



*White House Commission on Complementary  
and Alternative Medicine Policy*

**Final Report**

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# **White House Commission on Complementary and Alternative Medicine Policy**

## **FINAL REPORT**

**March 2002**

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## Transmittal Letters

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THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 22, 2002

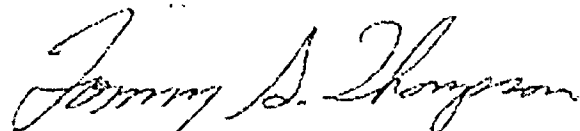
The President  
The White House  
Washington, DC 20500

Dear Mr. President:

I submit to you the Final Report of the White House Commission on Complementary and Alternative Medicine Policy in accordance with Executive Order 13147. The Report contains administrative and legislative recommendations.

The Department appreciates the time and effort taken by the Commission to examine this area in detail. We are forwarding the Report to you and making it available to the public immediately. We will review carefully the recommendations addressed to the Department, and I am sending copies of the full Report to Congressional leaders.

Sincerely,

  
Tommy G. Thompson

## Acknowledgements

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Many individuals and organizations assisted the Commission. The Commission is most grateful to the hundreds of individuals who devoted personal time and traveled great distance to participate in the ten meetings of the Commission and the four Town Hall meetings held in San Francisco, CA, Seattle, WA, New York City, NY and Minneapolis, MN. They included patients, their families, health care practitioners, research investigators, representatives of health insurers and managed care organizations, benefit experts, manufacturers and suppliers of CAM products, voluntary organizations, private foundations, and the Federal agency representatives associated with CAM activities. Their enthusiasm and willingness to assist the Commission deserve special thanks.

Many individuals in the Federal government assisted the Commission. We are unable to mention all who assisted, but there are many persons who deserve special mention including: Dr. Stephen Straus, Director, National Center for Complementary and Alternative Medicine for providing administrative support and facilitating the Commission's activities; Dr. William Harlan, Acting Director, National Center for Complementary and Alternative Medicine for his support and attention at the time of the formation of the Commission; Dr. Paul Coates, Director, Office of Dietary Supplements at the National Institutes of Health for his thoughtful comments and consideration of the serious issues before the Commission; and Christine Taylor, Ph.D., Director, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA for her assistance and guidance during the reviews of information related to dietary supplements.

The Commission gratefully acknowledges the efforts and contributions of the Commission's staff including Ms. Michele Chang, M.P.H., C.M.T., Executive Secretary to the Commission, Commander Corinne Axelrod, M.P.H., L.Ac., Dipl.Ac., Captain Joseph Kaczmarczyk, D.O., M.P.H., Ms. Geraldine Pollen, M.A., Ms. Doris Kingsbury and Ms. Joan Albrecht. Several individuals assisted the Commission and the staff in important consultant roles. The conscientious efforts of Kenneth Fisher, Ph.D., Ms. Maureen Miller, R.N., M.P.H., Mr. James P. Swyers, M.A., and Max Heirich, Ph.D. are recognized. Considerable effort was required to develop agenda issues and fully explore appropriate speakers and background information on issues prior to the discussion at the meetings. The assistance and dedication of the staff and the consultants involved in developing the Interim Progress Report, managing the numerous Commission work groups, and preparing the Final Report are particularly noteworthy.

The consideration of the issues under discussion by the Commission provided by John Whyte, M.D. and Carlos Zarabozo of the Centers for Medicare and Medicaid Services, Lisa Vincler, J.D., of the Attorney General's Office in the State of Washington, Alan Dumoff, J.D., M.S.W. in private practice in Rockville, MD

and Ms. Michele Rusk of the Federal Trade Commission are recognized and appreciated. A special mention of thanks is extended to Ms. Jean Kazares and Ms. Anita Allen of Palladian Partners, Inc. who provided logistical support services to the Commission. Likewise, Mr. Craig Powers of MemberWare Technologies, Inc. provided webmaster services to maintain and update the Commission's website and deserves a special thanks for keeping the site accessible to the public from the first meeting through the completion of the Final Report. Finally, sincere appreciation is extended to the copy editor, Ms. Blair Burns Potter for her talents and assistance in editing the Final Report of the Commission.

In this report, the Commission presents the Administration and Congress with recommendations and implementation actions to guide the nation's policies regarding CAM into the new century. It has been an honor to listen to the oral testimony and receive written testimony from supporters and critics alike on the issues before the Commission. It is a privilege to present these identified needs and suggested recommendations and actions to the President, the Secretary of the Department of Health and Human Services and the Congress, and the public. The Commission looks forward to the implementation of the recommendations and actions in this report.

Stephen C. Groft, Pharm.D.  
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## **Chairman's Vision**

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### **The Chairman's Vision**

James S. Gordon, M.D.

Two years ago, in March 2000, the President and Congress responded to public demand and public need by creating the White House Commission on Complementary and Alternative Medicine Policy. The Commission's mandate was to develop legislative and administrative recommendations that would help public policy maximize potential benefits, to consumers and American health care, of complementary and alternative medicine (CAM) therapies - chiropractic, acupuncture, massage, herbs, and nutritional and mind-body therapies, as well as a host of other approaches.

Many of the 20 Presidentially appointed Commissioners are conventionally trained health professionals and others are trained purely as CAM practitioners. Several more are conventional health professionals who integrate complementary and alternative approaches into their work. The Commission also includes a number of academic physicians and health and mental health professionals who joined the Commission interested in, but not experts in, CAM approaches. There are, as well, several business executives and patient advocates.

Though the Commissioners came from these diverse backgrounds, all swiftly agreed that our responsibility was to ensure the safety of products and practices that had been, or might be, labeled "CAM", as well as to maximize potential benefits of these approaches for the public.

For 18 months we listened and read, in 14 meetings, the testimony of over 700 individuals and organizations and we read over 1,000 written submissions. Commission members discussed what we had heard in subcommittees and in full Commission meetings. All participated actively in these discussions and learned from one another, as well as from those who testified.

In particular, I want to mention our friend and fellow Commissioner, William Fair, M.D., a world-renowned urologic surgeon, who contributed so much to this Report. Bill, who died two months before this Report was completed, reminded the Commission often about the value of this work and, particularly, about the importance of helping to prevent chronic illness by teaching children and young people the fundamentals of self-care. He taught all of us who knew him even more about how to live courageously and generously with life-threatening illness.

The Report that follows, which has been prepared with the invaluable support of the Commission's Executive Director, Stephen Groft, Pharm.D., and the

Commission staff, is a response to the public trust the Commission was given and to the questions we were asked by the President and Congress.

At times there were differences of opinion among us about, for example, the proper balance between freedom of choice and regulation as well as the appropriate roles of the various CAM professions in the health care system. Thanks to the persistence and dedication of the Commissioners, we were able to resolve many aspects of these and other questions. Still others remain to be addressed by the appropriate Federal agencies, and by the task forces and advisory groups whose creation this Report recommends.

We wrestled, as well, with other questions: What is the best way to discuss approaches like self-care and prevention that are very much a part of good conventional medicine as well as CAM? How to address the healing power of prayer and spirituality in the context of CAM when these are of such importance to so many Americans, whether or not they are using CAM, or conventional, approaches to cope with an illness.

I believe the Report reflects our best response to the complexity of the questions raised, as well as the diverse nature of the Commission and of those who testified. This introductory "Chairman's Vision" represents my own reflections on our work.

Over the last 30 years, increasing numbers of Americans, particularly those with chronic and life-threatening illnesses, have begun to look for health care answers in complementary and alternative approaches. They are not turning their back on conventional medicine - it is, in fact, those who have had all the benefits of modern scientific medicine who have led the search - but they are very much aware of its limitations and side effects. They are exploring approaches that would complement this medicine - or in some cases, be alternatives to it. And, most often, they are exploring these approaches without valid scientific information to guide them.

These people are looking for therapies that are both more helpful and less burdened by side effects. Many of them are searching for something else as well. They want more time with the professionals who will provide care for them - a sustained, healing partnership rather than a brief consultation, and an opportunity to participate in their own care as well as to "follow doctor's orders".

Now, at the beginning of the 21st century, this White House Commission's Report addresses the hopes and concerns of the American people and the professionals who serve them. It acknowledges and respects the American people's use of a variety of approaches to health care and emphasizes the need to use the tools of biomedical research to assess the perspectives and findings of a worldwide spectrum of approaches, techniques and systems of healing.

This Report is grounded in the conviction that first-class scientific research on these approaches and well-designed demonstration projects - of the same high quality required for conventional approaches - is crucial to helping all Americans, and those who care for them, make the wisest healthcare decisions.

The Report's vision is holistic. It is shaped by attention to the mind, body, and spirit of each person, and to the social and ecological world in which we all live. This perspective, which has also re-emerged over the last 30 years in Western medicine under the name "biopsychosocial", has long been the shaping principle of traditional systems of healing.

The Commission's Report is also defined by an emphasis on the importance of each person participating in his or her own care, and moderated by the understanding that government has a responsibility to facilitate this process. The Report recommends, as the Institute of Medicine has also done, active participation of the public in all aspects of their care, including the development of new research agendas.

There is a powerful emphasis in the Report on the importance of good information as the basis for health care decision-making. It recognizes the American people's pressing need to know, with as much authority as possible, what works and for whom, in complementary and alternative, as well as conventional medicine. Again and again the Report makes recommendations - for more and more rigorous and relevant research and for the training of researchers - to facilitate this process.

All Americans should have access to qualified and accountable practitioners and safe health care products. In this Report, there is an emphasis on the unique role the Federal government can take in making available and accessible the latest research findings; in ensuring the safety of products; in helping to assess the appropriate levels of training of various CAM practitioners and the evidence base for their practice; in evaluating the different ways that states are regulating CAM practitioners; and in facilitating dialogue among CAM and conventional providers, scientists and the public. The Report addresses as well the important leadership role that states can take in developing models for appropriate regulation of CAM practitioners and of conventional professionals who incorporate CAM approaches in their work.

