White House Commission on Complementary and Alternative Medicine Policy

FINAL REPORT

March 2002

Table of Contents

Transmittal Letters

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

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.
Executive Director
White House Commission on
Complementary
and Alternative Medicine Policy

Commission Members

CHAIRPERSON

James S. Gordon, M.D.
Director
The Center for Mind-Body Medicine
2934 Macomb Street, N.W.
Washington, DC 20008

COMMISSIONERS

George M. Bernier, Jr., M.D.
Vice President for Education
University of Texas Medical Branch
301 University Boulevard, Suite 1.116
Galveston, Texas 77555-0113

David Bresler, Ph.D, LAc, OME,
Dipl.Ac. (NCCAOM)
Founder and Executive Director
The Bresler Center, Inc.
30765 Pacific Coast Hwy #355
Malibu, California 90265

Thomas Chappell
Co-Founder and President
Tom's of Maine, Inc.
P.O. Box 710
Kennebunk, Maine 04043

Effie Poy Yew Chow, Ph.D., R.N.
DiplAc(NCCAOM), Qigong Grandmaster
President, East West Academy of
Healing Arts
117 Topaz Way
San Francisco, California 94131

George T. DeVries, III
Chairman, President & CEO
American Specialty Health
777 Front Street
San Diego, California 92101

William R. Fair, M.D.
Attending Surgeon, Urology (Emeritus)
Memorial Sloan-Kettering Cancer Center
435 L'Ambiance Drive, #806
Longboat Key, Florida 34228

Joseph J. Fins, M.D., F.A.C.P.
Associate Professor of Medicine
Weill Medical College of Cornell University
Director of Medical Ethics
New York Presbyterian Hospital-Cornell Campus
525 East 68th Street, F-173
New York, New York 10021

Veronica Gutierrez, D.C.
Gutierrez Family Chiropractic
3704 172nd Street, NE-Suite N
Arlington, Washington 98223

Wayne B. Jonas, M.D.
Department of Family Medicine
Uniformed Services University of the
Health Sciences
4301 Jones Bridge Road
Bethesda, Maryland 20814-4799

Charlotte R. Kerr, R.S.M.
Traditional Acupuncture Institute, Inc.
American City Building
10227 Wincopin Circle, Suite 100
Columbia, Maryland 21044

Linnea Signe Larson, LCSW, LMFT
455 Washington Blvd.
Oak Park, Illinois 60302

Tieraona Low Dog, M.D., A.H.G.
4840 Pan American Freeway, N.E.
Albuquerque, New Mexico 87109

Dean Ornish, M.D.
President and Director
Preventive Medicine Research Institute
Clinical Professor of Medicine

Deceased

University of California, San Francisco
900 Bridgeway, Suite 2
Sausalito, California 94965

Conchita M. Paz, M.D.
1510 Altura Avenue
Las Cruces, New Mexico 88001

Joseph E. Pizzorno, Jr., N.D.
President Emeritus, Bastyr University
14500 Juanita Drive, N.E.
Kenmore, WA 98028-4966

Buford L. Rolin
Poarch Band of Creek Indians
308 Forest Avenue
P.O. Box 19
Atmore, Alabama 36504

Julia Scot, R.N.
1306 Palmyra Lane
Bowie, MD 20716

Xiaoming Tian, M.D., L.Ac
Director, Wildwood Acupuncture Center
Director, Academy of Acupuncture & Chinese Medicine
Wildwood Medical Center
Bethesda, Maryland 20814

Donald W. Warren, D.D.S.
Diplomate of the American Board of Head, Neck & Facial Pain
390 Factory Road
Clinton, Arkansas 72031

EXECUTIVE STAFF

White House Commission on Complementary
and Alternative Medicine Policy
6707 Democracy Boulevard
Room 880, MSC-5467
Bethesda, Maryland 20817-5467

Stephen C. Groft, Pharm.D.
Executive Director

Michele M. Chang, C.M.T., M.P.H.

Executive Secretary

Corinne Axelrod, M.P.H., L.Ac., Dipl.Ac
Senior Program Analyst

Joseph M. Kaczmarczyk, D.O., M.P.H.
Senior Medical Advisor

Geraldine B. Pollen, M.A.
Senior Program Analyst

Doris A. Kingsbury
Program Assistant

Joan Albrecht
Program Assistant

CONSULTANT STAFF
Kenneth D. Fisher, Ph.D.
Senior Scientific Advisor

Maureen Miller, RN, MPH
Senior Policy Analyst

James Swyers, M.A.
Writer-Editor

Commission's website: whccamp.hhs.gov

Chairman's Vision

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

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 additional, more information is needed on what constitutes "appropriate access" to CAM services.

A few community health centers have begun to use the services of CAM practitioners, such as chiropractors, naturopathic physicians, and acupuncturists. These centers might provide models for other community health centers and public health service programs, but first their impact on access to care and the cost-benefit picture needs to be determined. Hospice care for the terminally ill is

another important model of care that should be evaluated. Some hospice programs are beginning to include CAM practitioners on the treatment team. The Federal government should support demonstration projects that integrate safe and effective CAM services into the health care programs of hospices and community health centers.

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

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

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

Ensuring CAM Practitioners' Accountability to the Public

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

Nationally recognized accrediting bodies should evaluate how health care organizations are using CAM practices and develop strategies for the safe and

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

Coverage and Reimbursement

The coverage and reimbursement policies of public and private organizations that pay for, provide, or insure conventional health care services have played a crucial role in shaping the health care system-and they will play an increasingly important role in determining the future of CAM and its place in the nation's health care system

Coverage of CAM services and products varies among purchasers of health plans, but employer-sponsored plans appear more likely than others to offer them. These plans generally offer a chiropractic benefit, and a growing number cover acupuncture and massage therapy. When offered, CAM coverage often places a ceiling on the number of visits, restricts the clinical applications, and specifies the qualifications of the practitioner. Typically, CAM is offered as a supplemental benefit rather than as a core or basic benefit. Benefit designs also include discount programs, in which covered individuals pay reduced fees for services provided by a network of CAM practitioners, and annual benefit accounts against which services may be purchased.

Barriers to Coverage

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

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

To conduct health services research, investigators need data from claim and encounter forms, specifically data coded using nationally accepted, standardized systems. National coding systems such as Common Procedure Terminology recognize some CAM interventions, but they are currently limited in scope and specificity. More recently, a coding system for CAM procedures, services, and products-ABCcodes-has been developed and is being used in a number of settings. The National Committee for Vital and Health Statistics and DHHS should authorize a national coding system that supports standardized data on CAM for use in clinical and health services research. In addition, the coding system should support practitioners and insurers who cover CAM services in complying with the electronic claims requirements of the Health Insurance Portability and Accountability Act.

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

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

Criteria for Using CAM

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

to guide changes in health plan coverage for safe and effective CAM services and products and to develop criteria for use of CAM interventions. Purchasers, health insurers, and managed care organizations will need CAM expertise when developing changes in coverage and reimbursement policies that involve CAM. CAM practitioners and experts should be included on advisory bodies and work groups considering CAM benefits and other appropriate health benefit issues.

