COORDINATION OF RESEARCH

The public's increased use of complementary and alternative medicine has added urgency to the need to examine the safety, efficacy, and cost effectiveness of CAM practices and products and to discover the basic mechanisms underlying them. Basic, clinical, and health services research in CAM are all essential to achieving the integration of CAM into the health care system. Public and private funding for this research should be increased and the paucity of private investment in research on herbal and other CAM products popular with the public should be addressed.

Rigorous research provides the information needed to increase the public's knowledge about complementary and alternative medicine (CAM) and to educate and train CAM and conventional health care professionals. It also provides a basis for regulating the quality and use of CAM products and devices as well as improving access to safe and effective CAM practices and products and the health insurance coverage for them. In addition to questions of safety and efficacy, further studies should be undertaken to determine why people use CAM, how lifestyle and self care affect health and disease, and how practitioner-patient interactions affect treatment outcomes. Research is also needed to pursue answers to questions posed by CAM that are outside of the conventional medical paradigm.

Establishing a strong scientific base in CAM is necessary for acceptance and integration of safe and effective CAM therapies into the health care system. In conventional medical practice, professional judgments are based on the practitioner's training and experience and an accepted and expanding body of knowledge based on research findings published in peer-reviewed journals. Professional judgments in the practice of CAM are often not viewed in a similar light because of the lack of a sufficient body of evidence-based knowledge on which to form them. As the body of research literature in CAM expands, the professional judgments of trained and experienced CAM practitioners will be accepted more readily.

An important milestone towards the goal of increasing the body of evidence-based knowledge in CAM occurred in 1992 with the establishment of the NIH Office of Alternative Medicine at the

National Institutes of Health (NIH). The mandate of this Office was to facilitate and coordinate CAM research and related projects with the NIH Institutes, Centers and Offices, and to provide information to the public. In 1998, CAM research took another major step forward when The Office of Alternative Medicine became, through Congressional mandate, the National Center for Complementary and Alternative Medicine (NCCAM). NCCAM's expanded resources enhanced its ability both to continue and to build upon the work of the earlier Office ~~and to contribute to the integration of safe and effective CAM treatments and approaches into the health care system~~ *to provide for the public the evidence needed on the safety and efficacy of CAM practices and products.*

RESEARCH SUPPORT AND SCOPE

1. Current CAM Research Activities

The Commission commends NCCAM for its leadership and contributions to CAM research, methodology, training, and infrastructure development and supports increasing the Center's crucial activities in these areas, including its database development and information dissemination responsibilities. NCCAM collaborates with NIH Institutes, Centers and Offices, as well as other government agencies and non-government sectors. It initiates and funds research projects and establishes research centers at conventional medical institutions and CAM institutions. It also supports the training of CAM researchers and the research infrastructure at conventional and CAM institutions, supports educational activities, and offers opportunities for collaborations between CAM practitioners and researchers and mainstream investigators. The Commission commends current collaborations and encourages further collaborations between NCCAM and other Federal agencies, such as the Agency for Health Care Research and Quality, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Research and Services Administration.

The NIH Office of Dietary Supplements Important work is also carrying out important work. The mandate of this Office includes exploring the role of dietary supplements in the

improvement of health care, promoting scientific study, and supporting conferences, workshops and symposia, which it does in conjunction with NCCAM, other NIH Institutes and Centers, other government agencies, professional organizations, and public groups.

The Commission recognizes the support for CAM research by the other NIH components, encourages them to increase their support, and notes especially the work of the National Cancer Institute (NCI)'s Office of Cancer Complementary and Alternative Medicine and the National Library of Medicine. ~~All Federal agencies with research or health care responsibilities need to be more proactive in evaluating aspects of CAM and developing programs to ensure that CAM is properly integrated into the health care system~~. All Federal agencies with research or health care responsibilities need to be more proactive in *developing programs to evaluate either biomedical or health services aspects of CAM to ensure that CAM use by the public is safe and effective.*

In response to the public's use of CAM practices and products, funding for CAM research from FY 1999 to FY 2002 for overall NIH increased from *$116 million to an estimated $221.5 million (update these numbers "from $124.4 million to an estimated $226.0 million).* During the same period, funding for CAM research by NCCAM increased from $48.9 million to an estimated $104.6 million. Despite the increase in the budget, an analysis of NCCAM's extramural trends between FY 1999 and 2003 estimates a growing number of applications and a decreasing number of new awards, resulting in a declining success rate, which is the percentage of research project grant applications that receive funding.

WB: (2) The need for prioritization of Research

Research grants are awarded for an average of four years during which time they are considered non-competing grants. As an increasing number of quality CAM research applications are submitted and awarded, the number of non-competing grants to which funds are committed (the commitment base) grows. The decline in new awards is most likely caused by an increasing commitment base that includes among the new awards some that may be larger and longer-term clinical studies. Therefore, in order to build the *much needed* evidence base for CAM, funding increases are essential to support NCCAM's commitment base, grant renewals, and as many meritorious new awards as possible. Historically, as new NIH grant-awarding organizations

move through budget allocation cycles and develop longer grant histories, they gradually improve the balance between non-competing and competing grants, but are always aware of the need for adequate funding to support both. The Commission believes that NCCAM's budget increases should be sufficient to support growing numbers of awards so that the Center can meet driving research needs and research opportunities in crucial areas.

In addition, funding for CAM research by other NIH components should continue to increase and adequate support for other Federal agencies with health care missions should be increased for conducting CAM research and related activities.

2. Public and Private Research Funding for CAM Products That May Not be Patentable

The funding of research on frequently used or promising dietary supplements and other natural products that may not be patentable *is a public health need* of paramount importance. This research is needed to determine whether the products are safe to use alone and with other CAM and non-CAM products, and whether they are effective. Research is also needed on the development of analytical methods for producing better quality products, as well as on CAM therapeutic devices that may not be patentable. ~~This research will require both substantial Federal support and increased incentives to stimulate more private sector support~~. *This research requires substantial Federal support now and in the immediate future. Along with the need for public funding, however, is the need for incentives to stimulate* ~~much~~ *more private sector support in this area.* Congress and the Executive Branch might consider *incentives such as* low interest loans, tax incentives, market exclusivity, and resolution of intellectual property issues. Workshops supported by the public and private sectors should be convened to discuss the research needed, *including discussions on funding issues and sources, and on the research needed* by regulatory agencies for their review and approval processes. Private companies should recognize how important clinical research, product quality *and dependability*, and accurate information are to the public's perception of CAM products. *[1] Federal support for research on practices that may not be profitable, such as biofeedback, meditation and guided imagery, is also needed.*

Federal agencies need to develop outreach programs to inform manufacturers of CAM products and devices about the Federal research support available to private industry, such as the Small Business Innovative Research Grant (R43/44), the Small Business Technology Transfer Research Grant (R41/42), [2] and the Cooperative Research and Development Agreement. [3] The manufacturers of CAM products and devices should become acquainted with potential sources of funding and with the requirements they must meet to receive such funds. Federal agency staff members are available to assist applicants with protocol development and to help them understand the grant process.

3. CAM's Emphasis on Health and the Whole Person

Public interest in CAM has renewed awareness of and respect for the importance of the whole person in maintaining health and treating disease. Members of the public have expressed appreciation for the attention many CAM practitioners and disciplines give to wellness and health promotion, self care, lifestyle, quality of life, behavior, and their recognition that mind, body, and spirituality play a combined role in health, disease, and healing. People also appreciate the importance many CAM practitioners and disciplines place on the interactions between patient and practitioner and on individualizing treatments. CAM's emphasis on the individual's biochemical uniqueness [4] and the value of tailoring treatments to the biological, psychological, sociological and spiritual aspects of the person, reinforces the need to increase studies on individualized CAM treatments and the variations in patient responses to conventional medical treatments. ~~Areas such as these merit further research and increased public and private investment.~~ *CAM research in these areas, which converges to some extent with conventional behavioral and psychosocial research*, merits increased public and private investment. This research could contribute in important ways to health care, particularly in the management of chronic diseases and disorders and in rehabilitation practices.

4. Pluralism in Research Approaches anything else WJ

Various research approaches, if they are pertinent to the question being asked, contribute in valuable way to developing evidence of safety, clinical efficacy and general effectiveness and to understanding the basic mechanisms of action underlying CAM practices and products. Among these approaches are basic research, randomized controlled clinical trials, non-randomized studies, empirical observation, case studies, evaluations of practice-based data, epidemiologic and surveillance studies, outcomes research, behavioral and quality-of-life studies, cost-effectiveness studies, population and utilization studies, studies on health care delivery, and health care demonstration projects on various aspects of CAM use and services.

4. Research Methodology

To be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified and appropriately constituted research team; objective, verifiable data; carefully defined outcome measures; 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 and systems of care, while complying with protections for human subjects and institutional review board (IRB) guidelines. Questions of standardization and non-standardization, individualization and generalization, blinding, randomization, the placebo effect, compound mixtures, and many other research methodology challenges need to be resolved within the context of the study design.

It is important to note that in conventional clinical research investigators have also adapted methodology and design to meet the needs of the study. Scientists have always followed quests for knowledge by developing new ways to answer difficult questions, and pluralism in research design will allow scientists to develop innovative methods to examine complex CAM questions. Funding mechanisms that have promoted interdisciplinary exchange of ideas in addressing difficult research questions in conventional research may offer settings in which creative ways of approaching difficult CAM research questions can be developed. Examples of such mechanisms

include Specialized Center Awards (P50), Exploratory Grants (P20), and Center Core Grants (P30). Other awards of interest are the Exploratory/Developmental Grants (R21), which encourage the development of new research activities in categorical program areas, and the James A. Shannon Director's Award (R55), which is a limited grant mechanism for developing, testing, and defining research techniques and the feasibility of innovative, creative, research approaches. [2] In addition, multidisciplinary conferences, workshops, and expert panels, such as the CAM cancer symptom management research panel convened in November 2001, provide effective forums for exploring ways to address CAM research challenges. The results of meetings such as these are often published in peer-reviewed journals and can stimulate new research and public and private investment.

5. Expanding Areas of Scientific Inquiry

In addition to the primary task of identifying practices and products that could become either complementary to conventional care or alternative treatments, CAM research may go beyond isolated treatments and contribute new and innovative ideas to emerging areas of scientific study that might help expand our understanding of health, disease, and healing. The CAM research spectrum is broad. It includes areas that in some cases may be almost indistinguishable from conventional medicine except for pharmacological agents, techniques or application, such as exercise/diet/lifestyle therapies; herbal/nutritional supplements; behavioral/mind-body methods; pain management; the effects of culture on health and treatment; and the ability of the body to heal. The spectrum also includes areas that may receive less attention but are, or are becoming, areas of interest to conventional science, such as increasing our understanding of complete biological systems and how they interact, the placebo effect, spirituality, consciousness, and electromagnetic fields. Finally, the spectrum includes areas that challenge *current biological and scientific* concepts and assumptions, such as homeopathy, bioenergy (vital force; e.g., Qi, prana), bioelectromagnetic therapy, and therapeutic prayer. Answers to some of these and other research questions posed by such CAM concepts may be found in the study of Ayurvedic medicine, Traditional Chinese Medicine, Tibetan medicine, Native American medicine, medicine of Africa, as well as naturopathic medicine, chiropractic, and other systems of healing.

Applying rigorous scientific methods to the exploration of such frontier areas of inquiry may require merging whole system concepts with ~~modern reductive expertise~~ *current biomedical knowledge*. It will also require the input of CAM professionals working with experts in a wide variety of fields, including but not limited to physics, cell and molecular biology, genetics, immunology, physiology, chemistry, neurobiology, epidemiology, psychology, sociology, and engineering. In addition to NCCAM, which has issued a request for applications to foster research in frontier areas of inquiry, the National Institute of General Medical Sciences of the NIH, the Department of Energy, the Department of Defense, and the National Science Foundation are examples of Federal organizations that should consider contributing collaboratively or independently to the support of research on core CAM questions in areas described in many CAM systems.

6. Moving Non-approved Treatments to Clinical Investigation

The Commission recognizes that physicians and other health care practitioners who believe they have promising data on non-approved CAM treatments need more assistance in moving successfully to clinical investigation of the treatment while meeting their professional, ethical, and human subject protection responsibilities. It is essential to note here that, i*n addition to Federal requirements concerning research,* all CAM and conventional practitioners, whether or not they are engaged in research, must meet the same licensing, *credentialing* or other authorizing standards of care that apply to ~~all~~ similarly licensed, *credentialed*, or authorized practitioners ~~to protect their privilege to practice.~~ ~~(see Joe P's comment)~~

In CAM research, as in conventional research, the following standards apply: (1) the practitioner engaging in research must be knowledgeable about the collection of objective and valid observational data and record keeping; (2) the investigation of the treatment must be part of a well designed study that meets rigorous scientific standards; and (3) protections for human subjects and IRB guidelines must be in place and followed. Practitioners, however, often do not have the expertise, the resources, or the time to conduct high quality, scientifically rigorous

practice-based research. They need both the support of research institutions and the opportunity to partner with expert researchers in the evaluation of their observations and in designing and implementing clinical studies.