The Report's approach is pluralistic. The American people want their conventional healthcare practitioners to help them make wise decisions about whether to use complementary and alternative therapies - and which ones to use - and they want their CAM practitioners to be responsive and informed partners with their mainstream medical caregivers. The Report offers guidance for both the integration of complementary and alternative therapies that are safe and effective into conventional medicine, and for respectful collaboration and cooperation between conventional health professionals and those whose

practices are shaped by other healing traditions. It looks forward to cross-fertilization among these disciplines in education and research as well as clinical care.

It seems to me that this Report is shaped by the Commission's particular concern for an aging population with an increasing incidence of chronic illness - for precisely those people who are among the most frequent users of CAM products and services. It makes clear that people with chronic illness and those who are dying need to have available approaches that can reduce their stress and suffering, approaches - including CAM therapies - that recognize the spiritual, as well as the physical and emotional dimensions of their lives.

The Report also makes clear that those in the greatest need - including, most particularly, those with limited incomes - must have available the most accurate, up to date information about which techniques and products may help and which may harm, and which practitioners are basing their recommendations on solid research and which are not. These Americans and their families must be offered this information in easily accessible forms - from the Federal government, in the practitioner's office, and in pharmacies and health food stores, as well as on the Internet.

There is an emphasis as well on the singular importance to the long-term health of the American people of approaches that prevent disease and promote health and wellness. Some of these approaches have been presented in government reports like Healthy People 2000 and 2010. Many of the principles and practices of CAM approaches are, like some of these more conventional health care practices, aimed at enhancing health and well-being, and promoting each person's capacity for self-healing. The Report highlights the opportunity that Federal agencies now have to evaluate the ways that safe and effective CAM therapies may be integrated into their ongoing efforts to promote health among all children and adults.

It seems to me, that the intentions of the Commission members were to engage Americans to participate actively in their own care; to stimulate research that will fairly test promising new and ancient approaches; to fully inform all health professionals and the people they serve about what is, and is not, known about CAM therapies; to make sure safe and reliable products are available to all Americans; to expand all Americans' options for safe and effective care; and to promote the study of approaches that may save us all money as well as enhance our health and well being.

My larger concern - and that of the Report - is not, of course, complementary and alternative therapies, but the health and wellness of all Americans. I believe that this Report helps create the foundation for a more comprehensive health care system, a system responsive to the unique needs of each person.

As research determines which approaches are safe and effective and for whom, as that information is widely disseminated, and as health care evolves, I expect that the words "complementary" and "alternative" will become far less important. We will be concerned then only with making what has been determined to be safe and beneficial as widely available as possible and with bringing the same rigorous but open-minded study to a new generation of approaches which we have not yet examined.

I look forward to a health care practice in which engaged and informed patients form healing partnerships with respectful and collaborative practitioners who are offering a wide range of safe and effective approaches, a health care practice in which all of us learn to take better care of ourselves and one another. I hope that this Commission's Report will help to provide a map that will guide Americans in making some next steps toward these goals.

## **Executive Summary**

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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 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 addition, 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 scarce 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.

## **Chapter 1: Introduction**

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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 %<sup>1</sup> to as much as 43%<sup>2</sup> 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, scientific evidence has begun to emerge suggesting that some CAM approaches and products, when used appropriately, can be beneficial for treating illness and promoting health. As this evidence is collected and disseminated to the wider health care community and the public, it should provide a reliable basis for making policy decisions that will facilitate the public's access to safe and effective CAM approaches and products.

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established in March 2000 to address issues related to access and delivery of CAM, priorities for research, and the need for better education of consumers and health care professionals about CAM. 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.

### **Overview of the Commission's Mission and Activities**

Specifically, the Commission's mission is to address:

- education and training of health care practitioners in CAM;
- coordination of research to increase knowledge about CAM products;
- provision of reliable and useful information on CAM to health care professions, and,
- 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, practitioners, and others were asked to provide recommendations regarding Federal policies related to CAM and documentation to support those recommendations. The Commission meetings were initially focused around four primary areas:

- 1 Coordinated research and development to increase knowledge of complementary and alternative medicine practices and interventions;
- 2 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 Availability of reliable and useful information on complementary and alternative medicine to health care professionals and the public.

The Commission also solicited public testimony on these topics during its meetings as well as during a series of four Town Hall meetings held at various sites around the country. 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 observe how CAM and conventional health care providers in integrated and collaborative care settings.

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 possible role of CAM approaches in supporting health and wellness. The second is the need for a centralized coordination of Federal efforts regarding CAM. The Commission also recognized early into the discussions of its charges that not only were the four topics very complex, but time and resources were inadequate to address these topics in as much depth as each topic needed.

In developing recommendations, Commissioners divided into eight work groups formed around specific topics areas, e.g., education and training, research, information dissemination. Each Commissioner served on at least two work groups. 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 in 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.<sup>3</sup> The IOM report recommended 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. The IOM report also recommended 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 guiding principles also are consistent 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*.<sup>4</sup> 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 analogous to 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. As noted in subsequent chapters, 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 health care reform. The report addresses ways in which resources and technologies that have not 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 reform of the health care delivery system and on the promotion of health and the prevention of illness.

### **Commission Concerns**

In a group as diverse as the members of this Commission and a field as diverse as CAM, it is not surprising that areas of significant disagreement, particularly about tone and emphasis, remained to the end. In particular, several Commissioners were concerned that the report needs to state even more clearly than it already does that most CAM interventions have not yet been scientifically studied and found to be either safe or effective.

Some Commissioners suggest that because the Report makes so many recommendations about including CAM practices in a variety of areas, it may imply to some readers that more has been shown to be safe and effective than evidence yet indicates. Some Commissioners believe there is or may be an unstated ethos throughout the document that could be construed that many, if not most, CAM modalities are beneficial. Adding the qualifiers "safe and effective" helps, but the fact that the report makes so many recommendations may imply that more have been shown to be safe and effective than evidence yet indicates. None of the Commissioners want the report to be interpreted in these ways.

Although most CAM modalities have not yet been proven to be safe and effective, it is likely that some of them eventually will be proven to be safe and effective, whereas others will not. Thus, some Commissioners have agreed to many recommendations that they believe are premature in hopes that it may be useful to lay out a road map and context now to guide research and policy decisions over the next several years as more science and other information become available.

The question is not, "Should Americans be using complementary and alternative medicine modalities?" as many--perhaps most--already are doing so. For the most part, however, they are making these choices in the absence of valid scientific information to guide them in making informed and intelligent choices.

Many of the commissioners agree with the editors of *The New England Journal of Medicine* who stated in 1998: "There cannot be two kinds of medicine--conventional and alternative. There is only medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted."<sup>5</sup> But this presumes that sufficient funding is available for rigorous testing.

All the Commissioners believe that substantially more funding for CAM research is needed to help citizens understand the benefits and the liabilities of various CAM modalities and approaches, especially those that are already in widespread use and those that have the greatest potential for addressing the nation's most serious health care problems. They understand the limitations of science but also its power. They also know how difficult the obstacles can be in conducting good science.

Good science can help sort out what is true from what is not, what works from what does not, for whom, and under what circumstances and which conditions. Well-designed scientific research and demonstration projects can help to determine which CAM modalities and approaches are clinically effective and cost effective, as well as the mechanisms involved. Americans can then make more informed and intelligent decisions about their own health and well-being.

Some modalities of conventional medicine are widely used and some are being reimbursed but have not been proven to be either medically effective or cost effective, and some have side-effects that may be more harmful than many CAM modalities. However, the Commissioners believe and have repeatedly stated in this Report that our response should be to hold all systems of health and healing, including conventional and CAM, to the same rigorous standards of good science and health services research. Although the Commissioners support the provision of the most accurate information about the state of the science of all CAM modalities, they believe that it is premature to advocate the wide implementation and reimbursement of CAM modalities that are yet unproven.

Also, the Commission as a whole is concerned that the report, in using the term, CAM generically brings well established modalities under the same umbrella as those with little or no scientific evidence. The report does its best to distinguish in its recommendations between those proven safe and effective, such as exercise, nutrition, and stress management, and those that are not. But the Commission recognizes that this distinction may not always be completely clear. The Commissioners want to state in the Introduction the importance of this distinction and the role of research as the crucial instrument for determining what is safe and what is not, as well as what works and what does not.

### **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 incorporation into the nation's health care system.

Chapter 3 addresses the need for research coordination at the Federal level and with new directions and opportunities for CAM 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, including dietary supplement labeling; the Federal Government's role in this process; and, strategies for promoting public-private ventures.

Chapter 6 discusses access to and delivery of CAM practices 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.

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## Chapter 2: Overview of CAM in the United States: Recent History, Current Status, And Prospects for the Future

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Complementary and alternative medicine, or CAM, can be defined as a group of medical, health care, and healing systems other than those included in mainstream health care in the United States. CAM includes the worldviews, theories, modalities, products, and practices associated with these systems and their use to treat illness and promote health and well-being.

Although heterogeneous, the major CAM systems have many common characteristics, including a focus on individualizing treatments, treating the whole person, promoting self-care and self-healing, and recognizing the spiritual nature of each individual. In addition, many CAM systems have characteristics commonly found in mainstream health care, such as a focus on good nutrition and preventive practices. Unlike mainstream medicine, CAM often lacks or has only limited experimental and clinical study; however, scientific investigation of CAM is beginning to address this knowledge gap. Thus, boundaries between CAM and mainstream medicine, as well as among different CAM systems, are often blurred and are constantly changing.\*

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

Table 1. CAM Systems of Health Care, Therapies, or Products\*\*

| Major Domains of CAM            | Examples Under Each Domain                                                                                                                                                                                                       |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Alternative health care systems | Ayurvedic medicine<br>Chiropractic<br>Homeopathic medicine<br>Native American medicine (e.g., sweat lodge, medicine wheel)<br>Naturopathic medicine<br>Traditional Chinese Medicine (e.g., acupuncture, Chinese herbal medicine) |

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\* In this report, "mainstream," "conventional," "allopathic," and "biomedical" are used synonymously to refer to the principal form of health care and medicine available in the United States.