CAM in Wellness and Health Promotion

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

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

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

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

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

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

Wellness and Health Promotion in Programs for Special and Vulnerable Populations

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

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

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

The Secretary of Health and Human Services should bring together public and private health care organizations to evaluate the contribution of safe and effective CAM practices and products to wellness and health and to determine how they may be used in health systems and programs, especially in the nation's hospitals

and long-term care facilities and in programs serving the aged, persons with chronic illness, and those at the end of life.
CAM and conventional health professional training programs should offer students training and education in self-care and lifestyle decision-making, both to improve practitioners' health and to enable them to impart this knowledge to their patients or clients.

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

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

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

Chapter 1: Introduction

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

Until recently, the primary response of Federal, state, and local health care regulatory agencies to this phenomenon was to restrict access to and delivery of CAM services to protect the public from unproven and potentially dangerous treatments. Since the early 1990s, however, 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 the National Academy of Sciences' Institute of Medicine (IOM) report on ways to improve health care in the 21st century (see Appendix B). That report, ***Crossing the Quality Chasm: A New Health System for the 21st Century***, found that the nation's health care industry has "foundered" in its ability to provide safe, high-quality care consistently to all Americans, but particularly to those with chronic conditions.[3] The IOM report 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***.[4] The two overarching goals of ***Healthy People 2010*** are to: 1) increase quality and years of healthy life, and 2) eliminate disparities in access to health care. ***Healthy People 2010*** enumerates 28 focus areas to which these two overarching goals are to be applied. Among these 28 focus areas are several that are 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 heath 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."[5] 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.

References:

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

2. Eisenberg DM, Davis RB, Ettner SL, Appel S, et al. Trends in alternative medicine use in the United States. Journal of the American Medical Association. 1998;280:1569-1575.

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

4. U.S. Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. (2nd ed. 2 vol). Washington, D.C.: U.S. Government Printing Office, 2000.

5. Angell, M, Kassirer,JP. Alternative Medicine-The Risks of Untested and Unregulated Remedies. New England Journal of Medicine. 1998;339:839-841.

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

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 Chiropractic Homeopathic medicine Native American medicine (e.g., sweat lodge, medicine wheel) Naturopathic medicine Traditional Chinese Medicine (e.g., acupuncture, Chinese herbal medicine)

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

Major Domains of CAM	Examples Under Each Domain
Mind-Body interventions	Meditation Hypnosis Guided imagery Dance therapy Music therapy Art therapy Prayer and mental healing
Biological based therapies	Herbal therapies Special diets (e.g. macrobiotics, extremely low-fat or high carbohydrate diets) Orthomolecular medicine (e.g., megavitamin therapy) Individual biological therapies (e.g., shark cartilage, bee pollen)
Therapeutic Massage, Body Work, and Somatic Movement Therapies	Massage Feldenkrais Alexander Method
Energy Therapies	Qigong Reiki Therapeutic Touch
Bioelectromagnetics	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.[1]

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.[2]

Mainstream or conventional health care also has long-recognized that good nutrition and exercise are important components of a healthy lifestyle.[3, 4] 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.[5, 6]

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," [7] and a survey by Cooksey et al.[8] 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 dieticians 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,[9] 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[10]. 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.[11,12] 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.[13,14] 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.[15,16]

A more recent and detailed survey conducted by Astin[17] 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.[18-20]

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.[21] This revolution culminated with the release of a report by Abraham Flexner in 1910[22] 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.[21]Schools for many unorthodox healing systems either ceased to exist or became marginalized.[20]

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,

---

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.[23] 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.[24] 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.[25] 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.[20] 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.[26] It gained its greatest

following among nurses.[27] 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.[28, 29] 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.[30]

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 Unites 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.[31-36] 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.[37]

Another survey of almost 2,000 tumor registry patients selected at random found that 75 percent had used at least one CAM modality.[38] 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.[39] 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.[40] 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[17] 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.[41,42] 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[43] 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.[44] 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.[13, 45]

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).[46] 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.[47] 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.[48,49] 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[50] and are also frequent users of herbal remedies, spiritual healing techniques, and traditional healers.[51] Income, not belief systems, prohibits interaction with traditional healers by Native Americans.[51]

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.[16] 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.[17, 52, 53]

Although Astin's survey[17] 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,[44] 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 to seeking CAM therapies was that patients believed they would work.[54] 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.[55] 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.[56] 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[57] 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.[58]

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,[59] and in many states CAM professions have faced strong opposition from conventional health care organizations in gaining licensing from state regulatory agencies.[60]

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[61]
- Acupuncture in the management of low back pain and recurrent headaches [62,63]
- St John's Wort for treating mild to moderate depression[64]
- Herbal and glucosamine therapy for treating osteoarthritis,[65,66] and
- Nutritional supplements for several neurological conditions [67,68]

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.[69] 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.[70]

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.[71]

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.[72] 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.[20]

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. [73, 74]

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.[75] 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.[54] 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[76] 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.[77]

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.[58]

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.[78]

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,[79] 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.[80]

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.[81,82] 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.[20]

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,[10] to having to physician-centered models, where CAM practitioners provide services independently but under the supervision of a primary or a specialty care physician.[83] 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.

References:

1. House of Lords. Science and Technology - Sixth Report. London: Science and Technology Committee Publications, 2000.

2. Moore SR.125 years of public health in the USA. Journal of the Royal Society of Health 2001;121(4):262-267.

3. Exercise. Staying physically active is essential to good health. Harvard Health Letter. 2001;27(1):6-7.

4. Russell RM. Nutrition. Journal of the American Medical Association 1994;271(21):1687-1689.
5. American Association of Medical Colleges. Contemporary Issues in Medicine: Communication in Medicine. Medical Schools Objectives Project Report III (MSOP III). Washington D.C.: American Association of Medical Colleges, 1999.

6. Carroll D, Sheffield D. Social psychophysiology, social circumstances, and health. Annals of Behavioral Medicine 1998;20(4):333-337.

7. Nutrition Education Consortium. Bringing physician nutrition specialists into the mainstream: rationale for the Intersociety Professional. American Journal of Clinical Nutrition 1997;65: 568-571.

8. Cooksey K, Kohlmeier M, Plaisted C, Adams K, et al. Getting nutrition education into medical schools: a computer-based approach. American Journal of Clinical Nutrition 2000; 71(5):1048-1053.

9. Gordon RJ, Nienstedt BC, Gesler WM (eds). Alternative Therapies: Expanding Options in Health Care. Springer Publishing Company, 1998.

10. Muscat, M. Beth Israel's Center for Health and Healing: Realizing the Goal of Fully Integrative Care. Alternative Thearapies in Health and Medicine 2000; 6(5):100-101.

11. Furnham A, Smith C. Choosing alternative medicine: A comparison of the beliefs of patients visiting a general practitioner and a homoeopath. Social Science and Medicine 1988;26(7):685-689.

12. Murray J, Shepherd S. Alternative or additional medicine? A new dilemma for the doctor. Journal of the Royal College of General Practice 1988;38(316):511-514.