To help implement and accelerate the process, the Commission would like to see NIH Institutes, Centers, and Offices, and other Federal agencies, as appropriate, develop programs to evaluate practice-based observational data as the basis for potential research support, and communicate the availability of such programs to practitioners. If a project merits funding, CAM practitioners and CAM-trained researchers should be part of the research team. These programs may also offer training in data collection, the scientific method, protocol development, and ethical guidelines and human subject protection. Support for research can be obtained as well from reputable, high quality private or nonprofit institutions or organizations, which also should develop ways to assist practitioners in moving successfully from preliminary data to quality clinical research.

The NCI's Office of Cancer Complementary and Alternative Medicine conducts reviews of practice-based data through its best-case series program. Members of the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM), medical oncologists, and CAM experts also provide NCCAM with a field investigation function to collect and evaluate outcome data on promising alternative cancer therapies. To stimulate practitioner response, NCCAM in collaboration with NCI, has called for the submission of case histories through notices in leading conventional and CAM periodicals, at meetings, and with letters. This effort has resulted in one study under way, another under negotiation, and a third under review. NCCAM has also, through the Agency for Health Care Research and Quality, contracted with the RAND Corporation to compile data histories of best-case studies for review and assessment by CAPCAM. Two such analyses will be presented in an upcoming meeting. NCCAM has also initiated a pilot project with the Centers for Disease Control and Prevention (CDCP) to develop methods for identifying practitioners who have data on new therapies and conduct systematic reviews of the case files and identify practices worthy of research support.

Using both the NCI best-case series and the NCCAM collaboration with NCI as a model, concerted efforts are needed to continue strengthening current outreach activities to CAM practitioners and conventional researchers and to create outreach programs for evaluating practice-based observational data in additional areas of research. Activities should also offer guidance and training to facilitate the move by CAM professionals from promising preliminary data to scientifically rigorous clinical studies.

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

Actions

1.1 Federal agencies ~~with research or related health care missions~~ should increase their ~~research and related~~ *activities with respect to CAM in accordance with their research or health care-related responsibilities and make these activities known to CAM professionals*. Activities ~~should~~ *could* include funding initiatives such as requests for applications and proposals; CAM-focused offices or centers; CAM-focused staff positions; CAM planning and advisory committees or the representation of qualified CAM professionals on such groups.

1.2 *Wayne's proportionality action (if added, must be added to the text)*

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

Recommendation 2: Congress and the Administration should enact legislative and administrative ~~reforms to provide greater~~ incentives to stimulate private sector investment in CAM research on products that may not be patentable.

Actions

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

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

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

~~2.4 Manufacturers of cAM products and devices should become acquainted with potential sources of research funding and the requirements they must meet to access such resources successfully.~~

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

Action

~~3.1 The Federal government should stimulate private investment in research on CAM modalities and approaches that are designed to improve self care and wellness behaviors.~~

3.1 *Federal, private, and nonprofit sectors should support research on CAM practices that may not be profitable, such as biofeedback, meditation, and guided imagery.*

~~4.1~~ *3.2* The Federal, private, and nonprofit sectors should support more research on (1) complex compounds/mixtures frequently found in CAM products, (2) clinical interventions consisting of multiple treatments, (3) how patient-practitioner interactions affect treatment outcomes, and (4) individualizing treatments.

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

Actions

4.1 NCCAM, assisted by the National Science Foundation or the Institute of Medicine~~, or other Federal or non-Federal body,~~ should conduct a review of core research questions associated with CAM that are outside the current research paradigm *and examine methodological approaches to studying these questions.*

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

4.3 The National Institute of General Medical Sciences of the NIH, the Department of Energy, the Department of Defense, and the National Science Foundation are among the Federal organizations that should consider contributing collaboratively

or independently to the support of research on core questions in areas described in many CAM systems.

4.4 NCCAM, working with the World Health Organization, should examine investigative approaches for studying the traditional practices of indigenous peoples.

Recommendation 5: ~~It should be duly noted~~ ~~Federal agencies responsible for research oversight should ensure that~~ Investigators engaged in research on CAM should ensure that human subjects participating in clinical studies receive the same protections as are required in conventional medical research and to which they are entitled.

Actions

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

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

5.3 IRBs that review CAM research studies should include the expertise of qualified CAM professionals in the review.

5.4 Research institutions, NIH Institutes and Centers, and other Federal research

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

Recommendation 6: ***The Commission recommends that*** **state professional regulatory bodies ~~should~~ include language in their guidelines stating ~~*as applicable*~~ that licensed, *credentialed, or otherwise* authorized practitioners who are engaged in research on CAM will not be sanctioned *solely* because they are engaged in *such* research if they are (1) engaged in research *that is well designed* ~~that is~~ *and* approved by an appropriately constituted IRB, (2) following the requirements for the protection of human subjects, and (3) meeting their professional and ethical responsibilities. [All CAM and conventional practitioners, whether or not they are engaged in research, must meet ~~the same~~ licensing, credentialing, or other authorizing ~~standards of care~~ to which all similarly licensed, credentialed, or authorized practitioners are held.]**

(see Joe P's change and get back to this one " are meeting the same licensing [requirements] or other authorization to practice to which all...)

DIALOGUE, PARTNERSHIPS, AND PUBLIC INPUT

1. Emerging Dialogue and Integration of CAM into the Health Care System

Largely in response to the public's use of CAM practices and products, an emerging dialogue between CAM and conventional medicine appears to be taking place, along with a growing willingness to experiment with integration. [5] These gradual changes, which present an exciting and hopeful prospect for meaningful collaborations, are reflected in an increase in cooperation and opportunities for cooperation between CAM and conventional health care professionals and institutions. A major challenge facing both CAM and conventional medicine is to foster this

emerging dialogue and, by doing so, increase mutual respect and better understanding of one another's expertise, concerns, and contributions. Strengthening the dialogue will not only help protect the public from unsafe treatments, but will also expand opportunities to improve health care.

A recent national survey indicates that most people value both CAM and conventional approaches. [6] The goal of integrative medicine is to identify the most appropriate treatments available from a broad spectrum of evidence-based care. [7] To name just a few examples, in integrative cancer treatment, a patient may undergo individualized acupuncture treatment for nausea and vomiting following chemotherapy; relaxation techniques and support groups are used with cancer patients to reduce stress, improve mood, and enhance the immune system; and mind-body interactions and stress management are being studied with respect to the treatment of hypertension and coronary heart disease. The Commission supports the integration of CAM and conventional medicine and believes that combining the best of CAM with conventional medical care may help reunite the art and science of medicine.

2. Applying the Same Standards

It is the view of some CAM professionals that the requirements for CAM research are higher than for conventional research. On the other hand, some 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 the same high standards of quality, rigor, and ethics must be met in 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.

3. Cooperation and Partnerships

Cooperation and partnerships are at the heart of the challenge to foster dialogue and improve the quality of CAM research and the success of research applications, including those that may lie

outside mainstream research. Building 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 and establishing the appropriate use of CAM within the heath care system.

To be most effective, CAM and conventional researchers, clinicians and practitioners, and the leadership of their institutions and organizations need to communicate with one another and form working relationships. Federal and state research and health care agencies, the private and nonprofit sectors and the public are also integral to this cooperative environment that gives the scientific and health care community an opportunity to raise the quality of CAM research and improve the research infrastructure. The effective regulation of CAM research, the publication of CAM research results, and the review and approval of CAM practices and products also depend on increased interaction among these various constituencies. Therefore trained, experienced, and properly qualified CAM and conventional medical professionals need to be represented on research, journal, regulatory, and health insurance review and advisory committees, as well as in discussions on CAM-related research policy issues.

Because conferences, workshops, and expert panels are excellent instruments for enhancing communication, participants at such meetings should include CAM and conventional medical and health care professionals and the public, private, and nonprofit sectors. As stated earlier, multidisciplinary meetings offer the opportunity people from a broad variety of disciplines and interests to build on each others' knowledge and experience in discussions about promising research topics and research planning, program development, and policy considerations, and to explore innovative methodological approaches to solving difficult research questions in focused CAM areas.

Examples of interdisciplinary activities the have contributed to progress in CAM include NCCAM's conference on "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 Center for Mind-body Medicine's "Comprehensive Cancer Care Conference," cosponsored by NCI and NCCAM. 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 another example of this type of activity. Federal public health grants for conference support, such as the R13, H13, and T14, [2] are available to qualified applicants.

Partnerships and collaborations between and among public, private, and nonprofit organizations are also very important to the support of CAM research. Interested nonprofit organizations should consider pooling their resources, independently or collaboratively with the public or private sectors, to support interdisciplinary conferences on CAM research, as well as to support CAM research, research infrastructure and training at CAM institutions, and the dissemination of CAM information.

4. Public Input and Public Use

The public's growing influence on the health care system has created a need for more research, including population-based research on why people are turning to CAM, as well as a need to ensure public participation in shaping the direction of CAM research. In its 1998 report on "Scientific Opportunities and Public Needs," the Institute of Medicine described public input as an essential and integral part of the democratic process which, if done well, can improve the knowledge base for public policy decisions. The report goes on to recognize the intense public interest in health issues, and agreement on the part of the public, Congress and the Executive Branch that investing in research is the right thing to do. [8]

Federal requirements and opportunities for public participation in the shaping of health care research and related activities currently exist. Examples include the NIH Director's Council of Public Representatives, which was recommended by the Institute of Medicine, and the long

standing requirement that there be public members on NIH Institute and Center advisory councils, boards, and committees, Food and Drug Administration advisory committees, and IRBs [9]. Such opportunities are available to members of the public representing CAM research and related areas. Public members of Federal advisory committees as well as the agencies they advise would gain from programs designed to orient and train them on how to provide their input most effectively, particularly with regard to (1) moving from promising basic science findings to clinical treatments, (2) identifying health services research needs, and (3) improving the dissemination of research information.

Because of the increased use of CAM products and the published reports of adverse events, including loss of therapeutic drug effectiveness and compromised perioperative care, the NIH Warren Grant Magnuson Clinical Center established a policy in June 2001 requiring that all inpatients and outpatients be asked, during the admission process, about their use of herbal or other dietary supplements. ~~The inquiry includes discussions with the patient on what is known or not known about the product being used and a determination made with a physician's order on whether to continue or discontinue the patient's use of the product. An online database of herbal monographs, the "Natural Medicines Comprehensive Database," [10] and consultation by knowledgeable staff help in this decision making process. An interdisciplinary task force established by the Clinical Center Quality Committee evaluated similar practices in eighteen hospitals nationwide. The collection of such information may in the future offer a data source for research on CAM use by the public. [11]~~

There is also a growing trend to include questions about herbal or other dietary supplement use in research protocols. The possibility of including such questions in all Clinical Center IRB protocols is being considered. The knowledge gained from this questioning would benefit research subjects and future protocol development by contributing important information about the use of dietary supplements and other natural products. [10] *The collection of such information may in the future also offer a data source for research on CAM use by the public.* [*12*] Because reliable information, including patient disclosure, is necessary for insuring informed decision making, patient safety and valid research outcomes, it is once again clear that (1) more research is

needed on CAM practices and products and (2) health care professionals and researchers need to be knowledgeable about CAM.

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

Actions

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

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

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

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

7.5 The nonprofit sector and the private sector should create funding partnerships, whether independently or with Federal agencies, to augment support for CAM

research, research infrastructure and training, research conferences, and information dissemination.

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

7.7 To benefit patients and future research protocol development and to add to our knowledge about the use of CAM, IRBs should consider requiring that all research subjects be asked about their use of herbal or other dietary supplements. ~~and hospitals should consider requiring that all inpatients and outpatients be asked about their supplement use.~~

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

RESEARCH TRAINING AND INFRASTRUCTURE

A strong research infrastructure is crucial to training skilled researchers to study CAM questions, producing grant applications in CAM that successfully compete for support, and conducting rigorous CAM research. Sustained, adequate funding is essential to building and maintaining long-term research capacity for training clinical investigators and health services researchers in CAM, and scientists who are interested in studying the underlying mechanisms of CAM products, practices, systems and concepts. A government-wide effort involving NIH, the Department of Defense, the Department of Veteran's Affairs and other Federal agencies would strengthen the funding and strategic planning for developing or enhancing CAM research sites and training programs. Supporting research training and infrastructure in accredited CAM institutions would help build their capability to conduct high quality research and enhance their opportunities to

form research collaborations with conventional medical research centers.

1. The Need for Rigorous Training

The same rigorous training is required for both CAM and conventional medical researchers and must be available to both. Conventional researchers need to understand CAM concepts and approaches, and both CAM and conventional investigators must have thorough training in the fundamental elements of quality clinical, basic, or health services research. This training should include a strong grounding in (1) the research process and methodology, (2) the collection and recording of unbiased data, (3) all aspects of protocol or study design and execution, (4) an understanding of the expertise needed to form a research team, (5) IRB and other regulatory requirements, and (6) the grant application, submission, and review processes.