\*\* This table was adapted from the major domains of CAM and examples of each developed by the National Center for Complementary and Alternative Medicine, National Institutes of Health

| <b>Major Domains of CAM</b>                                           | <b>Examples Under Each Domain</b>                                                                                                                                                                                                 |
|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Mind-Body interventions</b>                                        | Meditation<br>Hypnosis<br>Guided imagery<br>Dance therapy<br>Music therapy<br>Art therapy<br>Prayer and mental healing                                                                                                            |
| <b>Biological based therapies</b>                                     | Herbal therapies<br>Special diets (e.g. macrobiotics, extremely low-fat or high carbohydrate diets)<br>Orthomolecular medicine (e.g., megavitamin therapy)<br>Individual biological therapies (e.g., shark cartilage, bee pollen) |
| <b>Therapeutic Massage, Body Work, and Somatic Movement Therapies</b> | Massage<br>Feldenkrais<br>Alexander Method                                                                                                                                                                                        |
| <b>Energy Therapies</b>                                               | Qigong<br>Reiki<br>Therapeutic Touch                                                                                                                                                                                              |
| <b>Bioelectromagnetics</b>                                            | Magnet therapy                                                                                                                                                                                                                    |

Many of the CAM systems of health care listed in Table 1 have evolved from the collective clinical experiences of many practitioners over generations of practice, such as in Traditional Chinese Medicine. Others have evolved from the clinical experiences of a single practitioner or small groups of practitioners who have developed a particular intervention.

Despite their diversity, there are some common threads that run among many traditional systems of health care as well as systems that have emerged more recently. These similarities include an emphasis on whole systems, the promotion of self-care and the stimulation of self-healing processes, the integration of mind and body, the spiritual nature of illness and healing, and the prevention of illness by enhancing the vital energy, or subtle forces, in the body.<sup>1</sup>

### **Convergence of CAM and Mainstream Healthcare**

Some of the common threads that run through CAM health care systems also are part of mainstream, or conventional, health care. For example, conventional medicine has a long tradition of being concerned with preventing disease as evidenced by the development of programs for immunizations, healthier mothers and babies, family planning, safer and healthier foods, fluoridation of drinking water, control of infectious diseases, reducing deaths from heart disease and stroke, decreasing the use of tobacco products, and promoting motor vehicle safety and safer workplaces.<sup>2</sup>

Mainstream or conventional health care also has long-recognized that good nutrition and exercise are important components of a healthy lifestyle.<sup>3,4</sup> There also is a growing recognition within conventional health care that biopsychosocial and spiritual factors may play an important role in promoting health and preventing illness.<sup>5,6</sup>

The difference between conventional and CAM health care systems in many of these areas, however, is one of emphasis. In part, because of the many technological advances that have occurred in conventional health care over the years (see Recent History of CAM section, below), pharmacological, surgical, and other technological approaches have come to dominate conventional health care. While acknowledged, prevention and wellness promotion have been underemphasized. For example, according to a recent report by the Nutrition Education Consortium, the teaching of nutrition in medical schools and residency programs remains "woefully inadequate,"<sup>7</sup> and a survey by Cooksey et al.<sup>8</sup> found that most medical schools do not have faculty trained specifically in nutrition. As a result of this lack of training in nutrition in medical education, many practicing physicians are not adequately prepared to provide nutrition counseling to their patients. However, registered dietitians and clinical nutritionists are employed by hospitals and clinics. These are the specialists who are trained in this area and are well established in the conventional health care system.

Because many CAM approaches often focus on prevention rather than cure,<sup>9</sup> they have come to be identified with wellness and self-care. This may be a reflection of history, as effective treatments for many of the infections and severe injuries that occurred were lacking. Traditional systems were better able to strengthen the individual and attempt to prevent disease than to treat many of the illnesses that killed millions even one hundred years ago. This is not to imply that CAM systems of health care are more effective than conventional health care in promoting health and preventing illness, as many have not been scientifically shown to prevent disease or promote health.

The perception that conventional health care emphasizes high technology approaches to treating patients, while CAM health care emphasizes low technology approaches to promoting health and preventing disease, has led some to suggest that conventional and CAM health care may eventually converge to form a new health care system that integrates the best of each<sup>10</sup>. However, there are not only scientific, but also educational, regulatory, and political obstacles to integration of the two systems.

### **Evolution of CAM Terminology**

As interest in and use of non-mainstream health care practices has evolved in this country over the past several decades, the terminology used to describe CAM systems, practices, and products has had to evolve accordingly. Rather than focus on what these "other" health care systems are not (i.e., "unorthodox,

"unconventional," or "unscientific"), more recent terminology has begun to focus on what these systems are and how they might be used.

For example, because many consumers appeared to be using unconventional health care practices as alternatives to conventional health care, the term "alternative medicine" was widely adopted in the United States and Europe in the later 1980s.<sup>11,12</sup> This perception, however, was largely dispelled by surveys in the early 1990's, which found that people were using the two systems of health care—mainstream and alternative—simultaneously.<sup>13,14</sup> These surveys found that health care consumers were accessing a range of therapeutic and preventive options, both alternative and conventional, to essentially "complement" one another. As a result, the term "complementary medicine" was widely adopted not long afterwards to describe systems of health care and individual therapies that people used as adjuncts to their conventional health care.<sup>15,16</sup>

A more recent and detailed survey conducted by Astin<sup>17</sup> has found that, although many unconventional therapies were being used to complement mainstream medical care, some were being used instead of conventional medical care. These data suggested that the term "complementary" was only partially descriptive of what was occurring in the marketplace. To acknowledge this dichotomy, Congress adopted the phrase "complementary and alternative medicine" and applied it to the National Institutes of Health's National Center on Complementary and Alternative Medicine (NCCAM), when the Office of Alternative Medicine was elevated to the status of a coordinating research "Center" in 1999.

Even this terminology is unsatisfactory to many because it does not reflect emerging models of health care that have arisen in the overlapping areas between these various systems. Nor does it account for the fact that health care systems, practices, and products that are not widely accepted or readily available in one part of the United States may be fully accepted and easily available in another. Members of the Commission considered other terms, such as "integrative health care," "collaborative health care," "comprehensive health care," and "holistic health care," but chose to use the term "complementary and alternative medicine" because it is used in the President's Executive Order and is widely recognized by the media and in the scientific literature.

To fully understand the complexities of CAM as well as its current relationship with conventional health care in this country, it is necessary to understand its recent history, its current status, and future prospects, including emerging models of integrative and collaborative care.

### **Recent History of CAM in the United States**

The history of CAM in the U.S. is a long, complex story that has been shaped by scientific, economic, and social factors. A detailed rendering of this history is beyond the scope of this report. This section instead provides a brief overview of

the more recent developments that have helped shape the present status of CAM in this country and its prospects for contributing to the health and well being of our nation.

Early American health care consisted of an eclectic mix of systems. In fact, until the middle of the 19th century, the vast majority of primary medical care in this country was provided by botanical healers, midwives, chiropractors, homeopaths, and an assortment of other lay healers offering a variety herbs and nostrums for a range of illnesses.<sup>18-20</sup>

This began to change in the latter part of the 19th century, however, with the development and validation of the germ theory and significant scientific advances in antiseptic techniques, anesthesia, and surgery. Beginning in the late 1800s and lasting until the early 20th century there also was a major revolution in medical education that helped scientific medicine evolve into the dominant health care system in this country.

This revolution in medical education began with the publication of William Osler's (1847-1919) textbook, *The Principles and Practice of Medicine* in 1892, which brought diagnostic clarity to medical practice. By 1905 Osler's textbook was the primary medical textbook in the vast majority of U.S. medical schools.<sup>21</sup> This revolution culminated with the release of a report by Abraham Flexner in 1910<sup>22</sup> that served to crystallize the educational reform movement. After the release of the Flexner's report, many medical institutions that did not meet its standards were driven out of business or forced to implement significantly more rigorous training programs.<sup>21</sup> Schools for many unorthodox healing systems either ceased to exist or became marginalized.<sup>20</sup>

The isolation and elaboration of life-saving hormones, sulfa drugs, and other antibiotics in the early and middle of the 20th century, conventional medicine cemented its place as the nation's preeminent form of health care in this country. Although most of the other health care systems and their therapies did not disappear, they were considered by most of the public and the mainstream medical community to be unscientific relics of the past. As a result, many were practiced in relative obscurity.\*

With the reduced threat of infectious diseases and other acute illnesses, conventional medicine began turned its focus to the more complex and costly problems of chronic, degenerative illnesses. As a result of public health interventions developed earlier in the 20th century, people began living significantly longer. This gradual aging of the population began to significantly increase the prevalence of chronic conditions, such as arthritis, back pain,

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\* For a brief overview of medicine and health care in the 19th and early 20th centuries in the United States, see Acknerknecht EA. *A Short History of Medicine*. Baltimore, MD: John Hopkins University Press, 1982 or Duffin J. *History of Medicine: A Scandalously Short Introduction*. Buffalo, NY: Toronto University Press, 1999.

diabetes, hypertension, heart disease, and cancer, putting further pressure on conventional medicine to address these conditions.

As the health care system developed more sophisticated means of diagnosing and managing chronic illnesses, the cost of health care began to rise dramatically. Between 1965 and 1975, national health care expenditures more than tripled, rising from just over \$41 billion to nearly \$130 billion. Although employers and government programs covered some of these increases, out-of-pocket expenditures more than doubled during this same period.<sup>23</sup> Since then costs have continued to rise, with national health care expenditures reaching more than \$1.2 trillion in 2000, the latest year for which such figures are available, and they are expected to reach more than \$2.6 trillion by 2010.

It was during this time of increasing rates of chronic illness and escalating health care costs that medical pluralism began to reemerge in this country. This reemergence was spurred on by a number of overlapping and sometimes interrelated movements. Beginning in the 1950s, the whole foods and dietary supplement movements began to change Americans' view of food as not only something they needed to stay alive but also as potential therapeutic agents. In the late 1960s and early 1970s, Americans were increasingly exposed to a variety of traditional health care systems from foreign and indigenous cultures, many of which dated back to antiquity.<sup>24</sup> New York Times writer James Reston's account of his emergency appendectomy in a Chinese hospital during then Secretary of State Henry Kissinger's visit to China in 1971 was particularly influential in this process.<sup>25</sup> Reston's article described how his post-operative pain and discomfort were relieved by acupuncture and herbs. For most Americans, this was their first glimpse of Traditional Chinese Medicine and its potential uses.