13. Eisenberg DM, Kessler RC, Foster C, et al. Unconventional medicine in the United States: Prevalence, costs, and patterns of use. New England Journal

of Medicine 1993;328:246-252.

14. Lerner IJ, Kennedy BJ. The prevalence of questionable methods of cancer treatment in the United States. CA- A Cancer Journal for Clinicians 1992;42(3):181-191.

15. Ernst E. Complementary medicine: Common misconceptions. Journal of the Royal Society of Medicine 1995;88(5):244-247.

16. Joyce CR . Placebo and complementary medicine. Lancet 1994;344(8932):1279-1281.

17. Astin JA. Why patients use alternative medicine: Results of a national study. Journal of the American Medical Association 1998;279: 1548-1553.

18. Kaufman M. American Medical Education: The Formative Years, 1765-1910. Westport, Ct: Greenwood Press, 1971.

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

20. Whorton JC. The history of complementary and alternative medicine. In Jonas WB, Levin JS (eds.). The Essentials of Complementary and Alternative Medicine. Philadelphia: Lippincott Williams & Wilkins, 1999.

21. Edelson PJ. Adopting Osler's Principles: Medical textbooks in American medical schools, 1891-1906. Bulletin of the History of Medicine 1994;68:67-84.

22. King LS. The Flexnor Report of 1910. Journal of the American Medical Association 1984;251(8):1079-1086.

23. Health Care Financing Administration, Office of the Actuary. National Health Expenditure Projections 2000-2010 (Published March 2001). Available at: http://www.hcfa.gov/stats.

24. Berliner HS, Salmon JW. The holistic alternative to scientific medicine: History and analysis. International Journal of Health Services 1980;10:133-147.

25. Reston J. Now, let me tell you about my appendectomy in Peking. The New York Times, July 26, 1971.

26. Lowenberg JS. Caring and Responsibility: The Crossroads Between Holistic Practice and Traditional Medicine. Philadelphia: University of Pennsylvania Press, 1989.

27. Boschma G. The meaning of holism in nursing: historical shifts in holistic nursing ideas. Public Health Nursing 1994;11(5):324-330.

28. DeFriese GH, Woomert A, Guild PA, Steckler AB, et al. From activated patient to pacified activist: A study of the self-care movement in the United States. Social Science and Medicine 1989;29(2):195-204.

29. Kickbusch I. Self-care in health promotion. Social Science and Medicine 1989;29(2):125-130.

30. Goldstein MS. The culture of fitness and the growth of CAM. In: Kelner M, Wellman K (eds.), Complementary and Alternative Medicine: Challenge and Change. Canada:Harwood Academic Publishers, 2000.

31. Deyo RA. Practice variations, treatment fads, and rising disability. Spine 1993;18(15), 2153.

32. Deyo, RA. Effectiveness of treatment strategies for low back pain : final report. Rockville, MD: Agency for Health Care Policy and Research. 1999.

33. Frymoyer JW, Hanley E, Howe J, Kuhlmann D, et al. Disc excision and spine fusion in the management of lumbar disc disease. Spine 1978;3(1):1-6.

34. Frymoyer JW, Cats-Baril WL. An overview of the incidences and costs of low back pain. Orthopedic Clinics of North America 1991:22(2): 263-271.

35. Waddell G, Kummel EG, Lotto WN, et al. Failed lumbar disc surgery and repeat surgery following industrial injuries. Journal of Bone and Joint Surgery 1979;61: 210-235.

36. Waddell G: A new clinical model for the treatment of low-back pain. Spine 1987;12(7): 632.

37. Richardson MA, Sanders T, Palmer JL, Greisinger A, et al. Complementary/alternative medicine use in a comprehensive cancer center and the implications for oncology. Journal of Clinical Oncology 2000;18(13):2501-2504.

38. Morris KT, Johnson N, Homer L, Walts D. A comparison of complementary therapy use between breast cancer patients and patients with other primary tumor sites. American Journal of Surgery 2000;179(5):407-411.

39. Sparber A, Bauer L, Curt G, Eisenberg D, et al. Use of complementary medicine by adult patients participating in cancer clinical trials. Oncology Nursing Forum 2000;27(4):623-630.

40. Lippert MC, McClain R, Boyd JC, Theodorescu D. Alternative medicine use in patients with localized prostate carcinoma treated with curative intent. Cancer. 1999 Dec 15;86(12):2642-2648.

41. Shekelle PG, Markovich M, Louie R. An epidemiologic study of episodes of back pain care. Spine 1995; 20(15):1668-1673.

42. Shekelle PG, Markovich M, Louie R. Factors associated with choosing a chiropractor for episodes of back pain care. Medical Care 1995;33(8):842-850.

43. Krauss HH, Godfrey C, Kirk J, Eisenberg DM. Alternative health care: Its use by individuals with physical disabilities. Archives of Physical Medicine and Rehabilitation 1998 Nov;79(11):1440-1447.

44. Rao JK, Mihaliak K, Kroenke K, Bradley J, et all. Use of complementary therapies for arthritis among patients of rheumatologists. Annals of Internal Medicine 1999;131:409-416.

45. Eisenberg DM, Davis RB, Ettner SL, Appel S, et al. Trends in alternative medicine use in the United States. Journal of the American Medical Association 1998;280:1569-1675.

46. Standish LJ, Greene KB, Bain S, Reeves C, et al. Alternative medicine use in HIV-positive men and women: demographics, utilization patterns and health status. AIDS Care 2001;13(2):197-208.

47. Fairfield KM, Eisenberg DM, Davis RB, Libman H, et al. Patterns of use, expenditures, and perceived efficacy of complementary and alternative therapies in HIV-infected patients. Archives of Internal Medicine 1998;158:2257-2264.

48. Keegan L. Use of alternative therapies among Mexican Americans in the Texas Rio Grande Valley. Journal of Holistic Nursing 1996;14:277?299.

49. Zaldivar A, Smolowitz J. Perceptions of the importance placed on religion and folk medicine by non-Mexican-American Hispanic adults with diabetes. Diabetes Education 1994; 20:303-306.

50. Kim C, Kwok VS. Navajo use of native healers. Archives of Internal Medicine 1998;158:2245-2249.

51. Marbella AM, Harris MC, Diehr S. Ignace C. Use of Native American healers among Native American patients in an urban Native American health center. Archives of Family Medicine 1998:7:182-185.

52. Eliason BC, Huebner J, Marchand L. What physicians can learn from consumers of dietary supplements. Journal of Family Practice 1999; 48(6):459-463.

53. Wagner PJ, Jester D, LeClair B, Taylor AT, et al. Taking the edge off: why patients choose St. John's Wort. Journal of Family Practice 1999 Aug; 48(8):615-619.

54. Elder NC, Gillerist A, Mina R. Use of alternative health care by family practice patients. Archives of Family Medicine 1997;6:1131-1134.

55. Palinkas LA, Kabongo ML.The use of complementary and alternative medicine by primary care patients. A SURF*NET study. Journal of Family Practice 2000;49(12):1121-1130.

56. Astin JA, Marie A, Pelletier KR, Hansen E, et al. A review of the incorporation of complementary and alternative medicine by mainstream physicians. Archives Internal Medicine 1998;158(21):2303-2310.