Research training in CAM should also teach multiple outcome measures, including social and biopsychological measures of health, and offer experience working as part of a multdisciplinary research team. The opportunity to gain solid training in a supportive environment on how to conduct quality CAM research should continue to attract students from both CAM and conventional medicine who are interested in studying CAM questions. The Commission believes that all Federal agencies that have training programs as part of their health care missions should support the training of researchers to address CAM-related questions that are relevant to their missions.

2. Elements of a Strong Research Infrastructure

Research sites, whether supported publicly, privately, or by foundations, need to be strategically located and structured to conduct basic, clinical, and health services research, adequately train researchers and clinical experts, and deliver integrated care services. The success of each site depends on a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with patient access. The Commission would like to see CAM research sites developed at public, private and accredited CAM institutions with both

CAM-trained and conventional medical professionals serving on faculty 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 success in obtaining funding.

3. Current Research and Research Training Activities and Opportunities

Academic health centers at conventional institutions offer excellent venues for exchanging experiences with CAM professionals on how best to educate conventional researchers in CAM practices and how to introduce CAM practitioners to the conventional research culture. Conventional health centers are gradually including CAM in their research, research training, clinical, and medical education activities. For example, the Medical Center Health System of the University of Pennsylvania, recognizing that CAM therapies merit evaluation, recently incorporated the study of CAM therapies into its research, clinical, and educational activities by training faculty in CAM research, stimulating interdisciplinary collaboration, and identifying financial and other resources. [13] Harvard University, Duke University, the University of Maryland, University of Oregon, University of Washington, Georgetown University and many other institutions across the country have incorporated CAM into their academic health centers; each has done so in its own way. Some conventional health centers have cooperative arrangements with CAM institutions and such cooperation should be encouraged.

Accredited CAM institutions are gradually expanding their activities to develop research and research training capacity, form interdisciplinary collaborations, and establish cooperative arrangements with conventional health centers. For example, a neurophysiology laboratory focusing on research of interest to the chiropractic field has been established at the Parker College of Chiropractic by a conventionally trained neurophysiologist. NCCAM has awarded grants to CAM institutions, such as the Bastyr University Naturopathic Medicine Program, the Oregon College of Oriental Medicine, the Center for Natural Medicine and Prevention of the Maharishi University of Management, and a consortium of chiropractic colleges. The number of accredited CAM institutions that receive research support should increase as their capacity to conduct

rigorous research improves and they submit more applications.

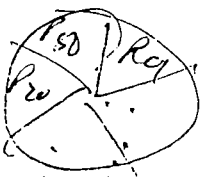
NCCAM provides funding for approximately 15 CAM Specialty Centers of Research in collaboration with other NIH Institutes and Centers and the Office of Dietary Supplements. In addition to botanicals, the Centers focus on such areas as arthritis, women's health, pediatrics, cardiovascular disease, addiction, cancer and craniofacial disorders. These Centers as well as others supported by the NCCAM offer research training opportunities. The Commission encourages NCCAM and the other Institutes and Centers, and other to develop a cadre of well-trained CAM and conventional medical investigators in basic, clinical, or health services CAM research and support career development awards. The Commission also encourages support of CAM research training and infrastructure by the private and nonprofit sectors.

The General Clinical Research Centers, supported by the NIH National Center for Research Resources, form a national network of hospital-based centers that provide a research infrastructure for clinical investigators who receive NIH and other Federal agency support, and an environment and resources for developing future scientists in clinical research. In addition to the NCCAM-supported centers, the General Clinical Research Centers might offer opportunities to conduct clinical research and training in CAM and examine the integration of CAM into the clinical setting.

In addition to continued strong support for pre- and post-doctoral fellowship (F) and institutional (T) research training awards, CAM research trainees need experienced mentors. Incentives may have to be developed to attract mentors to this field.. Strong support of career development (K) awards---including those that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards to provide the time required to mentor new CAM investigators---are of considerable importance. [2] Also, the NIH Loan Repayment Programs offers a program for individuals holding doctoral degrees who participate in clinical research. Among those who are eligible are, DCs, NDs, and OMDs. [14]

Recommendation 8: Public and private resources should be increased to strengthen *the*

infrastructure for CAM research and research training **at conventional medical and CAM institutions and to expand the cadre of basic, clinical, and health services researchers who are knowledgeable about CAM and have received rigorous research training.**



Actions

8. 1 ~~The leadership at~~ The Commission recommends that accredited CAM and conventional medical institutions ~~should~~ develop programs that examine CAM research questions and that stimulate cross-institutional collaborations involving faculty and students in research and research training.

8.2 ~~The leadership at~~ The Commission recommends that accredited CAM and conventional medical institutions ~~should~~ support joint research and professional education and training programs to enhance the quality and clinical relevance of CAM research and link the research with evidence-based education and training of practitioners.

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

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

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

CAM Research Results: Systematic Reviews and Evaluations

1. Publication of CAM Research Results in Peer-reviewed Journals

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 the use of and reimbursement for CAM therapies should be based on published evidence of safety (including toxicity and adverse interactions), clinical efficacy, general effectiveness, and cost-effectiveness analyses rather than depending on traditional use, anecdotal reports, consumer interest, and market demand. The quality of the research and the standards of review required for 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 and scientific expertise should be represented on journal review boards when reviewing CAM research submissions.

2. The Utilization of Systematic Reviews

Reviews of information available from the published research literature from sources such as the Cochrane Collaboration's collection of systematic reviews, the evidence-based reports developed by the Agency for Health Care Research and Quality, and the databases of the National Library of Medicine, such as PubMed and MedlinePlus, are valuable resources for scientists, research planners, practitioners, community health centers, policy makers, and the public. The Commission is pleased with these organizations' CAM-related activities and especially their efforts to cooperate with one another and NCCAM's collaborations with them.

Efforts to increase the availability of concise and understandable summaries of the research literature for the public and other audiences through NLM's MedlinePlus and other dependable information sources should be supported. Examples of efforts that could be effectively applied to CAM-related information 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.

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

Actions

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

9.2 NCCAM should issue a comprehensive, *understandable, and* regularly updated summary of current clinical evidence on the safety and efficacy of CAM systems and treatments for health care practitioners and the public.

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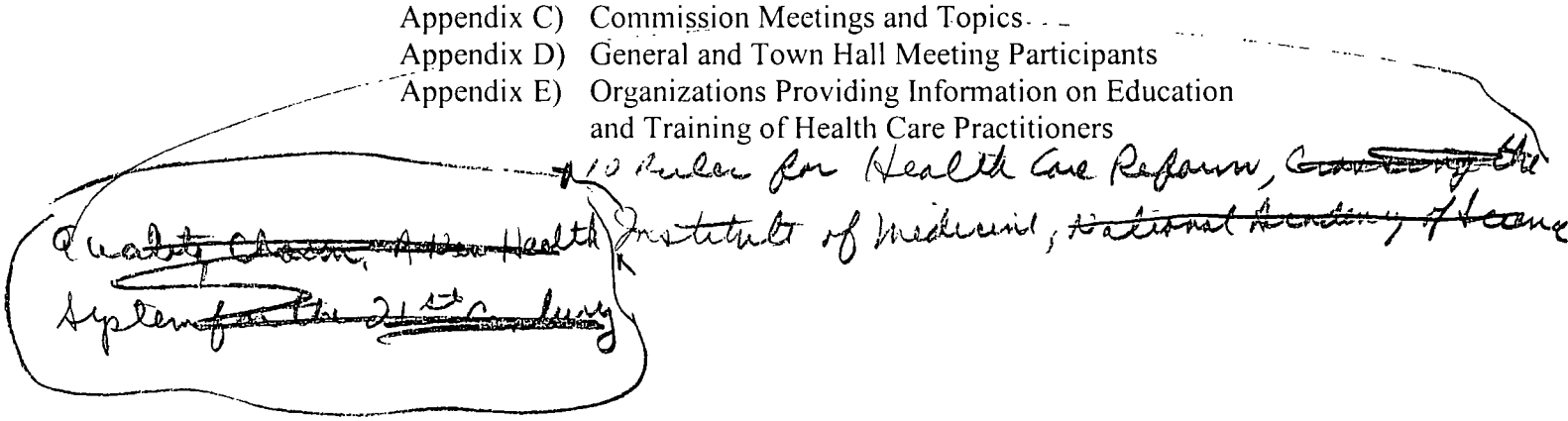

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Chapter 1:

Introduction

Over the past 30 years, public interest in and use of complementary and alternative medicine (CAM) systems, approaches, and products has risen steadily in the United States. Depending on how CAM is defined, an estimated 6.5 %[1] to as much as 43%[2] of the U.S. population has used some form of CAM.

Until recently, the primary response of Federal, State, and local health care regulatory agencies to this phenomenon was to restrict access to and delivery of CAM services to protect the public from unproven and potentially dangerous treatments. Since the early 1990s, however, more scientific evidence has emerged suggesting that some CAM approaches and products, when used appropriately, are beneficial for treating illness and promoting health (see Chapter 2). This evidence is collected and disseminated to the wider health care community and the public & helps to provide a reliable basis for making policy decisions that will facilitate the public's access to safe and effective CAM approaches and products.

To address issues related to access and delivery of CAM, as well as priorities for research and the need for better education of consumers and health care professionals about CAM, the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established in March 2000. The President's Executive Order No. 13147 establishing the Commission states that its primary task is to provide, through the Secretary of Health and Human Services, legislative and administrative recommendations for ensuring that public policy maximizes the potential benefits of CAM therapies to consumers (see Appendix A).

Overview of the Commission's Mission and Activities

Specifically, the Commission's mission is to address:

- the education and training of health care practitioners in CAM;
- coordinated research to increase knowledge about CAM products;
- the provision of reliable and useful information on CAM to health care professions, and
- the provision of guidance on the appropriate access to and delivery of CAM.

To accomplish its mission, the 20-member Commission solicited expert testimony at its 10 meetings, which were held in various locations in and around Washington, D.C. between July 2000 and February 2002. At the WHCCAMP meetings, clinicians, researchers, medical educators, regulatory officials, policymakers, and others were asked to provide recommendations regarding Federal policies toward CAM and documentation to support those recommendations. The Commission meetings were initially focused around four primary areas, with several questions posed in each area:

1) Coordinated research and development to increase knowledge of complementary and alternative medicine practices and interventions,

2) Guidance on access to, delivery of, and reimbursement for complementary and alternative medicine practices and interventions,

3) Training, education, certification, licensure, and accountability of health care practitioners in complementary and alternative medicine, and

4) Delivery of reliable and useful information on complementary and alternative medicine to health care professionals and the public.

During its deliberations, the Commission came to the conclusion that, in addition to the areas covered by the Executive Order, two other issues needed to be discussed and addressed in order to accomplish the four primary goals. The first is the need to evaluate the potential for CAM systems, therapies, and products to prevent chronic illness and maintain and promote health, or wellness. The second is the need for an office or body to coordinate Federal efforts regarding CAM.

The Commission also solicited public testimony on each of these topics during its meetings as well as during a series of 4 Town Hall meetings held at various sites around the country (see Appendix A for details on all meetings and the individuals and organizations who presented testimony.) Overall, the Commission heard from approximately 1700 consumers, professional groups, societies, and health care organizations interested in Federal policies regarding CAM. Commissioners also visited several medical institutions and CAM clinics throughout the country to see first-hand how CAM and conventional health care providers are working together in integrated and collaborative care settings.

In developing recommendations, Commissioners divided into 8 work groups formed around specific topics (e.g., education and training, research, information dissemination, etc.). The work groups' recommendations were presented to the whole Commission, discussed, and used as the basis for developing final recommendations.

Guiding Principles of the Commission and Linkages with Other Health Care Reform Efforts

Based on its mission and responsibilities, the Commission developed 10 principles to guide the process of making recommendations and to shape the recommendations themselves:

1. A wholeness orientation in health care delivery. Health involves all aspects of life—mind, body, spirit, environment—and high-quality health care must support care of the whole person.
2. Evidence of safety and efficacy. The Commission is committed to promoting the use of science and appropriate scientific methods to help identify safe and

effective CAM services and products and to generate the evidence that will protect and promote the public health.

3. The healing capacity of the person. The person has a remarkable capacity for recovery and self-healing, and a major focus of health care is to support and promote this capacity.
4. Respect for individuality. Every person is unique and has the right to health care that is appropriately responsive to him or her, respecting preferences and preserving dignity.
5. The right to choose treatment. Every person has the right to choose freely among safe and effective care or approaches, as well as among qualified practitioners who are accountable for their claims and actions and responsive to the person's needs.
6. An emphasis on health promotion and self-care. Good health care emphasizes self-care and early intervention for maintaining and promoting health.
7. Partnerships as essential for integrated health care. Good health care requires teamwork among patients, health care practitioners (conventional and CAM), and researchers committed to creating optimal healing environments and to respecting the diversity of all health care traditions.
8. Education as a fundamental health care service. Education about prevention, healthful lifestyles, and the power of self-healing should be made an integral part of the curricula of all health care professionals and should be made available to the public at all ages.
9. Dissemination of comprehensive and timely information. The quality of health care can be enhanced by promoting efforts that thoroughly and thoughtfully examine the evidence on which CAM systems, practices, and products are based and make this evidence widely, rapidly, and easily available.
10. Integral public involvement. The input of informed consumers and other members of the public must be incorporated in setting priorities for health care, health care research, and in reaching policy decisions, including those related to CAM, within the public and private sectors.