During this same period, the growing "counterculture" movement in America sparked a fascination with the religious and philosophical traditions of Asian cultures. Transcendental Meditation, which is derived from Hinduism, became widely known and practiced.<sup>20</sup> Meanwhile, there was a growing interest in indigenous health care traditions, such as Native American and Mexican-American health care practices, particularly their reliance on herbs and natural substances. This movement, in turn, led to a renewed interest in "natural" health care movements that had developed in this country in the 19th century but had been relegated to the background of the American health care landscape.

The late 1970s saw the emergence of the holistic health care movement in this country. Holistic practice (holism comes from the Greek word "holos" or "whole") emphasized an attention to the whole person, including the physical, spiritual, psychological, and ecological dimensions of healing. Holistic health care incorporates practices and concepts of Eastern philosophy and diverse cultural traditions, including acupuncture and the use of herbs, massage, and relaxation techniques as well as conventional medical practices.<sup>26</sup> It gained its greatest

following among nurses.<sup>27</sup> However, many physicians, particularly those in the new specialty of family medicine, also became interested in this movement. The American Holistic Medical and Nurses Associations were formed, large professional and public conferences held, and a number of holistic medical clinics and holistic health centers opened.

The late 1970s and early 1980s also was a time when a variety of self-care movements emerged; they offered programs or sponsored events to help individuals and families increase wellness or reduce their risk of onset of illness through diet or lifestyle changes.<sup>28, 29</sup> The years since then have been a particularly active time for the personal fitness movement, which increasingly is making use of the techniques of other systems of healing, such as yoga, tai chi, and massage.<sup>30</sup>

### **The Current Status of CAM in the United States**

Today, use of CAM approaches and therapies is more prevalent in a number of patient populations in the United States, no matter how narrowly or broadly it is defined. Physicians, hospitals, and other conventional health care organizations also are showing a growing interest in CAM. Although such prevalence of use and interest in CAM is not an indication that these practices are effective, it does suggest that those with chronic conditions and the physicians who treat them are looking for more therapeutic options than are widely available in conventional health care settings. Indeed, for some chronic conditions, state-of-the-art conventional therapies have provided only modest gains. For example, according to a number of assessments over the years, expensive mainstream health care approaches to managing chronic lower back pain often have not been very effective.<sup>31-36</sup> This is perhaps why individuals with back pain are some of the most frequent users of CAM practices.

### **Consumer Use of CAM Practices**

Because of the dramatic increase in the prevalence of chronic conditions, the past decade has witnessed an acceleration both in consumer interest in and use of CAM practices and/or products. Surveys indicate that those with the most serious and debilitating medical conditions, such as cancer, chronic pain, and HIV, tend to be the most frequent users of CAM practices. CAM usage also appears to be high among certain ethnic populations that have access to their traditional forms of healing.

### **CAM and Cancer**

A survey that assessed both the prevalence and predictors of CAM use in a comprehensive cancer center population where all were using conventional therapies found that 63 percent had used at least one CAM approach other than a spiritual practice. Women with cancer were more likely to use CAM than men with cancer, and those patients who had surgery, chemotherapy, or both were more likely to use CAM than cancer patients who had neither.<sup>37</sup>

Another survey of almost 2,000 tumor registry patients selected at random found that 75 percent had used at least one CAM modality.<sup>38</sup> The most frequently used therapies among this group of cancer patients were nutritional approaches (63 percent), massage (53 percent), and herbs (44 percent). The most common reason patients gave for using CAM was to "stimulate an immune response" (73 percent). Breast cancer patients were significantly more likely to be consistent users of CAM therapies compared to patients with tumors in other sites areas of the body (84 percent versus 66 percent, respectively).

The majority of cancer patients (63 percent) enrolled in clinical trials at the National Institutes of Health used at least one CAM therapy, with an average use of two therapies per person.<sup>39</sup> This same study found that the most frequently utilized therapies were spiritual approaches, relaxation, imagery, exercise, lifestyle, diet (e.g., macrobiotic, vegetarian), and nutritional supplementation therapies. Patients unanimously believed that these CAM treatments helped to improve their quality of life by helping them cope more effectively with stress, decreasing their discomforts related to treatment and the illness itself, and giving them a better sense of control. A similar pattern of CAM usage has been found among men with prostate cancer, with 42 percent of those surveyed using vitamins, prayer or religious practices, and herbs to treat their condition.<sup>40</sup> Most of the men in this survey did not report their use of CAM to their physicians.

Most of these surveys included prayer and spirituality under CAM. Many people that attend churches, synagogues, or mosques or other religious entities do not believe that this is essential information for their physician and would not feel compelled to share this information with their physician. On the other hand, the use of botanicals and other dietary supplements during cancer treatment would be a concern if the physician were unaware that their patient was using these products.

### **CAM and Chronic Pain**

A recent national survey by Astin<sup>17</sup> found that back problems were the most common medical condition (24 percent) for which people reported using CAM treatments. In this survey, neck problems also were associated with frequent use of CAM. Other studies have found that one-third of all patients suffering from back pain choose chiropractors over physicians to treat them, and that chiropractors provided 40 percent of primary care for back pain.<sup>41,42</sup> Moreover, these studies found that chiropractors retained a greater proportion of their patients (92 percent) for subsequent episodes of back pain care than did other providers. Similarly, Krauss and colleagues<sup>43</sup> found that CAM practitioners and products were chosen more often than conventional physicians and therapies by those persons with chronic pain (52 versus 34 percent) and headaches (51 versus 19 percent), as well as by persons suffering from other associated maladies, including depression (34 versus 25 percent), anxiety (42 versus 13 percent), and insomnia (32 versus 16 percent).

Surveys of rheumatology patients have found similarly high CAM utilization rates, ranging between 19 and 63 percent, depending on the type and severity of their condition.<sup>44</sup> Other studies have documented that people with painful chronic conditions, including arthritis and headache, and psychological problems (insomnia, depression, and anxiety) are frequent users of CAM therapies, particularly massage, chiropractic, and acupuncture.<sup>13, 45</sup>

### **CAM and HIV Infection**

A recent study of 1,675 HIV-positive men and women using CAM (usually in addition to conventional medication) found that the most frequently reported CAM substances were high doses of vitamin C (63 percent), multiple vitamin and mineral supplements (54 percent), vitamin E (53 percent), and garlic (53 percent).<sup>46</sup> The health practitioners most commonly consulted were massage therapists (49 percent), acupuncturists (45 percent), and nutritionists (37 percent). The CAM activities most commonly used were aerobic exercise (63 percent), prayer (58 percent), massage (53 percent), and meditation (46 percent). The majority of this group of HIV-infected individuals consulted with both conventional and CAM providers and used both conventional and CAM medications simultaneously, yet few reported that their conventional and CAM providers worked as a team.

Similar observations were made in a survey of 180 HIV-infected people.<sup>47</sup> This study found that almost half (45 percent) of this group had visited a CAM practitioner an average of 12 times per year, compared to only 7 visits per year to their conventional physician or nurse practitioner. More than two-thirds (68 percent) of the HIV-infected individuals in the study used herbs, vitamins, or dietary supplements. Eighty-one percent of those who used supplements said the remedies were "extremely" or "quite a bit" helpful. Approximately 24 percent reported using marijuana to treat weight loss, nausea, and vomiting in the previous year, and most (87 percent) said it was extremely or quite helpful.

### **Ethnic Differences in CAM Usage**

In addition to the type and severity of illness one has, people's cultural and ethnic backgrounds can influence their propensity for using CAM. For example, surveys of CAM usage among Mexican-American and Hispanic populations have demonstrated that almost half of respondents have used a CAM practitioner one or more times during the previous year.<sup>48,49</sup> Herbal medicine, spiritual healing techniques, and traditional healers are used quite frequently by these groups. Similarly, surveys of Native American populations have found that they tend to have higher rates of CAM usage than the general U.S. population<sup>50</sup> and are also frequent users of herbal remedies, spiritual healing techniques, and traditional healers.<sup>51</sup> Income, not belief systems, prohibits interaction with traditional healers by Native Americans.<sup>51</sup>

### **Reasons People Give for Using CAM**

The reasons people seek out and use CAM practices are not fully understood. However, strong associations have been found between CAM usage and: 1) an interest in spirituality and personal growth, 2) a commitment to environmentalism, and 3) feminism.<sup>16</sup> In addition, several other studies have found that belief in a holistic approach to health, a strong internal locus of control, and transformational life experiences also are associated with CAM usage.<sup>17, 52, 53</sup>

Although Astin's survey<sup>17</sup> found that only a small percentage (4.4 percent) of people used CAM therapies as alternatives to conventional practitioners and treatments, there is some evidence that they used CAM because they believed it is more effective than conventional medicine. For example, in the survey of rheumatology clinic patients mentioned above,<sup>44</sup> 50 percent of respondents reported turning to CAM because they perceived their conventional treatment (drugs) as ineffective. Similarly, when researchers interviewed 113 patients at a family practice, the top reason given for seeking CAM therapies was that patients believed they would work.<sup>54</sup> A similar study of primary care patients found that: 1) recommendations from friends or coworkers, 2) a desire to avoid the side effects of conventional treatments, and 3) failure of conventional treatments to cure a problem were the most frequently cited reasons for using CAM therapies.<sup>55</sup> In this study, use of practitioner-based CAM therapies was significantly and independently associated with patients' perceived poor health status and emotional functioning and a musculoskeletal disorder, usually low back pain. Patients who used CAM most commonly visited chiropractic (35 percent), used herbal remedies and supplements, (27 percent) and sought massage therapy (17 percent). Use of self-care-based therapies was associated with high education and poor perceived general health compared to the previous year. Use of traditional folk remedies was associated with Hispanic ethnicity.