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

58. Wetzel MS, Eisenberg DM, Kaptchuck TJ. Courses involving complementary and alternative medicine at US medical schools. Journal of the American Medical Association 1998; 280:784-787.

59. Berg RN. AMA enjoined from boycotting chiropractors. Journal of the Medical Association of Georgia 1990 Jun;79(6):391-393.

60. Baer HA. The sociopolitical status of U.S. naturopathy at the dawn of the 21st century. Medical Anthropology Quarterly 2001;15(3):329-346.

61. Hooper L, Summerbell CD, Higgins JPT, Thompson RL, et al. Reduced or modified dietary fat for preventing cardiovascular disease. Cochrane Database Systematic Review. 2000; (2):CD0002137. Available at: http://www.update-software.com/cochrane.

62. van Tulder MW, Cherkin DC, Berman B, Lao L, et al. The effectiveness of acupuncture in the management of acute and chronic low back pain. A systematic review within the framework of the Cochrane Collaboration Back Review Group. Spine 1999;24(11):1113?1123.

63. Melchart D, Linde K, Fischer P, White A, et al. Acupuncture for recurrent headaches: a systematic review of randomized controlled trials. Cephalalgia

1999 Nov;19(9):779-786.

64. Linde K, Mulrow CD. St John's wort for depression. Cochrane Database Systematic Review. 2000; (2):CD000448. Available at: http://www.update-software.com/cochrane.

65. Little CV, Parsons T. Herbal Therapy for treating osteoarthritis. Cochrane Database Systematic Review. In: The Cochrane Library, 1, 2001. Available at: http://www.update-software.com/cochrane.

66. Towheed TE, Anastassiades TP, Shea B, Houpt J, Welch V, Hochberg MC. Glucosamine therapy for treating osteoarthritis (Cochrane Review). In: The Cochrane Library, 1, 2001. Available at: http://www.update-software.com/cochrane.

67. Soares KVS, McGrath JJ. Vitamin E for neuroleptic-induced tardive. Cochrane Database Systematic Review. 2000; (2):CD000209. Available at: http://www.update-software.com/cochrane.

68. Olin J, Schneider L. Galantamine for Alzheimer's disease (Cochrane Review). In: The Cochrane Library, 1, 2001. Oxford: Update Software. Available at: http://www.update-software.com/cochrane.

69. National Institutes of Health, Office of the Director. NIH Consensus Statement: Acupuncture Volume 15 (5): November 3-5, 1997.

70. NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia. (1996). Integration of behavioral and relaxation approaches into the treatment of chronic pain and insomnia. Journal of the American Medical Association 276(4):313-318.

71. Cassileth BR. Complementary therapies: overview and state of the art. Cancer Nursing 1999 Feb;22(1):85-90.

72. Kaptchuk TJ. Intentional ignorance: the history of blind assessment and placebo controls in medicine. Bulletin of the History of Medicine 1998;72:389-433.

73. Clinical practice guidelines in complementary and alternative medicine. An analysis of opportunities and obstacles. Practice and Policy Guidelines Panel, National Institutes of Health Office of Alternative Medicine. Archives of Family Medicine 1997;6(2):149-154.

74. Ernst E, Fugh-Berman A. Complementary and alternative medicine needs an evidence base before regulation. Western Journal of Medicine

1999;171(3):149-150.

75. Ang-Lee MK, Moss J, Yuan CS. Herbal medicines and perioperative care. Journal of the American Medical Association 2001;286(2):208-216.

76. Adler SR, Fosket JR. Disclosing complementary and alternative medicine use in the medical encounter: a qualitative study in women with breast cancer. Journal of Family Practice 1999;48(6):453-458.

77. Oldendick R, Coker AL, Wieland D, Raymond JI, Probst JC, Schell BJ, Stoskopf CH. Population-based survey of complementary and alternative medicine usage, patient satisfaction, and physician involvement. South Carolina Complementary Medicine Program Baseline Research Team. Southern Medical Journal 2000;93(4):375-381.

78. Kohn LT, Corrigan JM, Donaldson MS (eds.). To Err is Human: Building a Safer Health System. Committee on Quality of Health Care in America, Institute of Medicine. Washington, D.C.: National Academy Press, 2000.

79. AHA News. Trend watch: Complementary growth. October, 2001. Available at: http://www.ahastatitics.org.

80. Podolsky D. A new age of healing hands. Cancer centers embrace alternative therapies as 'complementary care'. US News and World Report 1996;120(5):71, 74.

81. Dalen J.E. Is integrative medicine the future of medicine? A debate between Arnold S. Relman, MD, and Andrew Weil, MD. Archives of Internal Medicine 1999; 59:2122-2126.

82. Caspi O, Bell IR, Rychener D, Gaudet TW, et al. The Tower of Babel: Communication and medicine: An essay on medical education and complementary-alternative medicine. Archives of Internal Medicine 2000;160(21):3193-3195.

83. Starr C, Benjamin S, Berman B, Jacobs J. Exploring complementary therapies in conventional practice. Journal of the American Association of Physicians Assistants 1999;12(3):18-20, 23-26, 29-30.

Chapter 3: Coordination of Research

The public's increased use of complementary and alternative medicine has added urgency to the need to examine the safety, efficacy, and cost effectiveness of 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.

Research Support and Scope

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), [1] and the Cooperative Research and Development Agreement.[2] 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 [3] 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. [4] 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. [5] 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.

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.

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.

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.

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.

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.

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.

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.

Dialogue, Partnerships, and Public Input

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. [5] 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. [6] The goal of integrative medicine is to identify the most appropriate treatments available from a broad spectrum of evidence-supported care. [7] To name just a few examples, in integrative cancer treatment, a patient may undergo individualized acupuncture treatment for nausea and vomiting following chemotherapy; relaxation techniques and support groups are used with cancer patients to reduce stress, improve mood, and enhance the immune system; and mind-body interactions and stress management are being studied with respect to the treatment of hypertension and coronary heart disease. The Commission supports 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, [8] 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. [9]

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[10]. 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. [11] 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.

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 multdisciplinary 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. [12] 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 [15] CAM Specialty Centers of Research in collaboration with other NIH institutes and centers and the Office of Dietary Supplements. In addition to botanicals, the 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. [13] 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. [14]

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

Actions

8.1 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.

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.