These Guiding Principles are remarkably consistent with the 10 rules for health care reform listed the National Academy of Sciences' Institute of Medicine (IOM) report on ways to improve health care in the 21st century (see Appendix B). That report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, found that the nation's health care industry has "foundered" in its ability to provide safe, high-quality care consistently to all Americans, but particularly to those with chronic conditions.[3] The IOM report recommends that clinicians, health care organizations, and purchasers need to do a much better job of focusing on and improving care for common, chronic conditions such as heart disease, cancer, diabetes, and asthma, which are now the leading causes of disability and death in the United States and consume a substantial portion of health care resources. It also recommends some specific health care reforms, including better mechanisms for communication between patients and their health care providers, increased cooperation among clinicians, a significant expansion of the evidence base for care, improved safety, and improvements in the dissemination of health care information

to patients. The Commission's 10 Guiding Principles, therefore, are aligned with, and in some ways enlarge, the IOM's recommendations.

The Commission's guiding principles also have significant overlap with the U.S. Department of Health and Human Services' most recent 10-year health objectives for the Nation. These objectives are embodied in the report *Healthy People 2010: Understanding and Improving Health.*[4] The two overarching goals of *Healthy People 2010* are to: 1) increase quality and years of healthy life, and 2) eliminate disparities in access to health care. *Healthy People 2010* enumerates 28 focus areas to which these two overarching goals are to be applied. Among these 28 focus areas are several that are complemented by the Commission's Guiding Principles, including:

- Access to quality health services
- Educational and community based programs
- Health communication
- Medical product safety
- Physical activity and fitness
- Public health infrastructure

Healthy People 2010's focus areas are especially directed toward improving access to and delivery of high-quality health care services for people with chronic, debilitating conditions, such as arthritis, cancer, back pain, and HIV infection (see Appendix B). As we shall see in Chapter 2, individuals with these conditions are frequent users of CAM practitioners and practices. Thus, the Commission's focus on improving the quality of care for those with chronic conditions by increasing access to safe and effective CAM systems, approaches, and products, potentially could have a significant impact on *Healthy People 2010's* goals for these costly, debilitating conditions.

Crossing the Quality Chasm and *Healthy People 2010* emphasize better allocations and uses of existing conventional health care technologies and resources to address heath care reform. This report addresses ways in which resources and technologies that have not so are been part of the mainstream and that have not been applied to these problems on a large-scale basis may have a beneficial impact on health care reform and indeed on the prevention of illness and promotion of health.

Although many CAM practices have not yet been proven to be safe and effective, it is likely that some of them eventually will be, whereas others will not. The recommendations and actions in this report lay out a road map to help guide research and policy decisions over the next several years as more science and other information become available. In this context, many of the recommendations and actions may be useful immediately. Others may be more useful once a greater body of scientific evidence becomes available.

Overview of Remainder of Report

In addition to describing the use of CAM by people with chronic conditions, Chapter 2 also presents an overview of the recent history of CAM in this country, its current status, and its prospects for becoming a significant part of the nation's health care system.

Chapter 3 deals with the need for research coordination at the Federal level and with new directions and opportunities for that research

Chapter 4 covers issues surrounding the education and training of conventional and CAM health practitioners and ways to enhance communication and collaboration among them.

Chapter 5 addresses the need for better approaches to developing and disseminating timely, accurate, and authoritative information on CAM, the Federal Government's role in this process, and strategies for promoting public-private ventures.

Chapter 6 discusses access to and delivery of CAM systems, practices, and products, and ways to facilitate this process, including licensing and regulation.

Chapter 7 discusses the coverage of and reimbursement for CAM services and products by third-party payers, including the need for uniform coding strategies to make it easier for payers to reimburse for CAM services.

Chapter 8 contains information and recommendations on issues related to the potential role of CAM in wellness and health promotion programs and strategies for advancing this process.

Chapter 9 details the Commission's discussions and recommendations regarding the coordination of Federal CAM efforts.

Finally, Chapter 10 contains lists all of the recommendations and action items contained in this report.

References:

1. Druss BG and Rosenheck RA. Association between use of unconventional therapies and conventional medical services. *Journal of the American Medical Association* 1999; 282: 651-656.

2. Eisenberg DM, Davis RB, Ettner SL, Appel S, et ak. Trends in alternative medicine use in the United States. *Journal of the American Medical Association.* 1998;280:1569-75.

3. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, D.C.: National Academy of Sciences Press, 2001

4. U.S. Department of Health and Human Services. *Healthy People 2010: Understanding and Improving Health*. Washington, D.C.: U.S. Government Printing Office, 2000.

Executive Summary

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order No. 13147 in March 2000. The order states that the Commission is to provide the President, through the Secretary of Health and Human Services, with a report containing legislative and administrative recommendations that will ensure public policy maximizes the potential benefits of complementary and alternative medicine (CAM) to all citizens. The report of the Commission is to address:

- The coordination of research to increase knowledge about CAM products,
- The education and training of health care practitioners in CAM,
- The provision of reliable and useful information about CAM practices and products to health care professionals, and
- Guidance regarding appropriate access to and delivery of CAM.

The Commission's 20 Presidentially–appointed members represented an array of health care interests, professional backgrounds, and knowledge. Health care expertise was provided by both conventional and CAM practitioners.

To accomplish its mission, the Commission held four Town Hall meetings (San Francisco, Seattle, New York City, and Minneapolis) to listen to testimony from hundreds of individuals, professional organizations, societies, and health care organizations interested in Federal policies regarding CAM. In addition to the town hall meetings, the Commission invited expert testimony during its 10 regular meetings held in the Washington, D.C. area The Commission asked clinicians, researchers, medical educators, representatives of health insurers and managed care organizations, benefits experts, regulatory officials, and policymakers to provide informational recommendations and documentation to support them. The Commission also solicited testimony from the public at each of its regular meetings. Finally, the Commission conducted a number of site visits to see first-hand how various medical institutions are integrating CAM into clinical practice and collaboration between CAM and mainstream health care providers.

To develop recommendations, the Commissioners divided into work groups, each addressing a particular topic. The work groups' recommendations were then presented to the whole Commission, discussed, and used as a basis for developing final recommendations.

Based on its mission and responsibilities, the Commission endorsed the following 10 guiding principles to shape the process of making recommendations and to focus the recommendations themselves:

1. A wholeness orientation in health care delivery. Health involves all aspects of life—mind, body, spirit, and environment—and high-quality health care must support care of the whole person.
2. Evidence of safety and efficacy. The Commission is committed to promoting the use of science and appropriate scientific methods to help identify safe and effective CAM services and products and to generate evidence that will

protect and promote the public health.

3. The healing capacity of the person. People have a remarkable capacity for recovery and self-healing, and a major focus of health care is to support and promote this capacity.
4. Respect for individuality. Each person is unique and has the right to health care that is appropriately responsive to him or her, respecting preferences and preserving dignity.
5. The right to choose treatment. Each person has the right to choose freely among safe and effective care or approaches, as well as among qualified practitioners who are accountable for their claims and actions and responsive to the person's needs.
6. An emphasis on health promotion and self-care. Good health care emphasizes self-care and early intervention for maintaining and promoting health.
7. Partnerships as essential to integrated health care. Good health care requires teamwork among patients, health care practitioners (conventional and CAM), and researchers committed to creating optimal healing environments and to respecting the diversity of all health care traditions.
8. Education as a fundamental health care service. Education about prevention, healthy lifestyles, and the power of self-healing should be made an integral part of the curricula of all health care professionals and should be made available to the public of all ages.
9. Dissemination of comprehensive and timely information. The quality of health care can be enhanced by promoting efforts that thoroughly and thoughtfully examine the evidence on which CAM systems, practices, and products are based and make this evidence widely, rapidly, and easily available.
10. Integral public involvement. The input of informed consumers and other members of the public must be incorporated in setting priorities for health care and health care research and in reaching policy decisions, including those related to CAM, within the public and private sectors.

CAM is a heterogeneous group of medical, health care, and healing systems other than those intrinsic to mainstream health care in the United States. While "complementary and alternative medicine" is the term used in this report, the Commission recognizes that the term does not fully capture all of the diversity with which these systems, practices, and products are being used by consumers, CAM practitioners, and mainstream health care institutions.

The Commission recognizes that most CAM modalities have not yet been scientifically studied and found to be safe and effective. The fact that many Americans are using CAM modalities should not be confused with the fact that most of these modalities remain unproven by high-quality clinical studies. The Commission believes that conventional and CAM systems of health and healing should be held to the same rigorous standards of good science.

Therefore, substantially more funding for research is needed to determine the possible benefits and limitations of a variety of CAM modalities, especially those that are already

in widespread use. Well-designed scientific research and demonstration projects can help to determine which CAM modalities and approaches are clinically effective and cost-effective. With information from these studies, the public can make informed, intelligent decisions about their own health and well-being and the appropriate use of CAM interventions. Conventional and CAM practitioners also will benefit from the dissemination of this information.

Although most CAM modalities have not yet been proven safe and effective, it is likely that some of them eventually will be, whereas others will not. The recommendations and actions in this report constitute a road map to help guide research and policy decisions over the next several years as more scientific and other information becomes available. In this context, many of the recommendations and actions may be useful immediately. Others may be more useful once a greater body of scientific evidence has been developed and made available.

The Commission also notes the lack of an appropriate definition of complementary and alternative medicine and the need to differentiate between interventions that have been, or have the potential to be, found safe and effective and those that lack any scientific evidence of safety or effectiveness. Including the entire mix of CAM interventions under one umbrella fails to identify the merits and shortcomings of specific interventions. It is essential to begin separating the safe from the unsafe and the effective from the ineffective. Likewise, the heterogeneous array of education, training, and qualifications of CAM practitioners has made it difficult for the Commission to clearly and succinctly target its recommendations. This limitation must be addressed during the process of implementing the recommendations and actions.

Coordination of Research

The public's increased use of CAM has added urgency to the need to examine the safety and effectiveness of CAM practices and products and to discover the basic mechanisms underlying them. Basic, clinical, and health services research in CAM are essential for including CAM in the mainstream health care system.

In addition, the growing influence of consumers on the health care system has created a need for more population-based research on CAM use and for public participation in shaping the direction of CAM research. Federal requirements and opportunities for such participation currently exist. Public members of Federal advisory committees, as well as the agencies they advise, would gain from orientation and training programs on how to provide input most effectively.

Support for Research

The NCCAM at the NIH is an example of how quality research in CAM can be executed by a Federal agency. Similar efforts should now be extended to other Federal agencies. These agencies with research and health care responsibilities need to assess the scope of scientific, clinical practice, health services, and public needs regarding CAM that are related to their missions and develop funding strategies to address them. Federal support

is particularly needed for research on CAM products that are unpatentable and those that are frequently used by the public but unlikely to attract private research dollars. Congress and the Administration should consider simultaneous legislative and administrative incentives to stimulate private sector investment in such products. Also, CAM approaches that appear to be effective but may not attract private investment, should be considered for Federal support.

Federal, private, and nonprofit sector support is essential to developing a body of evidence-based knowledge about CAM. Among the areas in need of study are the complex compounds and mixtures found in CAM products, multiple-treatment interventions, the effect of patient-practitioner interactions on outcomes, the individualization of treatments, modalities designed to improve self-care and promote wellness behaviors, and core questions posed by CAM that might expand our understanding of health and disease.

The Commission commends the National Center for Complementary and Alternative Medicine (NCCAM) for its leadership and contributions to CAM research, methodology, research training, and infrastructure development and supports increases in these crucial activities, including database development and information dissemination. In addition, NCCAM should collaborate with 1) the Institute of Medicine, to develop guidelines for establishing research priorities in CAM and to address the ambiguity regarding definitions of CAM, thus making it easier to decide how to allocate resources; 2) the National Science Foundation, to examine frontier areas of science associated with CAM that lie outside the current research paradigm and to develop methodological approaches to study them; and 3) the World Health Organization, to study traditional systems of medical practice from a variety of cultures.

The Commission also recognizes the work of the Office of Dietary Supplements, the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine, the National Library of Medicine, and the other components of the National Institutes of Health (NIH) that are supporting research and related activities in CAM and recommends that they continue their efforts.

Scope of Research

A dialogue between CAM and conventional medicine appears to be emerging and efforts should be made to strengthen it. CAM and conventional medical practitioners and researchers; accredited research institutions; Federal and state research, health care, and regulatory agencies; private and nonprofit organizations; and the general public need to be included in the dialogue. Communication and cooperation are essential to improving the quality of CAM research and to the success of research applications.

The same high standards of quality, rigor, and ethics must be met in both CAM and conventional research, research training, publication of results in scientific, medical, and public health journals, presentations at research conferences, and review of products and devices. Properly qualified CAM and conventional medical professionals should be

represented on research, journal, regulatory, and health insurance review and advisory committees.