### **Conventional Health Care's Interest in and Use of CAM**

Evidence suggests that a growing number of physicians already use some CAM practices and consider them safe and effective in offering them to their patients. A comprehensive review of 25 surveys of physician practices and beliefs regarding five commonly used CAM practices-acupuncture, chiropractic, homeopathy, herbal medicine, and massage-found that about half of the surveyed physicians believed in the efficacy of these five CAM practices.<sup>56</sup> This study found that a significant proportion of conventional physicians were both referring patients to CAM practitioners and/or offering some of these CAM treatments in their practice.

In addition, Pelletier and colleagues<sup>57</sup> found that a small, but growing number of insurance companies are offering or are considering coverage for CAM services. CAM also has made significant inroads into conventional medical education, with more than two-thirds of mainstream medical schools currently offering elective courses in CAM or including CAM topics in required courses.<sup>58</sup>

However, the acceptance of some CAM practices by the conventional health care community did not come without economic and political power struggles. CAM practitioners have filed suit and won court cases against conventional health care professional associations,<sup>59</sup> and in many states CAM professions have faced strong opposition from conventional health care organizations in gaining licensing from state regulatory agencies.<sup>60</sup>

### **Evidence Base for CAM**

Surveys documenting the rise of interest in and use of CAM by consumers were a significant factor in the biomedical research community's decision to take a serious look at both the safety and efficacy of many CAM approaches and therapies. Federal expenditures for CAM research have risen dramatically since the early 1990s. To date, NCCAM has funded the establishment of 14 research centers to explore the safety and efficacy of a wide range of CAM therapies for a host of conditions. As a result of these and other international efforts, the evidence base for the efficacy a number of CAM approaches and treatments has grown significantly over the past decade.

More research on CAM currently exists than is commonly recognized. In fact, the Cochrane Collaboration, an international effort to develop an evidence base for a wide variety of medical therapies, both allopathic and CAM, lists more than 4,000 randomized trials for various CAM therapies in its electronic library. Furthermore, a number of Cochrane Collaboration systematic reviews of this worldwide research literature have identified the potential benefits of CAM and related approaches and products for a small number of chronic conditions, including:

- Low-fat or modified fat diets for preventing cardiovascular disease<sup>61</sup>
- Acupuncture in the management of low back pain and recurrent headaches<sup>62,63</sup>
- St John's Wort for treating mild to moderate depression<sup>64</sup>
- Herbal and glucosamine therapy for treating osteoarthritis,<sup>65,66</sup> and
- Nutritional supplements for several neurological conditions<sup>67,68</sup>

In addition to these Cochrane systematic reviews, an NIH scientific review panel concluded that acupuncture is a plausible option for treating several conditions, including nausea associated with chemotherapy and anesthesia, acute dental pain, headaches, temporomandibular joint dysfunction, fibromyalgia, and depression.<sup>69</sup> Another NIH review panel concluded that that mind-body techniques, such as meditation and guided imagery, are effective both in the management of painful conditions and the relief of stress and anxiety.<sup>70</sup>

All of these literature reviews have concluded that larger, more rigorous studies are needed before definitive statements can be made about the benefits of these therapies. These data, nevertheless, point to the need for a comprehensive and aggressive research program in several areas of CAM, particularly those areas

where CAM practices and products are frequently used adjunctively to mainstream medical care.<sup>71</sup>

The interaction of conventional and CAM health care systems over the years has made such a research program possible by producing significant improvements in CAM research methodology and data collection.<sup>72</sup> Conventional health care, in turn, has used these improved research methods to examine some CAM practices, found similarities between their practices and CAM practices, and has begun including them in comprehensive care programs.<sup>20</sup>

### **Safety Issues with CAM Use**

Despite the promising evidence that some CAM practices may be effective in managing and treating certain chronic conditions, most CAM therapies that are currently being used by consumers have not been studied adequately in regard to either efficacy or safety.<sup>73, 74</sup>

Even when evidence indicates that a particular CAM approach or modality is safe and effective for a particular condition, new safety concerns may arise when it is used in conjunction with conventional medications, which is the way most consumers use CAM.

Even when evidence indicates that a particular CAM approach is safe and effective for a certain condition, new safety concerns may arise when it is used in conjunction with conventional medications, which is the way most consumers use them. A recent review published in the *Journal of the American Medical Association* found that some commonly used herbal products can cause serious complications for surgery patients.<sup>75</sup> The potential complications included bleeding, cardiovascular instability, hypoglycemia, and there was evidence that some herbs may increase the strength of anesthetics or the metabolism of many drugs used during and after surgery.

The potential adverse interaction of CAM and conventional treatments is particularly troubling to public health officials because most people do not tell their conventional health care providers that they are using CAM services or products. A survey of health food stores customers found that although these CAM consumers welcomed a partnership with their physicians, they generally believed that physicians in general were closed-minded and had little knowledge about dietary supplements.<sup>54</sup> These consumers had decided to assess the effectiveness of dietary supplements through personal study and subjective experimentation and not discuss this experimentation with their doctors.

A similar lack of communication regarding CAM has been found between cancer patients and their physicians. For example, in a survey of women with breast cancer, Adler and Fosket<sup>76</sup> found that the majority of respondents (55 to 85 percent) used CAM therapies but did not divulge this use to their physicians because they assumed the physicians would not be interested, would respond

negatively, would not understand, or would dominate the conversation due to assumed disinterest. Another survey found that physicians were unaware of CAM usage by the majority (57 percent) of their patients.<sup>77</sup>

These studies suggest that physicians and patients must become more knowledgeable about the potential benefits and harms of CAM approaches and treatments, and physicians and other conventional health professionals must make significant efforts to open the lines of communication with their patients about their use of CAM approaches and products. Recently, a major effort has been made to increase conventional physicians' awareness and understanding of CAM through educational programs. However, there is a great deal of variability in the content of these programs.<sup>58</sup>

Although a few provide detailed information on potential CAM benefits and safety issues, most are too general in content to provide physicians with the knowledge base they need to feel more comfortable about the subject and to display a willingness to discuss CAM issues with their patients.

Concerns about the safety of CAM products and their interaction take place in the context of the larger public attention to the side effects and problems accompanying all medical treatment.<sup>78</sup>

### **Future Prospects of CAM**

Despite the increasing use and acceptance of CAM and emerging evidence supporting efficacy of some CAM approaches and therapies, it is difficult to predict whether many CAM systems and practices will ever be fully integrated into the conventional health care system. Although a significantly greater degree of cooperation between specific CAM and conventional health care approaches and practitioners in the future, how well they can integrate their practices depends to a great measure on the establishment of an evidence-base for safety and effectiveness of CAM approaches as well as the success of a variety of ongoing pilot programs to test the efficacy and feasibility of integrative and collaborative models of CAM and conventional health care delivery.

### **Models of Integration**

Over the past few years, a growing number of hospitals, major academic medical centers, managed care companies, and insurance carriers have become interested in integrating some aspects of CAM into their operations. According to the American Hospital Association,<sup>79</sup> nearly 16 percent of America's community hospitals offered CAM services in 2000, up from about 11 percent in 1999. Furthermore, many major medical centers, particularly comprehensive care cancer centers such as M. D. Anderson in Houston, Memorial Sloan-Kettering Cancer Center and Columbia-Presbyterian Medical Center in New York City, and Duke University in Durham, North Carolina, have begun integrating CAM services into all of their patient care.<sup>80</sup>

However, the development of integrative health care is still in its early stages and faces a number of challenges. Many of these approaches are still without an adequate scientific basis. Even where there is evidence of benefit, the delivery of CAM in a conventional health care setting often requires significant reconfigurations of the way both the conventional and CAM health care services are structured, conceptualized, and delivered.<sup>81,82</sup> Another significant challenge facing integration is many CAM practitioners' belief that they would have to dramatically alter or water down their approach to practice in order to adapt to a physician-dominated system. Some CAM professions would prefer not to integrate if it means giving up their identity and independence.<sup>20</sup>

### **Models of Collaboration**

Another model that is being tested in a number of conventional academic and CAM health care centers is collaborative model rather than an integrative one. This model does not require full integration of services but instead is based on conventional and CAM practitioners referring patients to one another within a clinic or network. The models that are currently being pilot tested range from having conventional and CAM practitioners working side-by-side as equals, collaborating both in the diagnosis and treatment of patient conditions,<sup>10</sup> to having to physician-centered models, where CAM practitioners provide services independently but under the supervision of a primary or a specialty care physician.<sup>83</sup> These models, however, reveal additional challenges, which are listed below.

### **Meeting Challenges**

As noted, many of these integrative and collaborative programs are in their infancy. As they grow and develop, they face a number of challenges, including addressing:

- Difficulties in communicating and significant differences in worldviews and methods of diagnosing and treating illness and promoting health;
- Certification and training standards for some CAM professions;
- Insurance reimbursement for safe and effective CAM practices;
- Appropriate research models;
- Comprehensive information on CAM for both the lay public and health care practitioners; and,
- Appropriate education of both conventional and CAM professionals about each other's disciplines at all stages of their training.

In the following chapters, the Commission discusses these and other challenges in depth and recommends strategies for addressing them at the national and state level. The ways in which individual practitioners and programs meet these challenges will help to shape the future of CAM practice and determine the access people have to CAM services.

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### **Chapter 3: Coordination of Research**

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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 complementary and alternative medicine (CAM) practices and products and to discover the basic mechanisms underlying them. Basic, clinical, and health services research in CAM are all essential to the inclusion of CAM in 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 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 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 lie outside the conventional medical paradigm.

Establishing a strong scientific base in CAM is necessary for acceptance and inclusion of safe and effective CAM therapies in health care. In conventional medical practice, professional judgments are based on practitioners' 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 toward the goal of increasing the body of evidence-based knowledge in CAM occurred in 1992 with the establishment of the 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 other NIH institutes, centers and offices, and to provide information to the public. In 1998, research in CAM took another major step forward when the Office of Alternative Medicine became, through congressional mandate, the National Center for Complementary and Alternative Medicine (NCCAM). The expanded resources available to NCCAM enhanced its ability both to continue and build upon the work of the earlier office to provide the public with evidence on the safety and efficacy of CAM practices and products.