References

1 National Institutes of Health, Office of Extramural Research. Index of Tables, Charts, and Lists. Activity Code Definitions. Available on-line at: http://grants2.nih.gov/grants/award/index.htm

2 The Bayh-Dole Act A Guide to the Law and Implementing Legislation. Available at: http://www.ucop.edu/ott/bayh.htm/. See also: Public Health Service Cooperative Research Development Agreement at http://niehs.nih.gov/techxfer/crada/htm

3 Williams, RJ. Biomedical Individuality. Austin, TX: University if Texas Press, 1980

4 Callahan D. Editor. The Role of Complementary and Alternative Medicine: Accommodating Pluralism. Washington, DC: Georgetown University Press, 2002

5 National Institutes of Health, Office of Extramural Research. Index of Tables, Charts, and Lists. Activity Code Definitions. Available at: http://grants2.nih.gov/grants/award/index.htm

6 Eisenberg DM. Kaptchuck TJ. Series Editors. Perceptions About Complementary Therapies Relative to Conventional Therapies Among Adults Who Use Both: Results from a National Survey. Academia and Clinic. Annals of Internal Medicine; 2001: 135:344-351

7 Welcome. Integrative Medical Center at Griffin Hospital Derby, CT. Available at: http://www.imc-griffin.org/

8 National Institutes of Health, Office of Extramural Research. Index of Tables, Charts, and Lists. Activity Code Definitions. Available at: http://grants2.nih.gov/grants/award/index.htm

9 Institute of Medicine. Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at the National Institutes of Health. National Academy of Sciences Press: Washington DC: 1998

10 Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators, 1988 Update. 21CFR Part 56-Institutional Review Boards Subpart B-Organization and Personnel. Available at: http://www.fda.gov/oc/ohrt/irbs/appendixc.html

11 Sparber A, Ford D, Kvochak PA. National Institutes of Health Clinical Center Sets New Policy on the Use of Herbal and Other Alternative Supplements by Patients Enrolled in Clinical Trials, Subsection: Around the Corner. Summary Available at: http://catalyst.cit.nih.gov/catalyst/2001/01.11.01/page4.html

12 Working Group on Role of Alternative Medicine in the University of Pennsylvania Medical Center and Health System. University of Pennsylvania Health System. Final Report June 5, 1998-June 30, 1999

13 National Institutes of Health, Office of Extramural Research. Index of Tables, Charts, and Lists. Activity Code Definitions. Available at: http://grants2.nih.gov/grants/award/index.htm

14 NIH Loan Repayment Programs Loan Repayment Program for Clinical Research 10 Most Frequently Asked Questions, 3. Who is Eligible to Reply? Available at: http://www.lrp.nih.gov/about/extramural/extramural_clinical_faq

Chapter 4: Education and Training of Health Care Practitioners

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.

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.[1] 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.[2] 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.[3] 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.[4] In light of this variation, consensus needs to be reached on the essentials of a core curriculum.1 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.[5] Addressing the myriad conventional health professions and programs will require a range of educational options.

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.[6] 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.[7] While many CAM courses are taught from either an advocacy or neutral view, all CAM courses should be taught critically.[8]

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.[9] 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.

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,[10] 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.

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.[11] 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 (BHPr), 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.

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.

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.

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.

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 BHPr. 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 BHPr 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 BHPr CAM activity that is legislatively authorized.

Both NCCAM and BHPr 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

development at accredited CAM and conventional institutions could be achieved through Federally sponsored workshops and conferences.

The challenges facing efforts to increase support for CAM faculty, curricula, and program development at accredited CAM and conventional institutions include:

- Limited availability of funding in an era of diminishing resources and increased competition,
- Resistance from conventional health professions' organizations and institutions,
- Equitable identification and prioritization of appropriate recipients for funding, and
- The need for Federal legislation and appropriations to support such programs.

Action

10.4 Increased Federal, state, and private sector support should be made available to expand and evaluate CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

CAM Student Participation in Existing Loan and Scholarship Programs

CAM students, institutions, and professional organizations have expressed considerable interest in participating in loan and scholarship programs. Chiropractic students were eligible for participation in the Health Education Assistance Loan (HEAL) program, the program has been phased out, and no initial loans are available. Chiropractic students at participating institutions now may be eligible for Stafford loans. Currently, the only CAM students eligible for the Scholarship for Disadvantaged Students (SDS) program are chiropractic students. No CAM students are eligible for the National Health Service Corps (NHSC) scholarship program at this time, because it is limited to U.S. citizens enrolled in or accepted for enrollment in fully accredited U.S. allopathic or osteopathic medical schools, nurse practitioner programs, nurse-midwifery programs, physicians assistant programs, or dental schools. In other words, only students of a health profession that is named specifically in authorizing legislation can be awarded an NHSC scholarship.

The purpose of the NHSC scholarship program is to provide primary health care to underserved and vulnerable populations in rural and urban areas designated by the Federal government as health professions shortage areas. As a result of program requirements and limitations as well as other factors, NHSC, which recently was transferred within HRSA from the Bureau of Primary Health Care to

As authorized by the Public Health Service Act, Title VII, Section 705.
As authorized by the Public Health Service Act, Title VII, Section 737.
As defined in the Public Health Service Act, Title III, Section 301.

BHPr, meets approximately 12-15 percent of the identified need for health care in underserved areas. Because of the enormous unmet need, especially for primary care, and the limited number of NHSC positions and funds available, the government's and medically underserved communities' clear preference for conventional health care providers should not be unexpected.

Any policy changes regarding CAM participation in Federal loan and scholarship programs would have to be mandated legislatively. Expansion of eligibility for loan programs administered by BHPr, such as Loans for Disadvantaged Students, Health Professions Student Loans, or Primary Care Loans, to CAM students would require, at a minimum, financial impact analyses by the Congressional Budget Office (CBO), determination of which CAM professions should participate, determination of which loan programs should be expanded, and amendment of the Public Health Service Act, Title VII. Since participation in these programs is based in part on financial need, only CAM students meeting the financial eligibility criteria would be eligible. Expansion of eligibility for the Stafford loan program administered by the Department of Education would have to be preceded by similar CBO evaluations, determination of which CAM professions should participate, and legislative changes. In addition, CAM institutions would have to be accredited by an approved accreditation agency, apply and be approved for participation in Title IV of the Higher Education Act student assistance program, and sign a participation agreement.

In general, expansion of Federal loan programs to CAM students appears easier than participation in the NHSC scholarship program. However, before considering any changes in NHSC policy or legislative, a number of critical aspects of CAM participation must be examined. Since the chief purpose of this program is not education, but the provision of health care to medically underserved and vulnerable populations, current participants must be able to provide the necessary health care services, which generally are described as or included as a component of primary care.

Section 330 of the Public Health Service Act defines primary care by delineating required community health center primary care services and provides examples of representative clinical competencies. These include:

- Health services related to family medicine, internal medicine, pediatrics, obstetrics, or gynecology that are furnished by physicians and where appropriate, physicians assistants, nurse practitioners, and nurse midwives;
- Diagnostic laboratory and radiologic services;
- Preventive health services (including prenatal and perinatal services; screening for breast and cervical cancer; well-child services; immunizations against vaccine-preventable diseases; screenings for elevated blood lead levels communicable diseases, and cholesterol; pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care; voluntary family planning services; and preventive dental services);

- Emergency medical services; and
- Pharmaceutical services.