Investigators engaged in research on CAM must ensure that people participating in clinical studies receive the protections to which they are entitled and which are required for all human subjects in clinical research. Moreover, licensed, certified, or otherwise authorized practitioners who are engaged in research on CAM should not be sanctioned solely because they are engaged in such research, as long as 1) their studies are well designed and approved by an appropriately constituted institutional review board (IRB), 2) they are following the requirements for the protection of human subjects, and 3) they are meeting their professional and ethical responsibilities. All CAM and conventional practitioners, whether they are engaged in research or not, must meet whatever state practice requirements or standards govern their authorization to practice. IRBs that review CAM research studies need the expertise of qualified CAM professionals, and accredited CAM institutions and professional organizations should establish IRBs whenever possible.

Publication of research results in recognized peer-reviewed research journals is needed to provide reliable information about CAM to researchers, clinical practitioners, health services professionals, third party payors and the public. In addition, the decisions of third-party payers regarding access to and reimbursement for CAM therapies should be based on published evidence. Public and private resources can be used to conduct and update systematic reviews of the research literature on CAM. The Agency for Health Care Research and Quality (AHRQ) should expand its systematic reviews of CAM systems and treatments for use by private and public entities, and NCCAM and AHRQ should issue and regularly update a comprehensive, understandable summary of current clinical evidence in CAM for health care practitioners and the public.

Research Training and Infrastructure

Sustained, adequate funding is essential to building and maintaining a strong infrastructure for training skilled CAM researchers and conducting rigorous research. Federal agencies that have training programs as part of their health care missions should support training that addresses CAM-related questions relevant to their missions. Academic health centers at conventional institutions are gradually developing venues for exchanging experiences with CAM professionals regarding the training of conventional researchers in CAM practices, the introduction of CAM practitioners to the conventional research culture, and inclusion of CAM in research, research training, clinical, and medical education activities. Accredited CAM institutions are gradually expanding their capacity to conduct research and research training and to establish cooperative arrangements with conventional medical health centers. Public and private resources should be increased to strengthen the infrastructure for CAM research and research training at conventional medical and CAM institutions.

Education and Training of Health Care Practitioners

Because the public uses both CAM and conventional health care, the education and training of conventional health professionals should include CAM, and the education and training of CAM practitioners should include conventional health care. The result will be conventional providers who can discuss CAM with their patients and clients, provide guidance on CAM use, collaborate with CAM practitioners, and make referrals to them, as well as CAM practitioners who can communicate and collaborate with conventional providers and make referrals to them.

The education and training of all practitioners should be designed to ensure public safety, improve health, increase the availability of qualified and knowledgeable CAM and conventional practitioners, and enhance collaboration among them. Education and training programs can do this by developing curricula and programs that facilitate communication and foster collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations.
Conventional health professional schools, postgraduate training programs, and continuing education programs should develop core curricula regarding CAM to prepare practitioners to discuss CAM with their patients and clients and help them make informed choices about the use of CAM. The challenges to developing these core curricula include:

- Professional, organizational, and institutional resistance to change,
- Lack of funding,
- Inadequate incentives to adopt the curricula,
- Logistical design, development, and implementation difficulties,
- Lack of consensus on curricula,
- Lack of adequately trained faculty and faculty development, and
- Limited ability to add to already very full curricula.

Likewise, CAM education and training programs need to develop core curricula that reflect the fundamental elements of biomedical science and conventional health care as they relate to and are consistent with the CAM practitioners' scope of practice. The challenges to developing such core curricula for CAM education are similar to those stated above.

Support for CAM Programs, Faculty, and Students

Access to increased funding and other resources for CAM faculty, curricula, and program development at both CAM and conventional institutions* could result in better CAM education and training, which, in turn, could translate into more skilled practitioners, improved CAM services, and greater patient satisfaction and safety. Faculty development is essential for improved CAM education and training at CAM and conventional institutions. Currently, funding is limited and appears to be directed toward only a small number of curricula and program development projects at largely conventional institutions. Increased Federal, state, and private support should be made

* Conventional institutions include not only allopathic medical schools, but also osteopathic medical schools and dental, nursing, pharmacy, and all other health professional and allied health schools.

available to expand and evaluate CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

CAM students, institutions, and professional organizations have expressed considerable interest in participating in loan and scholarship programs. Currently, the only CAM students eligible for participation in the Scholarship for Disadvantaged Students program are chiropractic students. No CAM students are eligible for the National Health Service Corps Scholarship program at this time.

In general, expansion of Federal loan programs to CAM students appears easier to accomplish than participation in the scholarship program. The Department of Health and Human Services (DHHS) should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners can enhance or expand health care provided by primary care teams. The feasibility study could be followed with demonstration projects to determine what types of CAM practitioners, education and training requirements, practice sites, and minimal clinical competencies result in improved health outcomes

Additional Education and Training in CAM

To improve the competency of practitioners and the quality of services, CAM education and training should continue beyond the entry, professional school, or qualifying degree level. However, before establishing new CAM postgraduate education and training programs or expanding current ones, appropriate CAM candidates must be identified and the feasibility, type, duration, and impact of the programs determined.

Since community health centers represent a unique opportunity for combining education in ethnically, racially, and culturally diverse learning environments with service to medically underserved populations who otherwise might not have access to CAM, current and proposed CAM postgraduate education and training programs affiliated with such centers should be given special consideration.

Continuing education can provide a powerful means of affecting conventional and CAM practitioners' behavior, thereby enhancing public health and safety. Currently, the number, type, and availability of programs with content appropriate for all practitioners who provide CAM services and products are not sufficient. Therefore, continuing education programs need to be improved and made available to all conventional health professionals as well as to all practitioners who provide CAM services and products.

Development and Dissemination of Information about CAM

One of society's greatest achievements—and one of its greatest challenges—has been the dramatic improvement in the development and dissemination of information. Not only does information travel faster, significantly more of it has become available. This is especially true of health information, including information about CAM.

To ensure public safety in the continually evolving area of CAM, accurate information

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

The ready availability of accurate information is especially important to people who are confronting a life-threatening illness. For someone newly diagnosed with a serious or life-threatening illness, seeking information about their disease and treatment options is often their first course of action. Many people quickly become overwhelmed by the vast array of often conflicting information that is available, and yet for some diseases and conditions, there is a scarcity of reliable information.

Promoting Accurate, Easily Accessible Information

To be effective, information must be tailored to the population it seeks to reach. People of different cultural, ethnic, and socioeconomic backgrounds frequently have different views of health and healing, different patterns of use of health care services and products, and different ways of acquiring information. People's views and behavior also vary with their age, literacy, and specific health conditions. Informational materials need to reflect the characteristics and behavior of the target population.

The Federal government should make accurate and easily accessible information on CAM practices and products available to the public. It can do this by establishing a task force to facilitate the development and dissemination of CAM information within the Federal government and to eliminate existing gaps in information about CAM. In addition, more librarians can be trained to help consumers find information on CAM.

The Internet has given people access to vast amounts of health care information that would not have been available to them previously, but this technology raises concerns about quality. People may be making life-and-death decisions based on information that is misleading, incomplete, or inaccurate. This is particularly true in the case of CAM, for which a broad base of evidence is not yet available. Establishing a public-private partnership to develop voluntary standards for CAM information on the Internet, and conducting a public education campaign to help people evaluate information, should improve the quality and accuracy of CAM information from this source. Actions should also be taken to protect consumers' privacy.

Training, licensing requirements, certification, and scope of practice; regulations; and even definitions of CAM practitioners can vary considerably. Therefore, practitioners' qualifications should be readily available to consumers to help them make informed choices about selecting and using practitioners. Information on State regulations, requirements, and disciplinary actions should also be readily available to help ensure consumers' safety.

Consumers frequently learn about CAM products and services through advertising and

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

Ensuring the Safety of CAM Products

One of the most rapidly growing areas in CAM has been the use of dietary supplements. Sales of these products totaled $17 billion in 2000, and more than 158 million consumers used them. Dietary supplements are not subject to the same rigorous testing and oversight required of prescription drugs, which are targeted toward disease conditions. While this has greatly increased the public's access to supplements, it has limited the information required on the label regarding potential risks, benefits, and appropriate use.

The public expects that products sold in the United States are safe. Since many dietary supplements are purchased without the knowledge or advice of an appropriately trained and credentialed provider, information on ingredients, benefits, appropriate use, and potential risks should be made easily available to consumers at the time of purchase, especially information affecting vulnerable consumers such as children, the elderly, pregnant or nursing women, and people with certain health conditions or compromised immune systems.

CAM products that are available to U.S. consumers must be safe and meet appropriate standards of quality and consistency. Efforts to ensure the development of analytical methods and reference materials for dietary supplements should be increased. Good Manufacturing Practices for Dietary Supplements should be published expeditiously, followed by timely review of comments and completion of a final rule. The Food and Drug Administration (FDA) will need adequate resources to complete this task. Federal agencies responsible for enforcing current laws monitoring the quality of imported raw materials and finished products intended for use as dietary supplements will also require adequate funding.

Manufacturers should have on file and make available to the FDA upon request scientific information to substantiate their determinations of safety, and current statutory provisions should be reexamined periodically to determine whether safety requirements for dietary supplements are adequate. An objective process for evaluating the safety of dietary supplement products should be developed by an independent expert panel.

Reporting of adverse events associated with dietary supplements is voluntary: Manufacturers and distributors are not required to notify the FDA of adverse reactions that have been reported to them. Congress should require dietary supplement manufacturers to register their products and suppliers with the FDA. Until this requirement is in place, the agency should encourage voluntary registration so that

manufacturers, suppliers, and consumers can be notified promptly if a serious adverse event is identified. Dietary supplement manufacturers and suppliers should be required to maintain records and report serious adverse events to the FDA.

Additional resources and support are needed to simplify the adverse event reporting system for dietary supplements. The system should be made easier to use, its database streamlined to permit timely review and follow-up on reports received, and its outreach to consumers and health professionals (including poison control centers, emergency room physicians, CAM practitioners, and midlevel marketers) improved. Simplifying the adverse event reporting system will improve both manufacturers' and consumers' awareness of and participation in voluntary reporting.

To ensure the safety of the public and to give consumers confidence in the products they are using, Congress should periodically evaluate the effectiveness, limitations, and enforcement of the Dietary Supplement Health and Education Act of 1994 and take appropriate action when needed.

Access and Delivery

The Commission heard numerous concerns about access to CAM practitioners and products, including access to qualified CAM practitioners, state regulation of CAM practitioners, integration of CAM and conventional health care, collaboration between CAM and conventional practitioners, and the cost of CAM services. Many people expressed a desire for increased access to safe and effective CAM, along with conventional services. The Commission recognizes that Americans want to be able to choose from both conventional and CAM practices and that they want assurances that practitioners are qualified.

Improving Access to CAM

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

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

A few community health centers have begun to use the services of CAM practitioners, such as chiropractors, naturopathic physicians, and acupuncturists. These centers might

provide models for other community health centers and public health service programs, but first their impact on access to care and the cost-benefit picture needs to be determined. Hospice care for the terminally ill is another important model of care that should be evaluated. Some hospice programs are beginning to include CAM practitioners on the treatment team. The Federal government should support demonstration projects that integrate safe and effective CAM services into the health care programs of hospices and community health centers.

Special populations, such as racial and ethnic minorities, and vulnerable populations, such as the chronically and terminally ill, have unique challenges and needs regarding access to CAM. Yet efforts to address their access to CAM must take into consideration their need for access to conventional health care, and scare resources must be allocated carefully. The Federal government should facilitate and support the evaluation of CAM practices to help meet the health care needs of these populations and support practices found to be safe and effective. Ways of supporting the practice of indigenous healing in the United States and improving communication among indigenous healers, conventional health care professionals, and CAM practitioners should also be identified.

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

To improve consumers' access to safe and effective CAM practices and qualified practitioners, and to ensure accountability, the Federal government should evaluate current barriers and develop strategies for removing them. It should also help states evaluate the impact of state legislation on access to CAM practices and on public safety. Health care workforce data and other studies can help identify current and future health care needs and the relevance of safe and effective CAM services to those needs.

Ensuring CAM Practitioners' Accountability to the Public

States should consider whether a regulatory infrastructure for CAM practitioners is necessary to promote quality of care and patient safety and to ensure practitioners' accountability to the public. The Federal government should offer assistance to states and professional organizations in developing and evaluating guidelines for practitioner accountability and competence, including regulation of practice and periodic review and assessment of the effects of regulations on consumer protection. When appropriate, states should implement provisions for licensure, registration, and exemption that are consistent with a practitioner's education, training, and scope of practice.

Nationally recognized accrediting bodies should evaluate how health care organizations are using CAM practices and develop strategies for the safe and appropriate use of qualified CAM practitioners. In partnership with other public and private organizations,

they should evaluate the present use of CAM practitioners in health care delivery settings and develop strategies for their appropriate use in ways that will benefit the public. Current standards and guidelines should be reviewed to ensure safe use of CAM practices and products in health care delivery organizations.