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## **Research Support and Scope**

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### **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 components, as well as other government agencies and non-government organizations. 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 collaboration 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 Substance Abuse and Mental Health Services Administration, the Department of Veterans Affairs, and the Department of Defense.

The NIH Office of Dietary Supplements 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, centers, and offices, other government agencies, professional organizations, and public groups. The Commission also recognizes the support for CAM research by the other NIH components, encourages them to increase their valuable 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.

In response to the public's use of CAM practices and products, overall NIH funding for research on CAM increased from \$116.0 million in FY 1999 to an estimated \$247.6 million in FY 2002. During the same period, funding by NCCAM increased from \$48.9 million to an estimated \$104.6 million. Despite this increase, an analysis of NCCAM's extramural research trends between FY 1999 and FY 2003 indicates 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.

Research project 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 increasing commitment base, which also may include some larger and longer-term clinical studies is a likely cause of the estimated decline in new awards. Therefore, in order to build the much needed evidence base for CAM, adequate funding is 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 they 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 to meet research needs and opportunities in crucial areas to ensure public health and safety.

To help identify research needs and promising research opportunities, NCCAM, assisted by the Institute of Medicine, should develop guidelines for establishing research priorities in CAM. Because of the diversity of CAM systems and practices and the wide range and fluidity of opinions on the definition of what constitutes complementary and alternative medicine, it is important also to address the issue of definition because the current ambiguity makes it difficult to set priorities for guiding the use of resources.

Other Federal agencies with research or health care responsibilities need to take a more active role in developing programs to evaluate biomedical and health services aspects of CAM to ensure that CAM use by the public is safe and effective. Funding for these programs should be sufficient to accomplish this goal. The Agency for Health Care Research and Quality together with NCCAM should develop ways to expand health services research in CAM and explore methodologies for conducting health services research in this area. Federal agencies should assess the scientific, clinical practice, and public needs regarding CAM that are relative to their missions, examine their portfolios, and develop funding strategies to address these needs. They should ensure that applicants are aware of any technical assistance available to them. Agencies might consider such activities as funding initiatives (requests for applications and proposals), establishing CAM-focused offices or centers, designating CAM-focused staff positions, and creating CAM advisory committees or ensuring the representation of qualified CAM professionals on such committees.

### **Public and Private Research Funding for CAM Products That May Not Be Patentable**

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),<sup>1</sup> and the Cooperative Research and Development Agreement.<sup>2</sup> 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.

### **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 the combined role of mind, body, and spirituality 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<sup>3</sup> 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 patients' responses to conventional medical treatments.

Research in these areas, which converges with conventional behavioral and psychosocial research, may contribute in important ways to health care, particularly in rehabilitation and the management of chronic diseases and disorders, and merits increased public and private investment. Treatments, such as biofeedback, meditation, guided imagery, art therapy and music therapy, which appear to be effective but may not be profitable to private investors, should also receive Federal support. In addition, research on 1) the synergistic activities of complex compounds and mixtures frequently found in CAM products; 2) clinical interventions consisting of multiple, combined treatments; 3) how patient-practitioner interactions affect treatment outcomes; and 4) the individualization of treatments should be supported by the public, private, and nonprofit sectors. Traditional Chinese Medicine and Ayurvedic medicine are examples of systems of practice that target specific conditions and might provide interesting and worthwhile research avenues to follow in studying some of these areas.

### **Pluralism in Research Approaches and Quality in Research Methodology**

Various research approaches, if pertinent to the CAM question being asked, contribute to developing evidence of safety and clinical efficacy, understanding basic mechanisms of action underlying practices and products, and evaluating general effectiveness in the health-care system. Among these approaches are basic research, randomized controlled clinical trials, non-randomized studies, empirical observation, case studies, evaluations of practice-based data, and practice-based outcomes research. Also included are epidemiological and

surveillance studies, behavioral and quality-of-life studies, qualitative research, systematic reviews and meta-analyses, cost-effectiveness and cost-benefit studies, population and utilization studies, studies on health care delivery, and health care demonstration projects on various aspects of CAM use and services. To be methodologically sound, CAM studies must have a clear question (hypothesis), a sound study design, a qualified and appropriately constituted research team, objective and 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 many clinical questions. Because of the complexity and uniqueness of illness and CAM approaches to illness, it may be necessary to adapt clinical trial methodology, in a flexible, 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 question and design and the overall research strategy.

It is important to note that investigators in conventional clinical research have also adapted methodology and design to meet the needs of a study. Scientists have always followed their 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.<sup>4</sup> 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.<sup>5</sup> 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-related issues and 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.

### **Exploring Whole Systems Concepts and Expanding Areas of Scientific Inquiry**

In addition to the primary task of identifying practices and products that could become complementary to conventional care or possibly alternative treatments,

CAM research may go beyond isolated treatments and contribute innovative ideas to emerging areas of science 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, Latin American and Caribbean medicine, 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 objective measurements used in research. 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.

### **Moving Non-approved Treatments to Clinical Investigation**

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, in addition to Federal requirements concerning research, all CAM and conventional practitioners, whether or not they are engaged in research, must meet whatever State practice requirements or standards govern their authorization to practice.

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 collaborate with expert researchers in evaluating their observations and in designing and implementing clinical studies.

To help implement and accelerate the process, NIH and other Federal agencies, as appropriate, should 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 could 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 outcomes data on promising complementary and 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, with letters, and at meetings. 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. NCCAM has also explored a pilot project with the Centers for Disease Control and Prevention to develop methods for identifying practitioners who have data on new therapies and to 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 existing 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.

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

**Actions**

- 1.1 Federal agencies should increase their activities with respect to CAM in accordance with their biomedical research, health services research, or other health care-related responsibilities and communicate to CAM and conventional researchers and practitioners about these activities, including available technical assistance. Activities might include funding initiatives such as requests for applications and proposals, CAM-focused offices or centers, CAM-focused staff positions, CAM advisory committees or the representation of qualified CAM professionals on such committees.
- 1.2 Federal agencies should assess the scientific, clinical practice, and public needs regarding CAM that are relative to their missions, examine their portfolios, and develop funding strategies to address these needs.
- 1.3 The Agency for Health Care Research and Quality together with NCCAM should develop ways to expand health services research in CAM and explore methodologies for health services research in this area.
- 1.4 The Federal, private, and nonprofit sectors should support more research on 1) the synergistic activities of complex compounds and mixtures frequently found in CAM products, 2) clinical interventions consisting of multiple, combined treatments, 3) how patient-practitioner interactions affect treatment outcomes, and 4) the individualization of treatments.
- 1.5 In order to protect public health and maximize benefits, Congress should provide adequate public funding for research on frequently used or promising CAM products that would be unlikely to receive private research support.
- 1.6 The Federal government should support research on CAM practices that appear to be effective but may not be profitable to private investors, such as biofeedback, meditation, guided imagery, art therapy, and music therapy.

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**Recommendation 2: Congress and the Administration should consider legislative and administrative incentives to stimulate private sector investment on research on CAM 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 improving the quality of CAM products.

- 2.2 The Federal and private sectors should provide support for workshops to discuss the research needed by regulatory agencies for the 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 agencies can assist them.

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

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

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#### **Actions**

- 4.1 NCCAM, assisted by the Institute of Medicine, should develop guidelines for establishing research priorities in CAM, and address the issue of definition to facilitate the allocation of resources.
- 4.2 The National Science Foundation, in collaboration with NCCAM, should examine areas of science associated with CAM that are outside the current research paradigm and methodological approaches to study them.
- 4.3 Multidisciplinary workshops and expert panels should be convened by Federal, private, and nonprofit organizations, collaboratively or independently, to explore the challenges in design and methodology presented by research questions in CAM areas that are outside the current research paradigm.
- 4.4 The National Institute of General Medical Sciences of the NIH, the Department of Energy, and the Department of Defense are among the Federal organizations that should consider contributing collaboratively or independently to the support of research on core questions in areas described in many CAM systems.
- 4.5 NCCAM, working with the World Health Organization, should examine investigative approaches for studying the traditional systems of medical practice of a variety of cultures.

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

**Actions**

- 5.1 Licensed practitioners using CAM systems and modalities who wish to conduct or collaborate in clinical research should be subject to the same requirements as conventional medical researchers. They should develop, or collaborate 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 in using 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 and NIH and other Federal research and health-care agencies should be more proactive in developing programs that 1) provide opportunities for expert review by experienced researchers of promising CAM practice-based observational data, 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.

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**Recommendation 6: The Commission recommends that State professional regulatory bodies include language in their guidelines stating that licensed, certified, or otherwise authorized practitioners who are engaged in research on CAM will not be sanctioned solely because they are engaged in such research if they: 1) are engaged in well-designed research that is approved by an appropriately constituted IRB, 2) are following the requirements for the protection of human subjects, and 3) are meeting their professional and ethical responsibilities. All CAM and conventional practitioners, whether or not they are engaged in research, must meet whatever State practice requirements or standards govern their authorization to practice.**

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## **Dialogue, Partnerships, and Public Input**

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### **Emerging Dialogue and Collaboration between CAM and Conventional Medicine**

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 study CAM and experiment with its inclusion in health care.<sup>5</sup> This gradual change, which presents an exciting and hopeful prospect for meaningful collaborations, is 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 who use CAM value both CAM and conventional approaches.<sup>6</sup> The goal of integrative medicine is to identify the most appropriate treatments available from a broad spectrum of evidence-supported care.<sup>7</sup> 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 collaboration between 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.

### **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. The Commission's position is 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.

### **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 conventional medical, allied health, 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 health care system.

To be most effective, CAM and conventional researchers, clinicians, 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 for 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 that have contributed to progress in CAM include the conference on "Exploring Opportunities for Collaboration with Industry" supported by NCCAM, the Josiah Macy, Jr. Foundation's "Conference on the 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,<sup>8</sup> 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.

### **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, *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.<sup>9</sup>

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 advisory councils, boards, and committees, Food and Drug Administration advisory committees, and IRBs<sup>10</sup>. 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. 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 NIH 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.<sup>11</sup> The collection of such information may in the future also offer a data source for research on consumer use of CAM. Because reliable information, including patient disclosure, is necessary to ensure 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.