The Department of Health and Human Services should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners enhance and/or expand health care provided by primary care teams. These primary care teams typically consists of family practitioners, internists, pediatricians, and obstetrician gynecologists as well as physicians assistants, nurse practitioners, nurse midwives, dentists, and mental health professionals. The feasibility study could be followed with demonstration projects to determine the type of practitioners, their education and training requirements, appropriate practice sites, minimal clinical competencies, and health outcomes attributable to the addition of these practitioners and services to comprehensive care. Then, the CBO should estimate the financial impact of CAM practitioner participation in these programs. Guidelines have been set for determining the number of a given type of conventional health care provider for a defined population size or geographic area (for example, an area that has a population to full-time-equivalent primary care physician ratio of at least 3,500 to 1), but not for CAM practitioners. Such guidelines would need to be developed for each type of CAM practitioners.

The challenges to expanding the eligibility of CAM students to participate in existing loan and scholarship programs include:

- A preference for conventional health care providers to fill the largely unmet need,
- Required changes in legislation and appropriations changes,
- Identification of specific CAM disciplines and practitioners, and
- Difficulty in administering CAM-inclusive programs particularly in the absence of population and geographic guidelines for CAM practitioners and financial impact data.

Action

10.5 Expansion of eligibility of CAM students at accredited institutions for existing Federal loan programs should be explored.

10.6 The Department of Health and Human Services should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners enhance and/or expand health care provided by primary care teams. This feasibility study could lead to demonstration projects to identify: 1) the type of practitioners, 2) their necessary education and training, 3) the appropriate practice settings, and 4) the health outcomes attributable to the addition of these practitioners and services to comprehensive care.

Typically, these primary care teams consists of family practitioners, internists, pediatricians, and obstetrician gynecologists as well as physicians assistants, nurse practitioners, nurse midwives, dentists, and mental health professionals.

National Guidelines for CAM Educational and Training

Questions about national guidelines for CAM education and training are by no means unique to the United States. In Great Britain, the House of Lords Select Committee on Science and Technology considered a number of issues related to CAM education and training.[12] Despite the exceedingly complex mosaic of CAM practices, therapies, modalities, disciplines, and professions, the committee recommended that CAM training courses, whether for conventional health professionals or CAM professionals, should be made more uniform and should be accredited by appropriate professional bodies.

National standards for CAM education and training may not be attainable in the United States for a number of reasons. For example, each of the 50 States has varying educational requirements for licensure for a multiplicity of professions. In addition, a given CAM modality or therapy may involve numerous CAM and conventional disciplines; but there may be no agreement among or between disciplines on accreditation requirements, processes, or body for that particular modality or therapy.

In an attempt to provide some uniform guidance, the Federation of State Medical Boards' Special Committee for the Study of Unconventional Health Care Practices has begun to develop guidelines for the use of CAM. These guidelines address education, but they focus on the scientific basis of treatment methods without delineating any specific education or training requirements. Simultaneously, nascent efforts by physician organizations to standardize CAM education and training for allopathic and osteopathic physicians have emerged. The American Board of Holistic Medicine, for example, has administered a board certification examination covering 13 areas of holistic medicine, including exercise medicine, nutritional medicine, environmental medicine, biomolecular medicine, behavioral medicine, spiritual medicine, energy medicine, social medicine, manual medicine, homeopathic medicine, botanical medicine, ethnomedicine including acupuncture, and conventional medicine. For physicians practicing medical acupuncture, the American Board of Medical Acupuncture has developed and administered a board certification examination.

Chiropractic has the most extensively developed and implemented national education and training standards of any CAM profession. Traditional Chinese acupuncture, therapeutic massage, and naturopathic medicine perhaps have moved closer than other CAM professions to establishing national education and training standards. Because of their progress, these CAM professions are appropriate candidates for conferences convened by DHHS and other Federal Departments and Agencies, although CAM professions and disciplines that are still in the process of developing standards should be included as well. Such conferences would assemble the leadership of CAM, conventional health, public

health, evolving health professions, and the public; educational institutions; and appropriate organizations to facilitate establishing CAM education and training guidelines. Subsequently, these guidelines would be made available to the states and professions for their consideration.
The challenges of establishing national CAM educational and training guidelines include:

- Their similarity to education and training requirements for licensure and therefore perceived encroachment on states' rights,
- Complexity-that is, the numerous disciplines or professions that may be associated with a given modality,
- Lack of educational standardization within professions,
- Absence of a clearly delineated scope of practice for each profession;
- Funding requirements, and
- Resistance from CAM and conventional professions and organizations.

Action

10.7 The Department of Health and Human Services and other Federal Departments and Agencies should convene conferences of the leaders of CAM, conventional health, public health, evolving health professions, and the public; of educational institutions; and of appropriate organizations to facilitate establishment of CAM education and training guidelines. Subsequently, the guidelines should be made available to the states and professions for their consideration.

Demonstration Projects of Postgraduate Training for Appropriately Educated and Trained CAM Practitioners

To improve education and training, 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, as previously noted, there are very few opportunities for postgraduate CAM education and training. Currently, the chiropractic profession appears to have the most extensive full-time postgraduate CAM education and training, offering residencies in radiology, orthopedics, family practice, and clinical sciences. A typical chiropractic residency program is two to three years in duration and includes outpatient care and inpatient clinical rotations at chiropractic and conventional medical facilities, along with classroom and research experiences.
Residencies in naturopathic medicine are less well developed. Postgraduate training has been in existence since 1979 and consists of a limited number of mainly one-year and some two-year residency programs with an emphasis on naturopathic family practice. Most of these residencies are based in outpatient clinics, some of which are affiliated with a hospital. Utah now requires at least a one-year residency for licensure of naturopathic physicians.

Before establishing new or expanding current CAM postgraduate education and training programs, appropriate CAM candidates for postgraduate education and training should be identified and the feasibility, type, duration, and impact of postgraduate education and training for these CAM practitioners should be determined. For example, should one-year postgraduate training programs be available for traditional Chinese acupuncturists or doctors of oriental medicine? Should three-year primary care or family practice residencies be available for naturopathic, Ayurvedic, or Tibetan medicine physicians?

The process of determining likely candidates could include demonstration projects of residencies and postgraduate training for appropriately educated and trained CAM practitioners. Federal Agencies and Departments such as NCCAM, BHPr, the Bureau of Primary Health Care, the Department of Defense, and the Department of Veterans Affairs could sponsor the projects. Because 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, any current or proposed CAM postgraduate education and training program affiliated with such centers should be given special consideration.

Demonstration projects should be awarded on a competitive basis and funded with monies that are distinct from the current graduate medical education funding streams. In addition, projects should include funds for financial analyses and longitudinal studies to assess the types of CAM practitioner, feasibility of residencies and postgraduate training, competency-based educational effectiveness, impact on health care quality, and collaboration between CAM and conventional providers.

The challenges to establishing demonstration projects of residencies and postgraduate training in CAM for appropriately educated and trained CAM practitioners include:

- Determining which practitioners should participate in postgraduate education and training demonstration projects,
- Developing and applying selection criteria and processes,
- Funding, and
- Limited availability of a sufficient number of training sites, patients, and faculty.

Action

10.8 Feasibility studies of postgraduate training for appropriately educated and trained CAM practitioners should be conducted to determine the type of practitioners, practice setting, and their impact on clinical competency, quality of health care, and collaboration with conventional providers.