Coverage and Reimbursement

The coverage and reimbursement policies of public and private organizations that pay for, provide, or insure conventional health care services have played a crucial role in shaping the health care system—and they will play an increasingly important role in determining the future of CAM and its place in the nation's health care system Coverage of CAM services and products varies among purchasers of health plans, but employer-sponsored plans appear more likely than others to offer them. These plans generally offer a chiropractic benefit, and a growing number cover acupuncture and massage therapy. When offered, CAM coverage often places a ceiling on the number of visits, restricts the clinical applications, and specifies the qualifications of the practitioner. Typically, CAM is offered as a supplemental benefit rather than as a core or basic benefit. Benefit designs also include discount programs, in which covered individuals pay reduced fees for services provided by a network of CAM practitioners, and annual benefit accounts against which services may be purchased.

Barriers to Coverage

Overcoming barriers to coverage and reimbursement will require first amassing scientific evidence to assess the benefits and cost-effectiveness of CAM and then giving equitable, impartial consideration to those practices and products proven to be safe and effective.

Gathering a body of evidence will require DHHS, other Federal agencies, states, and private organizations to develop a health services research agenda and to increase funding for studies of the outcomes of CAM interventions in treating acute, chronic, and life-threatening conditions. Research, demonstrations, and evaluations should focus not only on safety but also on clinical effectiveness, costs, and the ratio of costs to benefits. In addition, health services research can be used to support the development and study of models for providing safe and effective CAM within the nation's health care system. Prototypes should include integrative and collaborative models for CAM and conventional health care, comparisons of conventional and CAM treatments for the same condition, and evaluations of various combinations of services and products. Information on health services research should be made available through the clearinghouse of NCCAM.

To conduct health services research, investigators need data from claim and encounter forms, specifically data coded using nationally accepted, standardized systems. National coding systems such as Common Procedure Terminology recognize some CAM interventions, but they are currently limited in scope and specificity. More recently, a coding system for CAM procedures, services, and products—ABCcodes—has been developed and is being used in a number of settings. The National Committee for Vital and Health Statistics and DHHS should authorize a national coding system that supports

standardized data on CAM for use in clinical and health services research. In addition, the coding system should support practitioners and insurers who cover CAM services in complying with the electronic claims requirements of the Health Insurance Portability and Accountability Act.

Any medical or health care intervention that has undergone scientific investigation and has been shown to improve health or functioning, or to be effective in treating the chronically or terminally ill, should be considered for inclusion in health plan coverage. To accomplish this, health insurance and managed care organizations should modify their benefit design and coverage processes in order to offer purchasers health benefit plans that include safe and effective CAM interventions. Similarly, purchasers should enhance the processes they use to develop health benefits and give consideration to safe and effective CAM interventions. DHHS can support these efforts by convening work groups and conferences to assess the state-of-the-science of CAM services and products and to develop consensus and other types of guidance for Medicare, other public and private purchasers, health plans, and even consumer representatives.

Coverage of and reimbursement for most health care services are linked to a provider's ability to furnish services legally within the scope of his or her practice. This legal authority to practice is given by the state in which services are provided. Thus, even if insurers, managed care organizations, and other health plan sponsors are interested in covering safe, cost-effective CAM interventions, they cannot do so unless properly licensed, or otherwise legally authorized, practitioners are available in a state. State governments are encouraged to consider how regulation of CAM practitioners could affect coverage and third-party reimbursement of safe and effective CAM interventions.

Criteria for Using CAM

Once a CAM service is covered, health insurers, managed care organizations, and government agencies must be able to determine whether use of the service or product in a particular situation is generally accepted or investigational, and whether the service or product is medically necessary in that situation. Few criteria are available to guide practitioners in deciding the medical or clinical necessity of CAM interventions. DHHS, preferably through a centralized CAM office, should work with health care and professional associations, CAM experts, health insurance and managed care organizations, benefits experts, and others to guide changes in health plan coverage for safe and effective CAM services and products and to develop criteria for use of CAM interventions.

Purchasers, health insurers, and managed care organizations will need CAM expertise when developing changes in coverage and reimbursement policies that involve CAM. CAM practitioners and experts should be included on advisory bodies and work groups considering CAM benefits and other appropriate health benefit issues.

CAM in Wellness and Health Promotion

In recent years, people have come to recognize that a healthful lifestyle can promote

wellness and prevent illness and disease, and many people have used CAM approaches to attain this goal. Wellness is defined in many ways, but all agree that it is more than the absence of disease. Wellness can include a broad array of activities and interventions that focus on the physical, mental, spiritual, and emotional aspects of one's life. The concomitant rise in interest in CAM and in wellness and prevention presents many new and exciting opportunities for the health care system.

CAM's Role in Attaining the Nation's Health Goals

Since 1979, the U.S. Public Health Service has led a national initiative to define goals and objectives for the nation's health. As is clear from the resulting *Healthy People* series, a wide range of disciplines and social institutions is needed to improve health and wellness, prevent illness and disease, and manage disabilities and chronic conditions. The effectiveness of the health care delivery system in the future will depend upon its ability to make use of all approaches and modalities that provide a sound basis for promoting health.

There is evidence that certain CAM practices, such as acupuncture, biofeedback, yoga, massage therapy, and tai chi, as well as certain nutritional and stress reduction practices may be useful in contributing to the achievement of the nation's health goals and objectives. Federal agencies and public and private organizations should evaluate CAM practices and products that have been shown to be safe and effective to determine their potential for promoting wellness and helping to achieve the nation's health promotion and disease prevention goals. Demonstration programs should be funded for those determined to be beneficial

The Federal government, in partnership with public and private organizations, should support the development of a national campaign that teaches and encourages healthful behaviors for all Americans, including children. The campaign would focus on improving nutrition, promoting exercise, and teaching stress management. Safe and effective CAM practices and products should be included, where appropriate. The role of safe and effective CAM practices and products in the workplace should also be evaluated, and incentives should be developed to encourage the use of those found to be beneficial.

The application of CAM wellness and prevention practices to the management of chronic disease and disabilities is a largely unexplored area. CAM principles and practices may be useful not only in preventing some of these diseases and conditions, but also in enhancing recovery and preventing further illness. Increased research in this area will help to determine how CAM principles and practices can best be used to meet the goals of the health care system. DHHS and other Federal agencies should fund demonstration projects to evaluate the clinical and economic impact of comprehensive health promotion programs that include CAM. These studies should include underserved and special populations.

Wellness and Health Promotion in Programs for Special and Vulnerable Populations

Early interventions that promote the development of good health habits and attitudes

could help prevent many of the negative behaviors and lifestyle choices that begin in childhood or adolescence. Poor dietary habits, lack of exercise, smoking, suicide, substance abuse, homicide, and depression are epidemic among young people. The Commission believes that it is time for wellness and health promotion to be made a national priority. CAM practices and products that have been shown to be appropriate for children and young people should be included in this effort, which must involve all sectors of the community, particularly schools.

The Federal government funds many programs that serve vulnerable populations, such as children, the poor, and the elderly. The programs have a direct impact on the health and quality of life of the people they serve, and they may benefit from a wellness and prevention component that includes safe and effective CAM practices and products. The agencies that administer these programs should evaluate safe and effective CAM practices and products to determine their applicability to the programs and fund demonstration projects for those found to be beneficial.

Federally funded health care delivery programs, such as the Department of Veterans Affairs, The Department of Defense, the Indian Health Service, community and migrant health centers, maternal and child health programs, and school health programs, should also evaluate the applicability of CAM wellness and prevention activities to their services. Demonstration programs should be funded for CAM practices and products found to be beneficial to these populations. Other Federal, State, public, and private health care delivery systems and programs would also be well-advised to evaluate CAM practices and products to determine their applicability to programs and services that help promote wellness and health.

The Secretary of Health and Human Services should bring together public and private health care organizations to evaluate the contribution of safe and effective CAM practices and products to wellness and health and to determine how they may be used in health systems and programs, especially in the nation's hospitals and long-term care facilities and in programs serving the aged, persons with chronic illness, and those at the end of life.

CAM and conventional health professional training programs should offer students training and education in self-care and lifestyle decision-making, both to improve practitioners' health and to enable them to impart this knowledge to their patients or clients.

Coordinating Federal CAM Efforts

Integration of safe and effective CAM practices and products into the nation's health care system will require an ongoing, coordinated Federal presence. Establishment of a centralized office is the most effective means of accomplishing this goal. Responsibilities of the office should include:

- Coordinating Federal CAM activities,

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

The Commission recommends that the President, Secretary of Health and Human Services, or Congress create an office to coordinate Federal CAM activities and to facilitate the integration of safe and effective practices and products into the nation's health care system. The office should be established at the highest possible appropriate level in DHHS and be given sufficient staff and budget to meet its responsibilities. The office should charter an advisory council whose members would include representatives of the private and public sectors as well as CAM and conventional practitioners with the necessary expertise, diversity of backgrounds, and training to guide and advise the office about its activities.

Executive Summary

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order No. 13147 in March 2000. The order states that the Commission is to provide the President, through the Secretary of Health and Human Services, with a report containing legislative and administrative recommendations that will ensure public policy maximizes the potential benefits of complementary and alternative medicine (CAM) to all citizens. The report of the Commission is to address:

- The coordination of research to increase knowledge about CAM products,
- The education and training of health care practitioners in CAM,
- The provision of reliable and useful information about CAM practices and products to health care professionals, and
- Guidance regarding appropriate access to and delivery of CAM.

The Commission's 20 presidentially–appointed members represented an array of health care interests, professional backgrounds, and knowledge. Health care expertise was provided by both conventional and CAM practitioners.

To accomplish its mission, the Commission held four Town Hall meetings (San Francisco, Seattle, New York City, and Minneapolis)to listen to testimony from hundreds of individuals, professional organizations, societies, and health care organizations interested in Federal policies regarding CAM. In addition to the town hall meetings, the Commission invited expert testimony during its 10 regular meetings held in the Washington, D.C. area The Commission asked clinicians, researchers, medical educators, representatives of health insurers and managed care organizations, benefits experts, regulatory officials, and policymakers to provide informational recommendations and documentation to support them. The Commission also solicited testimony from the public at each of its regular meetings. Finally, the Commission conducted a number of site visits to see first-hand how various medical institutions are integrating CAM into clinical practice and collaboration between CAM and mainstream health care providers.

To develop recommendations, the Commissioners divided into work groups, each addressing a particular topic. The work groups' recommendations were then presented to the whole Commission, discussed, and used as a basis for developing final recommendations.

Based on its mission and responsibilities, the Commission endorsed the following 10 guiding principles to shape the process of making recommendations and to focus the recommendations themselves:

1. A wholeness orientation in health care delivery. Health involves all aspects of life—mind, body, spirit, and environment—and high-quality health care must support care of the whole person.
2. Evidence of safety and efficacy. The Commission is committed to promoting the use of science and appropriate scientific methods to help identify safe and effective CAM services and products and to generate evidence that will

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2. Evidence of safety and efficacy. The Commission is committed to promoting the use of science and appropriate scientific methods to help identify safe and effective CAM services and products and to generate evidence that will

protect and promote the public health.

3. The healing capacity of the person. People have a remarkable capacity for recovery and self-healing, and a major focus of health care is to support and promote this capacity.
4. Respect for individuality. Each person is unique and has the right to health care that is appropriately responsive to him or her, respecting preferences and preserving dignity.
5. The right to choose treatment. Each person has the right to choose freely among safe and effective care or approaches, as well as among qualified practitioners who are accountable for their claims and actions and responsive to the person's needs.
6. An emphasis on health promotion and self-care. Good health care emphasizes self-care and early intervention for maintaining and promoting health.
7. Partnerships as essential to integrated health care. Good health care requires teamwork among patients, health care practitioners (conventional and CAM), and researchers committed to creating optimal healing environments and to respecting the diversity of all health care traditions.
8. Education as a fundamental health care service. Education about prevention, healthy lifestyles, and the power of self-healing should be made an integral part of the curricula of all health care professionals and should be made available to the public of all ages.
9. Dissemination of comprehensive and timely information. The quality of health care can be enhanced by promoting efforts that thoroughly and thoughtfully examine the evidence on which CAM systems, practices, and products are based and make this evidence widely, rapidly, and easily available.
10. Integral public involvement. The input of informed consumers and other members of the public must be incorporated in setting priorities for health care and health care research and in reaching policy decisions, including those related to CAM, within the public and private sectors.

CAM is a heterogeneous group of medical, health care, and healing systems other than those intrinsic to mainstream health care in the United States. While "complementary and alternative medicine" is the term used in this report, the Commission recognizes that the term does not fully capture all of the diversity with which these systems, practices, and products are being used by consumers, CAM practitioners, and mainstream health care institutions.

The Commission recognizes that most CAM modalities have not yet been scientifically studied and found to be safe and effective. The fact that many Americans are using CAM modalities should not be confused with the fact that most of these modalities remain unproven by high-quality clinical studies. The Commission believes that conventional and CAM systems of health and healing should be held to the same rigorous standards of good science.