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**Recommendation 7: Increased efforts should be made to strengthen the emerging dialogue among CAM and conventional medical allied health 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 existing knowledge about the use of CAM, IRBs should consider requiring that research subjects be asked about their use of herbal or other dietary supplements.
- 7.8 Federal agencies supporting biomedical and health services research should develop orientation and training programs for public representatives to enhance the effectiveness of their participation on advisory committees concerned with CAM.

### **Research Training and Infrastructure**

A strong research infrastructure is crucial to training skilled investigators 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 a long-term research capacity for training clinical investigators and health services researchers in CAM, and for training 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 Veterans 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.

Accredited CAM and conventional medical institutions might consider developing 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.

### **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. 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 outcomes measures, including social and biopsychological measures of health, and offer experience working as part of a multidisciplinary research team. The opportunity to gain solid training in a supportive environment on how to conduct quality research in CAM should continue to attract students from both CAM and conventional medicine who are interested in studying CAM questions. In addition, 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.

### **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 access to patients.

CAM research sites should be developed at public, private and accredited CAM institutions with both CAM-trained and conventional medical professionals serving on faculty or as consultants and with experienced researchers serving as mentors. Cooperation between CAM and conventional medical researchers and institutions and joint research grant applications can contribute to success in obtaining funding.

### **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 reviewed the role of CAM in the medical center and health system and is beginning to incorporate the study of CAM therapies into its research, clinical, research training and educational activities, including stimulating interdisciplinary collaboration.<sup>12</sup> Harvard University, Duke University, the University of Maryland, the University of Oregon, the 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 to 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 <sup>15</sup> CAM Specialty Centers of Research in collaboration with other NIH institutes and centers and the Office of Dietary Supplements. In addition to botanicals, the specialty 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 NCCAM offer research training opportunities. NCCAM and the other institutes and centers are encouraged to develop a cadre of well-trained CAM and conventional medical investigators in basic, clinical, or health services CAM research and to 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 inclusion of CAM in 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. <sup>13</sup> Also, the NIH

Loan Repayment Program is offered to individuals holding doctoral degrees who participate in clinical research. Among those who are eligible are, DCs, NDs, and OMDs.<sup>14</sup>

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

**Actions**

- 8.1 Funding should be made available to accredited CAM and conventional medical institutions to develop programs that examine CAM research questions and that stimulate cross-institutional collaborations involving faculty and students in research and research training.
  - 8.2 Funding should be made available to accredited CAM and conventional medical institutions to 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 for conducting clinical research and training on CAM and to examine the possibility of including CAM in the clinical setting.
  - 8.5 Federal support for career development awards should be increased, including awards 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

**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, side effects, and adverse interactions),

clinical efficacy, general effectiveness, and cost-effectiveness and cost-benefit analyses rather than 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.

### **Systematic Reviews**

Reviews of published research 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, especially their efforts to cooperate with one another, and their collaborations with NCCAM.

Efforts to increase the availability of concise and understandable summaries of the research literature for the public and other audiences through MedlinePlus and other dependable information sources should be supported. Examples 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*, which regularly updates information on clinical evidence.

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**Recommendation 9: Public and private resources should be used to support, conduct, and update systematic reviews of the peer-reviewed research literature on the safety, efficacy, and cost-benefits 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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## **Chapter 4: Education and Training of Health Care Practitioners**

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Since the public utilizes both conventional health care and complementary and alternative medicine (CAM), the Commission believes that this reality should be reflected in the education and training of all health practitioners. Thus, the education and training of conventional health professions 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.

Reaching this goal will require development of CAM faculty, curricula, and programs at both CAM and conventional institutions. Because of increased consumer demand for CAM services and products, national curricular elements should be established for CAM education and training. However, the Commission recognizes the barriers to and voluntary nature of such national curricular elements. An evaluation should be undertaken of whether postgraduate training should be established for appropriately educated and trained CAM practitioners. Continuing education programs should be developed for and required of all practitioners who provide CAM services and products. Finally, students of CAM want to participate in loan and scholarship programs, and it is important that this participation be evaluated.

**Recommendation 10: The education and training of CAM and conventional practitioners should be designed to ensure public safety, improve health, and increase the availability of qualified and knowledgeable CAM and conventional practitioners and enhance the collaboration among them.**

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### **Education in CAM for Conventional Health Care Professionals**

In 1995, a national conference on complementary and alternative therapy education recommended that CAM be included in nursing and medical education.<sup>1</sup> Although there has been notable progress in introducing CAM into medical, nursing, and other fields of conventional health care education in recent years, more needs to be done. For example, in 1997, 64 percent of allopathic medical schools reported offering elective courses in CAM or including such topics in required courses.<sup>2</sup> Data from all 125 allopathic medical schools in response to the 2000-2001 Liaison Committee on Medical Education Annual Medical School Questionnaire indicate that although no medical school requires a separate CAM course, 91 schools include CAM in required conventional medical courses, 64 offer CAM as stand-alone elective, and 32 include CAM as

part of an elective.\* Required and elective courses included acupuncture, herbal medicine, homeopathy, meditation, manual healing techniques, nutritional supplement therapy, and spirituality, according to the questionnaire. (Table 1).

In a study of an allopathic medical school with no formal or elective courses in CAM, third-year medical students were found to have insufficient knowledge about the safety of 10 common CAM modalities.<sup>3</sup> These modalities included massage therapy, herbal medicine, meditation, chiropractic, hypnosis, spiritual healing, acupuncture, homeopathy, reflexology, and naturopathy. The authors of this study recommended including CAM topics in the medical school curriculum to better prepare the practicing physician for soliciting information from patients about current CAM use, responding to patients' inquiries about CAM, and assessing the merit of introducing a CAM modality into, or removing it from patients' care plans.

Courses in CAM offered at conventional medical schools differ widely in content, format, and requirements.<sup>4</sup> In light of this variation, consensus needs to be reached on the essentials of a core curriculum.<sup>1</sup> In November 2000, the Josiah Macy, Jr. Foundation convened a conference to develop guidelines for teaching CAM in medical and other health professional schools. The participants concluded that efforts to expand knowledge about CAM should extend beyond the education of medical students to all conventional health professionals.<sup>5</sup> Addressing the myriad conventional health professions and programs will require a range of educational options.

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### **CAM Conventional Health Care Professions Curricula in**

While CAM can be taught in stand-alone courses, it may be more effectively and efficiently integrated into allopathic medical school curricula by combining it with current initiatives such as evidenced-based medicine, cultural competence, and interdisciplinary collaboration. CAM in medical education has evolved to the point where two fundamental questions need to be answered: What should be taught, and how should it be taught?

CAM taught in the context of conventional medical education should be evidence-based.<sup>6</sup> New educational programs for physicians need to be developed that include the conceptual basis of CAM practices, along with a critical review of the safety and efficacy of CAM practices and products. This information should be incorporated into required courses of medical school curricula and graduate training programs, not relegated to electives, whose content may not be critically evaluated.<sup>7</sup> While many CAM courses are taught from either an advocacy or neutral view, all CAM courses should be taught critically.<sup>8</sup>

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\* More than one response could be chosen, so the total number of responses does not equal the number of respondents.

Georgetown University School of Medicine plans to integrate CAM into the entire medical school curriculum as part of a recent grant from the National Institutes of Health's (NIH) National Center for Complementary and Alternative Medicine (NCCAM). Other innovative efforts to integrate CAM with existing medical school curricula are already underway; however, these efforts are geographically dispersed, not well known, and not systematically studied. They range from informal CAM seminars, such as brown bag lunches with CAM practitioners sponsored by student groups, to formal symposia or debates of controversial CAM issues by authorities with opposing views. While survey and other lecture courses are efficient ways of presenting a large volume of information, CAM is being integrated into a variety of courses. For example, information on acupuncture is being integrated into basic science courses, such as anatomy or physiology, as well as clinical courses, such as neurology, while herb-drug interactions are being included in pharmacology.

All of these methods of teaching about CAM offer opportunities to present the history, culture, and philosophy of CAM and training of CAM practitioners as well as a critical analysis of published research on its safety and effectiveness. They also provide opportunities to communicate effectively with CAM practitioners and discuss CAM comfortably and accurately with patients. However, these didactic opportunities can be coupled with opportunities to experience CAM personally, particularly mind-body approaches and stress management, as part of self-care. This is being done at the George Washington University Center for Integrative Medicine through a Department of Education Fund for Improvement of Post-Secondary Education grant. A cogent argument for including self-care in medical education is that the health and well-being of medical students has been so neglected that by the end of their training, they often feel drained of the compassion and spirit that drew them to medicine.<sup>9</sup> In addition, students who learn the fundamentals of self-care will be better able to teach their patients to care for themselves. Medical education should include opportunities to experience CAM approaches, such as meditation and relaxation therapy, for students who personally may benefit from these approaches during their stressful journey through medical school.

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### **Postgraduate and Continuing Education**

Although the Society of Teachers of Family Medicine has published suggested curriculum guidelines on CAM and recommended that CAM knowledge, skills, and attitudes be incorporated into family practice residency training,<sup>10</sup> very few postgraduate CAM training opportunities exist for physicians and other conventional health care providers. One of the most extensive postgraduate CAM training programs is at the University of Arizona. This two-year fellowship in integrative medicine is limited to four allopathic or osteopathic physicians per year who have completed residency training. To expand the availability of training in integrative medicine, the University of Arizona recently created an

associate fellowship program. Combining distributed-learning and on-site training, this two-year associate fellowship is available to 50 allopathic and osteopathic physicians and a small number of nurse practitioners per class at a cost of \$27,500 for the class entering in 2003.

Other postgraduate training opportunities are evolving. One is at The Continuum Center for Health and Healing at New York's Beth Israel Medical Center, which has developed not only a required rotation in integrative medicine for a family medicine residency, but also a two-year fellowship in integrative medicine. Even though the number of postgraduate training opportunities in CAM is very small indeed, there are more CAM postgraduate educational opportunities for physicians than for other conventional health care professionals.

The number of continuing education programs in CAM for conventional health professionals appears to be growing. This is an important trend, since continuing education is one of the chief means by which the current generation of conventional health professionals learns about CAM.

