very important work. Although the recent tragedy of September 11th has forced us to focus most of our attention on the war on terrorism and the American economy, nevertheless, the Congress and the Administration will surely benefit from your recommendations. I am eager to review your guidelines and hopefully see the government translate your recommendations into health policy.

DSHEA

While many believe that dietary supplements are not well regulated, we all know the fact is that the FDA has the authority and the tools to protect the public from unsafe products under DSHEA. As one of the strongest proponents of DSHEA in Congress, I believe that any efforts to weaken or repeal this important law must be fought and I would hope that your recommendations will reflect the necessity of producing dietary supplements under a regulatory framework like DSHEA.

I want to see the FDA fully utilize its authority to ensure that consumers have access to only high quality, safe dietary supplements. When DSHEA was passed in the 103rd Congress, its intent was to ensure greater access to dietary supplements that provided health benefits. Since the industry lacked appropriate legislation, the FDA was charged with deeming safety of products. The FDA has not fully carried out their responsibilities in regard to this issue, nevertheless, it is now more important than ever that DSHEA remains enacted. It is crucial that your recommendations reflect the necessity of DSHEA, as it is currently the only law on the books that protects consumer access to safe dietary supplements.

GMPs

An issue that has been extremely frustrating for me, the industry, consumers and surely the Commission, is the unacceptable delay of the publication of the Good Manufacturing Practices (GMP) regulations. As you know, these are guidelines to be published by HHS for the dietary supplement industry.

Earlier this year, the Commerce Committee's Health Subcommittee, of which I am a Member, held two hearings – one with

Dr. Linda Suydam of the FDA and one with Secretary Tommy Thompson of HHS. At both of these hearings, I pressed these witnesses on the estimated date of publication of the GMPs and I received no guarantees of publication anytime in the near future. I believe the regulations are sitting at the Office of Management and Budget (OMB), however, I have not received any official word about the status of the regulations.

The importance of these regulations, as you know, is crucial to the sustenance and production of dietary supplements and unfortunately, this issue does not seem to be an HHS or FDA priority. In follow-up letters that I sent to both Dr. Suydam and to Secretary Thompson urging the publication of the GMPs, the importance of these regulations was clear yet I still do not have a response from either of them. From what I can gather, one of the reasons for the delay is that an FDA Commissioner has not been appointed yet. I read in Wednesday's New York Times that Secretary Thompson may choose Dr. Lester Crawford, a food safety expert, for the position, however, appointment of an FDA Commissioner is not an excuse for the near 7 year delay of publishing the GMPs.

I believe the immediate publication of the GMPs needs to be a priority for the dietary supplement community, and I would hope that this is reflected in your recommendations.

Legislation

I am pleased to announce that there will soon be bipartisan introduction of legislation as a House companion bill to S. 1330, the Dietary Supplement Tax Fairness Act. I will be taking the Democratic lead on this bill that would reform the Internal Revenue Code to allow insurance companies to provide coverage for dietary supplements, medical foods, and foods for special dietary use in a tax favorable way. In addition, I will be taking the Democratic lead on an additional piece of legislation that would provide coverage of dietary supplements through the Federal Food Stamp Program.

I know my constituents have always asked why there is no insurance coverage for dietary supplements. These two pieces of legislation potentially take a meaningful step in the direction of dietary supplement coverage. Many of my constituents and many Americans use these products to stay healthy and to stay out of the medical system and unfortunately, they are forced to pay out of pocket. I am looking

forward to working with my colleagues to hopefully pass ground-breaking legislation that will recognize the importance of dietary supplements and provide appropriate coverage.

Access

There are two access issues of particular concern to me. The first has to do with state licensure and the second has to do with access to dietary supplements throughout the underserved population.

From what I understand, currently CAM professions are not licensed in all 50 states. Although licensure of health professions is typically a state function, I believe the federal government can play a role in encouraging states to enact licensure statutes. For example, a proposal where states that enact licensure statutes would be provided access to certain federal health care funds, programs and research may be a reasonable approach. This type of a step would promote CAM health care and the related professions.