Therefore, substantially more funding for research is needed to determine the possible benefits and limitations of a variety of CAM modalities, especially those that are already

in widespread use. Well-designed scientific research and demonstration projects can help to determine which CAM modalities and approaches are clinically effective and cost-effective. With information from these studies, the public can make informed, intelligent decisions about their own health and well-being and the appropriate use of CAM interventions. Conventional and CAM practitioners also will benefit from the dissemination of this information.

Although most CAM modalities have not yet been proven safe and effective, it is likely that some of them eventually will be, whereas others will not. The recommendations and actions in this report constitute a road map to help guide research and policy decisions over the next several years as more scientific and other information becomes available. In this context, many of the recommendations and actions may be useful immediately. Others may be more useful once a greater body of scientific evidence has been developed and made available.

The Commission also notes the lack of an appropriate definition of complementary and alternative medicine and the need to differentiate between interventions that have been, or have the potential to be, found safe and effective and those that lack any scientific evidence of safety or effectiveness. Including the entire mix of CAM interventions under one umbrella fails to identify the merits and shortcomings of specific interventions. It is essential to begin separating the safe from the unsafe and the effective from the ineffective. Likewise, the heterogeneous array of education, training, and qualifications of CAM practitioners has made it difficult for the Commission to clearly and succinctly target its recommendations. This limitation must be addressed during the process of implementing the recommendations and actions.

Coordination of Research

The public's increased use of CAM has added urgency to the need to examine the safety and effectiveness of CAM practices and products and to discover the basic mechanisms underlying them. Basic, clinical, and health services research in CAM are essential for including CAM in the mainstream health care system.

In addition, the growing influence of consumers on the health care system has created a need for more population-based research on CAM use and for public participation in shaping the direction of CAM research. Federal requirements and opportunities for such participation currently exist. Public members of Federal advisory committees, as well as the agencies they advise, would gain from orientation and training programs on how to provide input most effectively.

Support for Research

The NCCAM at the NIH is an example of how quality research in CAM can be executed by a Federal agency. Similar efforts should now be extended to other Federal agencies. These agencies with research and health care responsibilities need to assess the scope of scientific, clinical practice, health services, and public needs regarding CAM that are related to their missions and develop funding strategies to address them. Federal support

is particularly needed for research on CAM products that are ~~are~~ unpatentable and those that are frequently used by the public but unlikely to attract private research dollars. Congress and the Administration should consider simultaneous legislative and administrative incentives to stimulate private sector investment in such products. Also,~~Also,~~ CAM approaches that appear to be effective but may not attract private investment, should ~~also~~ be considered for Federal support.

Federal, private, and nonprofit sector support is essential to developing a body of evidence-based knowledge about CAM. Among the areas in need of study are the complex compounds and mixtures found in CAM products, multiple-treatment interventions, the effect of patient-practitioner interactions on outcomes, the individualization of treatments, modalities designed to improve self-care and promote wellness behaviors, and core questions posed by CAM that might expand our understanding of health and disease.

The Commission commends the National Center for Complementary and Alternative Medicine (NCCAM) for its leadership and contributions to CAM research, methodology, research training, and infrastructure development and supports increases in these crucial activities, including database development and information dissemination. In addition, NCCAM should collaborate with 1) the Institute of Medicine, to develop guidelines for establishing research priorities in CAM and to address the ambiguity regarding definitions of CAM, thus making it easier to decide how to allocate resources; 2) the National Science Foundation, to examine frontier areas of science associated with CAM that lie outside the current research paradigm and to develop methodological approaches to study them; and 3) the World Health Organization, to study traditional systems of medical practice from a variety of cultures.

The Commission also recognizes the work of the Office of Dietary Supplements, the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine, the National Library of Medicine, and the other components of the National Institutes of Health (NIH) that are supporting research and related activities in CAM and recommends that they continue their efforts.

Scope of Research

A dialogue between CAM and conventional medicine appears to be emerging and efforts should be made to strengthen it. CAM and conventional medical practitioners and researchers; accredited research institutions; Federal and state research, health care, and regulatory agencies; private and nonprofit organizations; and the general public need to be included in the dialogue. Communication and cooperation are essential to improving the quality of CAM research and to the success of research applications.

The same high standards of quality, rigor, and ethics must be met in both CAM and conventional research, research training, publication of results in scientific, medical, and public health journals, presentations at research conferences, and review of products and devices. Properly qualified CAM and conventional medical professionals should be

represented on research, journal, regulatory, and health insurance review and advisory committees.

Investigators engaged in research on CAM must ensure that people participating in clinical studies receive the protections to which they are entitled and which are required for all human subjects in clinical research. Moreover, licensed, certified, or otherwise authorized practitioners who are engaged in research on CAM should not be sanctioned solely because they are engaged in such research, as long as 1) their studies are well designed and approved by an appropriately constituted institutional review board (IRB), 2) they are following the requirements for the protection of human subjects, and 3) they are meeting their professional and ethical responsibilities. All CAM and conventional practitioners, whether they are engaged in research or not, must meet whatever state practice requirements or standards govern their authorization to practice. IRBs that review CAM research studies need the expertise of qualified CAM professionals, and accredited CAM institutions and professional organizations should establish IRBs whenever possible.

Publication of research results in recognized peer-reviewed research journals is needed to provide reliable information about CAM to researchers, clinical practitioners, health services professionals, third party payors and the public. In addition, the decisions of third-party payers regarding access to and reimbursement for CAM therapies should be based on published evidence. Public and private resources can be used to conduct and update systematic reviews of the research literature on CAM. The Agency for Health Care Research and Quality (AHRQ) should expand its systematic reviews of CAM systems and treatments for use by private and public entities, and NCCAM and AHRQ should issue and regularly update a comprehensive, understandable summary of current clinical evidence in CAM for health care practitioners and the public.

Research Training and Infrastructure

Sustained, adequate funding is essential to building and maintaining a strong infrastructure for training skilled CAM researchers and conducting rigorous research. Federal agencies that have training programs as part of their health care missions should support training that addresses CAM-related questions relevant to their missions. Academic health centers at conventional institutions are gradually developing venues for exchanging experiences with CAM professionals regarding the training of conventional researchers in CAM practices, the introduction of CAM practitioners to the conventional research culture, and inclusion of CAM in research, research training, clinical, and medical education activities. Accredited CAM institutions are gradually expanding their capacity to conduct research and research training and to establish cooperative arrangements with conventional medical health centers. Public and private resources should be increased to strengthen the infrastructure for CAM research and research training at conventional medical and CAM institutions.

Education and Training of Health Care Practitioners

Because the public uses both CAM and conventional health care, the education and training of conventional health professionals should include CAM, and the education and training of CAM practitioners should include conventional health care. The result will be conventional providers who can discuss CAM with their patients and clients, provide guidance on CAM use, collaborate with CAM practitioners, and make referrals to them, as well as CAM practitioners who can communicate and collaborate with conventional providers and make referrals to them.

The education and training of all practitioners should be designed to ensure public safety, improve health, increase the availability of qualified and knowledgeable CAM and conventional practitioners, and enhance collaboration among them. Education and training programs can do this by developing curricula and programs that facilitate communication and foster collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations.
Conventional health professional schools, postgraduate training programs, and continuing education programs should develop core curricula regarding CAM to prepare practitioners to discuss CAM with their patients and clients and help them make informed choices about the use of CAM. The challenges to developing these core curricula include:

- Professional, organizational, and institutional resistance to change,
- Lack of funding,
- Inadequate incentives to adopt the curricula,
- Logistical design, development, and implementation difficulties,
- Lack of consensus on curricula,
- Lack of adequately trained faculty and faculty development, and
- Limited ability to add to already very full curricula.

Likewise, CAM education and training programs need to develop core curricula that reflect the fundamental elements of biomedical science and conventional health care as they relate to and are consistent with the CAM practitioners' scope of practice. The challenges to developing such core curricula for CAM education are similar to those stated above.

Support for CAM Programs, Faculty, and Students

Access to increased funding and other resources for CAM faculty, curricula, and program development at both CAM and conventional institutions* could result in better CAM education and training, which, in turn, could translate into more skilled practitioners, improved CAM services, and greater patient satisfaction and safety. Faculty development is essential for improved CAM education and training at CAM and conventional institutions. Currently, funding is limited and appears to be directed toward only a small number of curricula and program development projects at largely conventional institutions. Increased Federal, state, and private support should be made

* Conventional institutions include not only allopathic medical schools, but also osteopathic medical schools and dental, nursing, pharmacy, and all other health professional and allied health schools.

available to expand and evaluate CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

CAM students, institutions, and professional organizations have expressed considerable interest in participating in loan and scholarship programs. Currently, the only CAM students eligible for participation in the Scholarship for Disadvantaged Students program are chiropractic students. No CAM students are eligible for the National Health Service Corps Scholarship program at this time.

In general, expansion of Federal loan programs to CAM students appears easier to accomplish than participation in the scholarship program. The Department of Health and Human Services (DHHS) should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners can enhance or expand health care provided by primary care teams. The feasibility study could be followed with demonstration projects to determine what types of CAM practitioners, education and training requirements, practice sites, and minimal clinical competencies result in improved health outcomes

Additional Education and Training in CAM

To improve the competency of practitioners and the quality of services, CAM education and training should continue beyond the entry, professional school, or qualifying degree level. However, before establishing new CAM postgraduate education and training programs or expanding current ones, appropriate CAM candidates must be identified and the feasibility, type, duration, and impact of the programs determined.

Since community health centers represent a unique opportunity for combining education in ethnically, racially, and culturally diverse learning environments with service to medically underserved populations who otherwise might not have access to CAM, current and proposed CAM postgraduate education and training programs affiliated with such centers should be given special consideration.

Continuing education can provide a powerful means of affecting conventional and CAM practitioners' behavior, thereby enhancing public health and safety. Currently, the number, type, and availability of programs with content appropriate for all practitioners who provide CAM services and products are not sufficient. Therefore, continuing education programs need to be improved and made available to all conventional health professionals as well as to all practitioners who provide CAM services and products.

Development and Dissemination of Information about CAM

One of society's greatest achievements—and one of its greatest challenges—has been the dramatic improvement in the development and dissemination of information. Not only does information travel faster, significantly more of it has become available. This is especially true of health information, including information about CAM.

To ensure public safety in the continually evolving area of CAM, accurate information

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

The ready availability of accurate information is especially important to people who are confronting a life-threatening illness. For someone newly diagnosed with a serious or life-threatening illness, seeking information about their disease and treatment options is often their first course of action. Many people quickly become overwhelmed by the vast array of often conflicting information that is available, and yet for some diseases and conditions, there is a scarcity of reliable information.

Promoting Accurate, Easily Accessible Information

To be effective, information must be tailored to the population it seeks to reach. People of different cultural, ethnic, and socioeconomic backgrounds frequently have different views of health and healing, different patterns of use of health care services and products, and different ways of acquiring information. People's views and behavior also vary with their age, literacy, and specific health conditions. Informational materials need to reflect the characteristics and behavior of the target population.

The Federal government should make accurate and easily accessible information on CAM practices and products available to the public. It can do this by establishing a task force to facilitate the development and dissemination of CAM information within the Federal government and to eliminate existing gaps in information about CAM. In addition, more librarians can be trained to help consumers find information on CAM.

The Internet has given people access to vast amounts of health care information that would not have been available to them previously, but this technology raises concerns about quality. People may be making life-and-death decisions based on information that is misleading, incomplete, or inaccurate. This is particularly true in the case of CAM, for which a broad base of evidence is not yet available. Establishing a public-private partnership to develop voluntary standards for CAM information on the Internet, and conducting a public education campaign to help people evaluate information, should improve the quality and accuracy of CAM information from this source. Actions should also be taken to protect consumers' privacy.

Training, licensing requirements, certification, and scope of practice; regulations; and even definitions of CAM practitioners can vary considerably. Therefore, practitioners' qualifications should be readily available to consumers to help them make informed choices about selecting and using practitioners. Information on State regulations, requirements, and disciplinary actions should also be readily available to help ensure consumers' safety.

Consumers frequently learn about CAM products and services through advertising and

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

Ensuring the Safety of CAM Products

One of the most rapidly growing areas in CAM has been the use of dietary supplements. Sales of these products totaled $17 billion in 2000, and more than 158 million consumers used them. Dietary supplements are not subject to the same rigorous testing and oversight required of prescription drugs, which are targeted toward disease conditions. While this has greatly increased the public's access to supplements, it has limited the information required on the label regarding potential risks, benefits, and appropriate use.

The public expects that products sold in the United States are safe. Since many dietary supplements are purchased without the knowledge or advice of an appropriately trained and credentialed provider, information on ingredients, benefits, appropriate use, and potential risks should be made easily available to consumers at the time of purchase, especially information affecting vulnerable consumers such as children, the elderly, pregnant or nursing women, and people with certain health conditions or compromised immune systems.

CAM products that are available to U.S. consumers must be safe and meet appropriate standards of quality and consistency. Efforts to ensure the development of analytical methods and reference materials for dietary supplements should be increased. Good Manufacturing Practices for Dietary Supplements should be published expeditiously, followed by timely review of comments and completion of a final rule. The Food and Drug Administration (FDA) will need adequate resources to complete this task. Federal agencies responsible for enforcing current laws monitoring the quality of imported raw materials and finished products intended for use as dietary supplements will also require adequate funding.