Continuing Education in CAM for All Practitioners Who Provide CAM Products and Services

Continuing education represents a powerful means of affecting conventional and CAM practitioners' behavior, thereby enhancing public health and safety. Britain's House of Lords affirmed the importance of continuing education for CAM practitioners.12 The Josiah Macy, Jr. Foundation Conference on Education of Health Professionals in Complementary/Alternative Medicine recommended that professional and educational health care associations include high-quality, evidenced-based CAM information in continuing education programs.5

There are more programs in CAM continuing education for conventional health professionals than for CAM practitioners. However, the number, type, and availability of programs with content appropriate for all practitioners who provide CAM services and products are not sufficient to enhance and protect the public's health and safety regarding CAM. Therefore, continuing education needs to be improved and made available to all conventional health professionals as well as all practitioners who provide CAM services and products.

Action

10.9 Practitioners who provide CAM services and products should complete appropriate CAM continuing education programs that include critical evaluation of CAM to enhance and protect the public's health and safety.

REFERENCES:

1 Berman B. Complementary medicine and medical education. British Medical Journal. 2001;322:121-122.

2 Wetzel MS, Eisenberg DM, Kaptchuk TJ. Courses involving complementary and alternative medicine at US medical schools. Journal of the American Medical Association. 1998;280:784-787.

3 Chez RA, Jonas WB, Crawford C. A survey of medical students' opinions about complementary and alternative medicine. American Journal of Obstetrics and Gynecology. 2001;185:754-757.

4 Bhattacharya B. M.D. programs in the United States with complementary and alternative medicine education opportunities: An ongoing listing. The Journal of Alternative and Complementary Medicine. 2000;6:77-90.

5 Chairman's Summary of the Conference, Education of Health Professionals in Complementary/Alternative Medicine, Josiah Macy, Jr. Foundation, 44 east 64th Street, New York, NY 10021 Grollman AP. Is

there wheat among the chaff? Academic Medicine. 2001;76:221-223.

6 Marcus DM. How should alternative medicine be taught to medical students and physicians? Academic Medicine. 2001;76:224-229.

7 Sampson W. The need for educational reform in teaching about alternative therapies. Academic Medicine. 2001;76:248-250.

8 Gaudet TW. Integrative medicine: The evolution of a new approach to medicine and medical education. Integrative Medicine. 1998;1:67-37.

9 Kligler B, Gordon A, Stuart M, Sierpina V. Suggested curriculum guidelines on complementary and alternative medicine: Recommendations of the society of teachers of family medicine group on alternative medicine. Family Medicine. 1999;31:30-33.

10 Caspi O, Iris RB, Rychener D, Gaudet TW, Weil AT. The tower of Babel: Communication and medicine. Archives of Internal Medicine. 2000;160:3193-3195.

11 House of Lords Select Committee on Science and Technology. Sixth Report: Complementary and Alternative Medicine, 21 November 2000, Chapter 6: Professional Training and Education.

Table 1. CAM Topics Included in Required or Elective Courses at Medical Schools Accredited by the Liaison Committee on Medical Education.

Medical Schools Covering Topics

Topics	Required Course Only	Elective Course Only	Both
Acupuncture	18	54	28
Herbal medicine	28	45	33
Homeopathy	17	48	18
Meditation	13	53	17
Manual healing techniques	15	50	11
Nutritional supplement therapy	30	42	36
Spirituality	25	43	35

Source: 2000-2001 Liaison Committee on Medical Education Annual Medical School Questionnaire.

Chapter 5: CAM Information Development and Dissemination

One of society's greatest achievements - and one of its greatest challenges - has been the dramatic improvement in the development and dissemination of information. Over the past several decades, new technologies have enabled people all over to world to gain rapid access to information. Not only does information travel faster, significantly more of it has become available in the United States because of increased population, higher educational levels, and changes in the workforce and economic structure. This is especially true of health information, including information about complementary and alternative medicine (CAM).

In a desire for improved quality and length of life, the public has sought increased information on healing systems, practices, and products from other cultures and healing traditions. Many Americans use these in the context in which they were originally developed. Others have borrowed practices and products from these systems and adapted, changed, or used them in ways that are very different from their original design or intent. New therapies, practices, and products that lie outside the conventional health care system have also been developed. All of these fall under the rubric of CAM, and people have both benefited and suffered from information about their usage, benefits, safety, and effectiveness.

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

The ready availability of accurate information is especially important to people who are confronting a life-threatening illness. For someone newly diagnosed with a serious or life-threatening illness, seeking information about the disease and treatment options is often their first course of action. Many people quickly become overwhelmed by the vast array of often-conflicting information that is available, and yet for some diseases and conditions, there is a scarcity of information. Getting accurate and useful information should not be an additional burden during this difficult time.

To be effective, information must be tailored to the population it seeks to reach. People of different cultural, ethnic, and socio-economic backgrounds often have different views of health and healing, different patterns of use of health care services and products, and different ways of acquiring information. People's views and behavior also vary with their age, literacy, and specific health

conditions. Informational materials need to reflect the characteristics and behavior of the target population in content, style, language, and format.

The Internet has given people access to vast amounts of health care information that would not have been available to them previously. Along with the advantages of being able to find information on virtually any topic quickly, the Internet presents concerns about quality, particularly in regards to CAM information. People may be making life-and-death decisions based on information from the Internet that may be misleading, incomplete, or inaccurate. This is particularly true in the case of CAM, for which a significant amount of evidence-based material is not yet available. As people become more interested in CAM and explore the Internet looking for information about its usefulness, efforts should be made to ensure that they have access to the most reliable information possible.

Other avenues of finding information about CAM are also important. The Federal government is one of the largest developers of health information, and efforts should be made to expand its coordination of existing CAM resources. Public libraries are an important source of information in many communities. Training librarians in how to find information on CAM would help people navigate through the maze of available resources.

Advertising and marketing are another means through which people learn about CAM products and services. Although only a small percentage of the approximately $200 billion spent yearly on advertising [1] is for CAM products and services, that percentage nonetheless is significant. The vast majority of advertisers of CAM products and services comply with current laws, yet misleading and fraudulent health claims exist and are cause for great concern.

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

One of the fastest growing areas in CAM has been dietary supplements. Sales of these products totaled $17 billion in 2000 [2], and more than 158 million consumers used them [3]. Because they are classified as dietary supplements, these products are not subject to the rigorous testing and oversight required of prescription drugs, which are targeted toward disease conditions. For this reason, complete and accurate labeling and package insert information on ingredients and on potential benefits and risks is essential. The current system does not make such information easily available to consumers.

The use of CAM practices and products is a growing part of the American lifestyle. As CAM continues to grow and evolve, the development and dissemination of accurate, complete, and useful information on products, practices, and practitioners will be one of the most important mechanisms for ensuring the public's safety.

Availability of Reliable, Useful, and Accessible Information for the Public on CAM Practices and Products

CAM Information from the Federal Government

Consumers, health professionals, and the media often look to the Federal government for reliable and authoritative information on a wide range of health topics. The government produces thousands of fact sheets, reports, pamphlets, posters, books, and other materials that provide useful, accurate information on specific diseases, health care delivery services, research findings, and other health care topics. Information is also available though various government Internet sites and toll-free numbers, many of which are associated with a clearinghouse.