Additionally, at a time when the country is experiencing health care worker shortages and rising health care costs, necessary measures

should be taken to promote preventive health, especially among the underserved populations. Dietary supplements are widely used to promote health and to prevent disease - perhaps an integration of licensed CAM professionals into the National Health Service Corps would make these low cost, effective therapies a realistic option for underserved populations.

Research

The research arena of dietary supplements must be expanded in order to provide safe products and in order to discover beneficial uses of supplements for certain vulnerable populations.

Specifically, as we face increasing demand for health care services with an aging population, we need solutions in addition to prescription drug coverage for seniors and I suggest that the Commission focus on research on the elderly. We in Congress are fighting a battle to allow seniors to have better access to prescription drugs, but prescription drugs are not the only answer to better health. I would like to see more research done in this area and I would like to explore avenues for CAM providers to reach out to the elderly about dietary supplements that may provide for their special needs.

These are just several of the key concerns I have regarding dietary supplements and as I continue to work on these issues, I hope that the Commission will give these issues consideration while crafting recommendations and that we can work together in the near future.

I understand that you have held numerous hearings throughout the country and I salute your efforts. As this Commission enters the home stretch in formulating policy and legislative recommendations, I want to urge the Commissioners to carefully consider and evaluate what those recommendations will be. I have been following your work and look forward to being able to help translate solid policy recommendations into meaningful statutory and legislative reforms.

I assure you that I will remain committed as a Member of Congress to addressing and improving CAM healthcare issues and I want to thank you again for allowing me to speak with you today.

General observation on information development and dissemination: there is a danger to treating CAM information as a separate, segregable form of data rather than as a proper part of the larger "library" of health information. This might impede or slow the acceptance of certain aspects of CAM into the mainstream, and provide a convenient target for opponents seeking to slow the assimilation of CAM into accepted medical practice. For example, a convening such as that described in Recommendation 10 might hurt the growth of CAM if it were not part of a larger effort addressing conventional as well as alternative medicine.

Specific notes:

1. CAM web sites are currently subject to the jurisdiction of the FTC, FDA, SEC and other federal agencies for certain of their activities. Recommendation 1 should be clarified to reflect that any new voluntary standards are not intended to supplanting or replacing such existing jurisdiction.

2. There are a substantial number of existing initiatives to improve "health literacy" not only on the Internet but also on "old" media. To the extent that Recommendation 2 addresses the Internet it is duplicative, and to the extent it does not address other media, it is under-inclusive. At the very least, Recommendation 2 should make reference to working with such existing programs to insure that they accurately and comprehensively cover alternative medicine issues.

3. Although Recommendation 1suggests the use of voluntary guidelines, Recommendation 3 is silent as to the existence of several privacy self-regulatory certification programs, such as Trust-E. The privacy provisions outlined in Recommendation 3 fall far short of the "state of the art" used in these existing programs. For example, they do not address the prominence of privacy disclosures, the offering of either opt-in or opt-out choices and do not address whether privacy policies may be retroactively changed with or without notice, particularly when a web site is sold or becomes subject to sale in a bankruptcy proceeding.
   In calling for review of existing privacy laws, Recommendation 3 needlessly enters into an area of great controversy, inasmuch as partisan divisions have emerged in Congress and the FTC on this question.

4. No comment.

5. No comment.

6. No comment.

7. No comment.

8. No comment.

9. Recommendation 9 is unclear as to what constitutes "additional support." If this is in-

tended to call for increased expenditures, should this be from new appropriations from or from reallocating existing resources. If it is intended to call for broader legal powers, is this to come from new legislation or more aggressive use of existing authority.

10. No comment.

11. No comment.

12. Recommendation 12 is silent as to disclosure of adverse disciplinary proceedings and license revocations.

13. No comment.

14-20. No comment.

21h. The proposal in Recommendation 21h is heavily weighted towards expanding the rights of patent holders. Consideration should be given to emphasizing the importance of compulsory licensing and not creating excessively long patent terms. As CAM becomes more broadly accepted, patents are likely to be become an increasingly importance obstacle to the dissemination of CAM. Particular emphasis should be given to insuring that "prior arts" policies are maintained so that traditional medicinal practices and substances may not be removed from the public domain and turned into proprietary products.

22ff. No comment.