Manufacturers should have on file and make available to the FDA upon request scientific information to substantiate their determinations of safety, and current statutory provisions should be reexamined periodically to determine whether safety requirements for dietary supplements are adequate. An objective process for evaluating the safety of dietary supplement products should be developed by an independent expert panel.

Reporting of adverse events associated with dietary supplements is voluntary: Manufacturers and distributors are not required to notify the FDA of adverse reactions that have been reported to them. Congress should require dietary supplement manufacturers to register their products and suppliers with the FDA. Until this requirement is in place, the agency should encourage voluntary registration so that

manufacturers, suppliers, and consumers can be notified promptly if a serious adverse event is identified. Dietary supplement manufacturers and suppliers should be required to maintain records and report serious adverse events to the FDA.

Additional resources and support are needed to simplify the adverse event reporting system for dietary supplements. The system should be made easier to use, its database streamlined to permit timely review and follow-up on reports received, and its outreach to consumers and health professionals (including poison control centers, emergency room physicians, CAM practitioners, and midlevel marketers) improved. Simplifying the adverse event reporting system will improve both manufacturers' and consumers' awareness of and participation in voluntary reporting.

To ensure the safety of the public and to give consumers confidence in the products they are using, Congress should periodically evaluate the effectiveness, limitations, and enforcement of the Dietary Supplement Health and Education Act of 1994 and take appropriate action when needed.

Access and Delivery

The Commission heard numerous concerns about access to CAM practitioners and products, including access to qualified CAM practitioners, state regulation of CAM practitioners, integration of CAM and conventional health care, collaboration between CAM and conventional practitioners, and the cost of CAM services. Many people expressed a desire for increased access to safe and effective CAM, along with conventional services. The Commission recognizes that Americans want to be able to choose from both conventional and CAM practices and that they want assurances that practitioners are qualified.

Improving Access to CAM

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

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

A few community health centers have begun to use the services of CAM practitioners, such as chiropractors, naturopathic physicians, and acupuncturists. These centers might

provide models for other community health centers and public health service programs, but first their impact on access to care and the cost-benefit picture needs to be determined. Hospice care for the terminally ill is another important model of care that should be evaluated. Some hospice programs are beginning to include CAM practitioners on the treatment team. The Federal government should support demonstration projects that integrate safe and effective CAM services into the health care programs of hospices and community health centers.

Special populations, such as racial and ethnic minorities, and vulnerable populations, such as the chronically and terminally ill, have unique challenges and needs regarding access to CAM. Yet efforts to address their access to CAM must take into consideration their need for access to conventional health care, and scare resources must be allocated carefully. The Federal government should facilitate and support the evaluation of CAM practices to help meet the health care needs of these populations and support practices found to be safe and effective. Ways of supporting the practice of indigenous healing in the United States and improving communication among indigenous healers, conventional health care professionals, and CAM practitioners should also be identified.

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

To improve consumers' access to safe and effective CAM practices and qualified practitioners, and to ensure accountability, the Federal government should evaluate current barriers and develop strategies for removing them. It should also help states evaluate the impact of state legislation on access to CAM practices and on public safety. Health care workforce data and other studies can help identify current and future health care needs and the relevance of safe and effective CAM services to those needs.

Ensuring CAM Practitioners' Accountability to the Public

States should consider whether a regulatory infrastructure for CAM practitioners is necessary to promote quality of care and patient safety and to ensure practitioners' accountability to the public. The Federal government should offer assistance to states and professional organizations in developing and evaluating guidelines for practitioner accountability and competence, including regulation of practice and periodic review and assessment of the effects of regulations on consumer protection. When appropriate, states should implement provisions for licensure, registration, and exemption that are consistent with a practitioner's education, training, and scope of practice.

Nationally recognized accrediting bodies should evaluate how health care organizations are using CAM practices and develop strategies for the safe and appropriate use of qualified CAM practitioners. In partnership with other public and private organizations,

they should evaluate the present use of CAM practitioners in health care delivery settings and develop strategies for their appropriate use in ways that will benefit the public. Current standards and guidelines should be reviewed to ensure safe use of CAM practices and products in health care delivery organizations.

Coverage and Reimbursement

The coverage and reimbursement policies of public and private organizations that pay for, provide, or insure conventional health care services have played a crucial role in shaping the health care system—and they will play an increasingly important role in determining the future of CAM and its place in the nation's health care system Coverage of CAM services and products varies among purchasers of health plans, but employer-sponsored plans appear more likely than others to offer them. These plans generally offer a chiropractic benefit, and a growing number cover acupuncture and massage therapy. When offered, CAM coverage often places a ceiling on the number of visits, restricts the clinical applications, and specifies the qualifications of the practitioner. Typically, CAM is offered as a supplemental benefit rather than as a core or basic benefit. Benefit designs also include discount programs, in which covered individuals pay reduced fees for services provided by a network of CAM practitioners, and annual benefit accounts against which services may be purchased.

Barriers to Coverage

Overcoming barriers to coverage and reimbursement will require first amassing scientific evidence to assess the benefits and cost-effectiveness of CAM and then giving equitable, impartial consideration to those practices and products proven to be safe and effective.

Gathering a body of evidence will require DHHS, other Federal agencies, states, and private organizations to develop a health services research agenda and to increase funding for studies of the outcomes of CAM interventions in treating acute, chronic, and life-threatening conditions. Research, demonstrations, and evaluations should focus not only on safety but also on clinical effectiveness, costs, and the ratio of costs to benefits. In addition, health services research can be used to support the development and study of models for providing safe and effective CAM within the nation's health care system. Prototypes should include integrative and collaborative models for CAM and conventional health care, comparisons of conventional and CAM treatments for the same condition, and evaluations of various combinations of services and products. Information on health services research should be made available through the clearinghouse of NCCAM.

To conduct health services research, investigators need data from claim and encounter forms, specifically data coded using nationally accepted, standardized systems. National coding systems such as Common Procedure Terminology recognize some CAM interventions, but they are currently limited in scope and specificity. More recently, a coding system for CAM procedures, services, and products—ABCcodes—has been developed and is being used in a number of settings. The National Committee for Vital

and Health Statistics and DHHS should authorize a national coding system that supports standardized data on CAM for use in clinical and health services research. In addition, the coding system should support practitioners and insurers who cover CAM services in complying with the electronic claims requirements of the Health Insurance Portability and Accountability Act.

Any medical or health care intervention that has undergone scientific investigation and has been shown to improve health or functioning, or to be effective in treating the chronically or terminally ill, should be considered for inclusion in health plan coverage. To accomplish this, health insurance and managed care organizations should modify their benefit design and coverage processes in order to offer purchasers health benefit plans that include safe and effective CAM interventions. Similarly, purchasers should enhance the processes they use to develop health benefits and give consideration to safe and effective CAM interventions. DHHS can support these efforts by convening work groups and conferences to assess the state-of-the-science of CAM services and products and to develop consensus and other types of guidance for Medicare, other public and private purchasers, health plans, and even consumer representatives.

Coverage of and reimbursement for most health care services are linked to a provider's ability to furnish services legally within the scope of his or her practice. This legal authority to practice is given by the state in which services are provided. Thus, even if insurers, managed care organizations, and other health plan sponsors are interested in covering safe, cost-effective CAM interventions, they cannot do so unless properly licensed, or otherwise legally authorized, practitioners are available in a state. State governments are encouraged to consider how regulation of CAM practitioners could affect coverage and third-party reimbursement of safe and effective CAM interventions.

Criteria for Using CAM

Once a CAM service is covered, health insurers, managed care organizations, and government agencies must be able to determine whether use of the service or product in a particular situation is generally accepted or investigational, and whether the service or product is medically necessary in that situation. Few criteria are available to guide practitioners in deciding the medical or clinical necessity of CAM interventions. DHHS, preferably through a centralized CAM office, should work with health care and professional associations, CAM experts, health insurance and managed care organizations, benefits experts, and others to guide changes in health plan coverage for safe and effective CAM services and products and to develop criteria for use of CAM interventions.

Purchasers, health insurers, and managed care organizations will need CAM expertise when developing changes in coverage and reimbursement policies that involve CAM. CAM practitioners and experts should be included on advisory bodies and work groups considering CAM benefits and other appropriate health benefit issues.

CAM in Wellness and Health Promotion

In recent years, people have come to recognize that a healthful lifestyle can promote wellness and prevent illness and disease, and many people have used CAM approaches to attain this goal. Wellness is defined in many ways, but all agree that it is more than the absence of disease. Wellness can include a broad array of activities and interventions that focus on the physical, mental, spiritual, and emotional aspects of one's life. The concomitant rise in interest in CAM and in wellness and prevention presents many new and exciting opportunities for the health care system.

CAM's Role in Attaining the Nation's Health Goals

Since 1979, the U.S. Public Health Service has led a national initiative to define goals and objectives for the nation's health. As is clear from the resulting *Healthy People* series, a wide range of disciplines and social institutions is needed to improve health and wellness, prevent illness and disease, and manage disabilities and chronic conditions. The effectiveness of the health care delivery system in the future will depend upon its ability to make use of all approaches and modalities that provide a sound basis for promoting health.

There is evidence that certain CAM practices, such as acupuncture, biofeedback, yoga, massage therapy, and tai chi, as well as certain nutritional and stress reduction practices may be useful in contributing to the achievement of the nation's health goals and objectives. Federal agencies and public and private organizations should evaluate CAM practices and products that have been shown to be safe and effective to determine their potential for promoting wellness and helping to achieve the nation's health promotion and disease prevention goals. Demonstration programs should be funded for those determined to be beneficial

The Federal government, in partnership with public and private organizations, should support the development of a national campaign that teaches and encourages healthful behaviors for all Americans, including children. The campaign would focus on improving nutrition, promoting exercise, and teaching stress management. Safe and effective CAM practices and products should be included, where appropriate. The role of safe and effective CAM practices and products in the workplace should also be evaluated, and incentives should be developed to encourage the use of those found to be beneficial.

The application of CAM wellness and prevention practices to the management of chronic disease and disabilities is a largely unexplored area. CAM principles and practices may be useful not only in preventing some of these diseases and conditions, but also in enhancing recovery and preventing further illness. Increased research in this area will help to determine how CAM principles and practices can best be used to meet the goals of the health care system. DHHS and other Federal agencies should fund demonstration projects to evaluate the clinical and economic impact of comprehensive health promotion programs that include CAM. These studies should include underserved and special populations.

Wellness and Health Promotion in Programs for Special and Vulnerable

Populations

Early interventions that promote the development of good health habits and attitudes could help prevent many of the negative behaviors and lifestyle choices that begin in childhood or adolescence. Poor dietary habits, lack of exercise, smoking, suicide, substance abuse, homicide, and depression are epidemic among young people. The Commission believes that it is time for wellness and health promotion to be made a national priority. CAM practices and products that have been shown to be appropriate for children and young people should be included in this effort, which must involve all sectors of the community, particularly schools.

The Federal government funds many programs that serve vulnerable populations, such as children, the poor, and the elderly. The programs have a direct impact on the health and quality of life of the people they serve, and they may benefit from a wellness and prevention component that includes safe and effective CAM practices and products. The agencies that administer these programs should evaluate safe and effective CAM practices and products to determine their applicability to the programs and fund demonstration projects for those found to be beneficial.

Federally funded health care delivery programs, such as the Department of Veterans Affairs, The Department of Defense, the Indian Health Service, community and migrant health centers, maternal and child health programs, and school health programs, should also evaluate the applicability of CAM wellness and prevention activities to their services. Demonstration programs should be funded for CAM practices and products found to be beneficial to these populations. Other Federal, State, public, and private health care delivery systems and programs would also be well-advised to evaluate CAM practices and products to determine their applicability to programs and services that help promote wellness and health.

The Secretary of Health and Human Services should bring together public and private health care organizations to evaluate the contribution of safe and effective CAM practices and products to wellness and health and to determine how they may be used in health systems and programs, especially in the nation's hospitals and long-term care facilities and in programs serving the aged, persons with chronic illness, and those at the end of life.

CAM and conventional health professional training programs should offer students training and education in self-care and lifestyle decision-making, both to improve practitioners' health and to enable them to impart this knowledge to their patients or clients.

Coordinating Federal CAM Efforts

Integration of safe and effective CAM practices and products into the nation's health care system will require an ongoing, coordinated Federal presence. Establishment of a centralized office is the most effective means of accomplishing this goal.

Responsibilities of the office should include:

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

The Commission recommends that the President, Secretary of Health and Human Services, or Congress create an office to coordinate Federal CAM activities and to facilitate the integration of safe and effective practices and products into the nation's health care system. The office should be established at the highest possible appropriate level in DHHS and be given sufficient staff and budget to meet its responsibilities. The office should charter an advisory council whose members would include representatives of the private and public sectors as well as CAM and conventional practitioners with the necessary expertise, diversity of backgrounds, and training to guide and advise the office about its activities.

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