Despite these efforts and the creation of the Consortium of Academic Health Centers for Integrative Medicine, more needs to be done to move from discourse to implementation of CAM in the education, postgraduate training, and continuing education of not only allopathic physicians, but also osteopathic physicians, dentists, nurses, pharmacists, and all other conventional and allied health professions. A catalyst could be a conference or series of workshops facilitated by the Department of Health and Human Services (DHHS) and other Federal Departments and Agencies. These gatherings would bring together individuals and representatives of institutions, professional and accrediting organizations, and the Federal government who have been involved with recent and on-going efforts to develop core curricula of knowledge about CAM for conventional health professionals. The elements of these core curricula should be developed in conjunction with CAM experts and institutions and implemented in conventional health professional schools, postgraduate training programs, and continuing education programs. The core curricula, educational models, evaluations, recommendations, and other relevant information could be compiled and posted on the Internet at a variety of Federal and non-Federal websites, with links to related websites.

However, this strategy does not address the education and training needs of conventional health care students and providers who desire an integrative approach and wish to go beyond learning about CAM to learning how to provide CAM. This type of practice-oriented education and training in CAM should be obtained in appropriate conventional health care postgraduate training and continuing education and at CAM institutions.

The challenges to developing core curricula of knowledge about CAM for conventional health professional schools, postgraduate training programs, and continuing education programs include:

- Professional, organizational, and institutional difficulty changing,
- Lack of funding,
- Provision of adequate incentives to adopt these curricula,
- Logistical design, development, and implementation issues,
- Consensus on curricula,
- Availability of adequately trained faculty and faculty development, and
- Limited ability to add to already very full curricula.

### **Action**

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

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### **Education in Conventional Health Care for CAM Practitioners**

CAM education should be a symmetrical process. That is, the education and training of CAM practitioners should include exposure to conventional health care and its related sciences just as the education and training of conventional health professionals should include CAM.<sup>11</sup> CAM students should attain basic competency in the biomedical sciences and understand the components and functions of the conventional health care system, including public health. This foundation should be augmented by an evidence-based approach to education and training to achieve minimal competency in interpreting CAM and conventional literature and critiquing CAM research, particularly clinical trials.

The core curriculum for CAM students should include clinical competencies such as medical record keeping, knowledge of medico-legal aspects of care, practice in a referral environment, collaboration with conventional providers, and communication within a health care team. Students should learn to recognize the limits of their clinical expertise as well as potential complications of CAM interventions, the circumstances under which patients or clients should be referred to conventional health care providers, and the means of doing so. Additional competencies should include a basic knowledge of other CAM systems, modalities, practices, and approaches as well as when and how to refer patients or clients to those CAM practitioners.

The elements that should be contained in the core curriculum for CAM education and training and the best methods of incorporating them into existing curricula could be determined by conferences facilitated by DHHS and other Federal

Departments and Agencies or by a series of demonstration projects conducted at representative CAM education and training programs. These demonstration projects could be supported, for example, by NCCAM, Health Resources and Services Administration's (HRSA) Bureau of Health Professions (BHP), the Department of Education, foundations, and innovative partnerships. Since these two approaches are not mutually exclusive, both conferences and demonstration projects could be undertaken, if adequate funding were available. These models, evaluation results, and recommendations should be compiled and made available through several sources, including the Internet.

The challenges to developing a core curriculum about conventional health care for CAM education include:

- Professional, organizational, and institutional difficulty changing,
- Lack of funding,
- Provision of adequate incentives to adopt curriculum,
- Logistical design, development, and implementation issues,
- Consensus on curriculum,
- Availability of adequately trained faculty and faculty development, and
- Limited ability to add to already very full CAM curricula.

#### **Action**

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

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#### **Communication and Collaboration between CAM and Conventional Health Care Professionals**

The language of biomedicine is currently as foreign to many CAM professionals as much of CAM terminology is to conventional health care professionals. Therefore, commonality of language should be the initial focus of improving communication between CAM and conventional health care professionals, and it should begin in CAM education and training programs. Minimal fluency in biomedical language should be foremost in a core biomedical curriculum for CAM education and training programs.

CAM organizations could be the point of contact for conventional institutions seeking CAM practitioners to teach CAM courses and provide relevant examples of practice. These organizations also could help locate CAM practitioners to participate in CAM research projects conducted at conventional institutions. At the organizational level, joint conferences could be held between CAM and conventional organizations representing students, practitioners, researchers, educators, or institutions.

The challenges to attaining and improving communication and collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations include:

- Achieving consensus on biomedical fluency and other educational strategies,
- Professional, organizational, and institutional difficulty changing,
- Securing sufficient funding,
- Designing, developing, and implementing logistics involved with joint activities, and
- Providing adequate incentives to improve communication and collaboration.

### **Action**

10.3 CAM and conventional education and training programs should develop curricula and other methods to facilitate communication and foster collaboration between CAM and conventional students, practitioners, researchers, educators, institutions and organizations.

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### **Increased Support for CAM Faculty, Curricula, and Program Development**

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. This, in turn, could translate into more skilled practitioners, improved CAM services, and greater patient satisfaction and safety. Although CAM faculty, curricula, and program development can be regarded as a continuum, faculty development is the most important and pragmatic point at which to begin. Faculty development is not only absolutely essential for any educational improvement, but also the cornerstone of CAM education and improved training at CAM and conventional institutions. However, the current, limited funding for this purpose appears to be directed toward only a small number of curricula and program development projects at largely conventional institutions.

The type of faculty development needed by CAM and conventional institutions may be different and may vary from institution to institution. For conventional institutions, it can include providing experience in CAM systems, modalities, and therapies; teaching faculty how to collaborate with CAM practitioners and educators; and instructing them how and what to teach about CAM. For CAM institutions, faculty development can include how to teach using evidence-based, problem-based, and competency-based approaches and other educational techniques appropriate for their students and how to collaborate with conventional providers and educators.

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\* 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

CAM programs at conventional health care institutions could encompass a variety of activities, including the development of CAM, integrative health, or integrative medicine clinics or centers, integrative medicine residencies and fellowships, and CAM research programs. These clinics or centers can be sites for student clinical rotations, residency and fellowship training, and clinical research and research training, particularly health services research. Juxtaposing CAM education, training, and research with conventional approaches can focus CAM research on clinically relevant topics, improve the quality of research, especially that conducted by CAM practitioners, and link CAM research with evidence-based education and training. This juxtaposition is essential for acceptance of CAM by evidenced-based conventional health care.

Because CAM institutions are more heterogeneous than conventional institutions, the program needs of CAM institutions are significantly more varied. Although CAM institutions ought to be able to pursue support of their unique program needs, some CAM institutions may be more successful by forming partnerships with conventional institutions to undertake joint activities and programs. Examples of successful partnerships between CAM and conventional institutions include the Bastyr University and University of Washington and the National College of Naturopathic Medicine and the Oregon Health Sciences University.

According to the available data, most support from NCCAM for education and training has been given to conventional institutions.\* Between fiscal years 2000 and 2001, 10 CAM Education Project Grants (R25) were made by NCCAM to accelerate the development, refinement and expansion of innovative educational approaches to incorporate CAM into medical, dental, nursing, and allied health professional school curricula, into residency training programs, and into continuing education courses. Grant recipients in 2000 were the Boston's Children's Hospital, the University of North Carolina - Chapel Hill, the University of Minnesota - Twin Cities, the Rush-Presbyterian - St. Luke Medical Center, and the University of Texas Medical Branch-Galveston. Recipients in 2001 were the Maine Medical Center, the Georgetown University School of Medicine, the Tufts University School of Medicine, the University of Michigan School of Medicine, and University of Washington School of Medicine/Bastyr University. It is important to note that NCCAM is considering a similar program for CAM institutions, but this program has not gone through the concept clearance process.

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\* NCCAM established the CAM Education Project Grant (PAR-00-027) in response to Public Law 105-277, which mandated that the director of NCCAM "study the integration of alternative treatment, diagnostic and preventive systems, modalities, and disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States."

Limited support of CAM training and education programs also has been provided by BHP. The Bureau's Division of Nursing has funded three graduate programs that contain content on CAM, as well as the Chiropractic Demonstration Project Grants Program. The latter supports research projects in which chiropractors and physicians collaborate to identify and provide effective treatment for spinal and low-back conditions. All of the BHP education and training programs are established legislatively through Titles VII and VIII of the Public Health Service Act. These programs are directed toward specific health disciplines delineated in the legislation and allow very little, if any, latitude in allocation of funds. Currently, chiropractic research is the only BHP CAM activity that is legislatively authorized.

Both NCCAM and BHP examples illustrate how legislation drives funding of CAM education and training. Therefore, it ultimately may be necessary to pass new legislation or amend current legislation to support CAM education and training. Before that can be done, however, it is necessary to identify effective CAM education and training strategies and programs. This can be accomplished through a series of demonstration projects for CAM faculty, curricula, and program development at accredited CAM and conventional institutions and subsequent evaluation of the various models and publication of the findings in print and on-line.

Since faculty, curricula, and program development at both CAM and conventional institutions can benefit from collaborations and the economies of scale they provide, collaboration should be an essential element of these demonstration projects. Wherever possible, joint demonstration projects should be undertaken to take full advantage of combining programs and sharing faculty, expertise, facilities, and resources.

Additional sources of funding sources for CAM education and training need to be found. It may be possible to obtain funding from other NIH institutes and Federal Agencies, such as the Centers for Disease Control and Prevention, Agency for Health Care Quality and Research, and Department of Education. Funding from states, foundations, and other public and private sources should be explored also.

Bringing funding sources together with organizations such as the Association of American Medical Colleges, the American Association Colleges of Osteopathic Medicine, the American Dental Education Association, the American Association of Colleges of Nursing, the Association of Schools of Allied Health Professions, the Association of Schools of Public Health and comparable CAM organizations can help in identifying programs, faculty, resources, and opportunities to improve CAM education and training. Identification of funding sources, collaboration between funding sources and organizations, and development of selection criteria for competitive awards for CAM faculty, curricula, and program