The National Center for Complementary and Alternative Medicine (NCCAM), located in the National Institutes of Health (NIH), has a congressional mandate to "establish a clearinghouse to exchange information with the public" about CAM [4]. The clearinghouse has a toll-free telephone number and provides fact sheets, information packages, and publications on CAM research and NCCAM activities. Consumers and health care professionals can also obtain CAM- related information from NIH's National Cancer Institute and the Office of Dietary Supplements. The Food and Drug Administration's (FDA) Center for Food, Safety, and Applied Nutrition has a website with information on dietary supplements. Other government entities, such as the Department of Agriculture and the Federal Trade Commission (FTC), also have information related to specific CAM topics.

Despite these resources, information on CAM from the Federal government is inconsistently available and often difficult to locate. For a variety of reasons, including limited awareness or acceptance of CAM by Federal staff or leadership, lack of agency policy on the inclusion of CAM information, and limited availability of research on many of the CAM products and services people are using, government agencies with oversight responsibilities for various aspects of health care often do not include any information on CAM in their materials. This has resulted in significant gaps in information on diseases, health conditions, practitioners, and products. Existing materials should be reviewed and, where appropriate, CAM information should be added and new materials developed.

Even when high-quality, comprehensive information on CAM is available from the Federal government, it is often difficult for the public to navigate the system and locate the desired information in a timely manner. Greater efforts should be made to promote the use of the Firstgov.gov search engine, an easy-to-use government-wide search engine. For people who do not use the Internet, a centralized, toll-free telephone number would help direct callers to the appropriate department or agency to answer their questions. Consumers, health care practitioners, the media, and other members of the public have expressed a desire for a centralized place in the Federal government to get objective, comprehensive information on CAM quickly.

CAM Information From Public Libraries

Many people, especially elderly and low-income people, do not have access to the Internet or do not know how to use a computer to get CAM information on the Internet. People without access to the Internet at home or at work often use publicly available resources - such as libraries - to find information. Public libraries exist in most communities and are a source of Internet access and guidance. However, many librarians lack training in how to find reliable information about CAM on the Internet. They may also be unaware of other sources of information on CAM such as books, periodicals, and newsletters. The National Library of Medicine has begun working directly with public libraries through the American Library Association to train local librarians in how to use the Internet to find health information. This effort should be expanded to include more training and focus on how to find information about CAM, both on the Internet and in other resources.

The Role of Public and Private Organizations in Developing and Disseminating Information about CAM

Differences in how people find and use information are an important consideration in the development, distribution, and evaluation of information about CAM. According to the most recent National Adult Literacy Survey, 48 percent of U.S. adults, or close to 100 million people, have very limited literacy because they lack English skills, have reading disabilities, or lack sufficient education [5]. In addition to varying literacy skills, differences in how information is located and used can exist among men and women, people in different age or income groups, and people with different racial, ethnic, and cultural backgrounds.

Health information materials (print, radio, television, or other media) are often targeted toward specific audiences, particularly populations at higher risk of developing a particular disease or condition or those with a higher propensity for using a particular practice or product. Materials may be produced in different languages, and the content, illustrations, and style may be altered to reach the intended population.

Currently available demographic data do not provide adequate information about CAM usage among various population subgroups or the range of methods and patterns in accessing CAM information. However, it is known that the use of CAM varies significantly by racial, ethnic, and cultural background, age group, health status, income, and literacy. CAM materials should be developed for each of these specific groups.

Some populations are particularly susceptible to advertisements of CAM products such as herbs, tonics, and vitamins that have not been shown to be effective or that, in some cases, are even harmful. These populations may also be vulnerable to the fraudulent claims of services that promise to cure disease and treat health care problems not addressed through the conventional health care system. The involvement of trusted community leaders is essential to any effort to educate vulnerable consumers and develop strategies to prevent them from being targeted by marketing of unnecessary, harmful, exorbitantly priced, or otherwise detrimental products.

CAM Information from Other Countries

Lack of information on the effectiveness of CAM therapies is often cited as the reason for not providing them or reimbursing consumers for them. However, a potentially significant amount of high-quality CAM information has been published in other countries but is not available in English or in the United States. As globalization of information increases, the research, findings, and experiences of people in other countries can provide valuable information on the safety and efficacy of CAM. Identifying and analyzing studies published in languages other than English requires expertise in both languages and science. Greater efforts should be made to make these resources available.

Recommendation 11: The Federal government should make available accurate, useful, and easily accessible information on CAM practices and products, including information on safety and effectiveness.

Actions

11.1 The Secretary of Health and Human Services should establish a task force to facilitate the development and dissemination of CAM information within the Federal government and to eliminate existing gaps in CAM information. The task force should include consumers, CAM providers, scientists, and conventional health care practitioners. Resources should subsequently be provided to close identified gaps and improve the availability, coordination, and dissemination of information.

11.2 Federal Departments and agencies with missions or activities relevant to CAM should 1) develop informational materials about CAM that are easy to understand and use, and 2) support and collaborate with national and

local community leaders and CAM leaders and organizations to identify strategies for enhancing the development, availability, and accessibility of information on the safety and effectiveness of CAM practices and products.

11.3 Increased funding should be provided to the National Library of Medicine and the American Library Association to expand training of librarians to include helping consumers find information on CAM.

11.4 The Secretary of Health and Human Services should direct resources to streamline the process of identifying and making available relevant, high-quality CAM information from other countries and in other languages.

Quality and Accuracy of CAM Information on the Internet

The Internet has emerged as a major source of information about health care, including information related to CAM, for both consumers and providers. According to the most recent estimates by the U.S. Census Bureau, over half of all households in the United States have computers, 90 percent of all children age 6 to 17 have access to computers through their home or school, and 42 percent of all households can log onto the Internet [6]. An estimated 60 million U.S. adults used it to obtain health-related information last year [7]. Most Internet sites are general health information sites that include CAM information, but some sites are specific to CAM.

The quality, accuracy, accessibility, and timeliness of Internet information vary greatly. Some sites provide accurate, up-to-date information, while many others contain information that is inaccurate, misleading, or outdated. The ability to ensure the quality of information on the Internet is extremely limited, both because of the nature of the technology and the First Amendment's protection of free speech.

Several organizations have developed standards on ethics-related issues such as privacy and financial sponsorship of health sites on the Internet. However, some of these same organizations have developed websites that have been cited as having problems with quality, accuracy, accessibility, or timeliness of CAM-related information. Some do not have any qualified CAM practitioners on their review boards, and the standards do not appear to have had much impact on the quality of information on these Internet health sites.

Public-private partnerships that include industry groups, consumers, and governments have been successful in developing guidelines and establishing standards for many products and services. Examples include the World Wide Web Consortium, a group of more than 500 public and private organizations that have developed guidelines to make web content accessible to people with

disabilities, and the Healthy People Consortium, composed of hundreds of public and private organizations that have developed objectives for the Nation's health. The government can play an important role in bringing key people together to develop voluntary, non-binding guidelines that will assist industry in setting minimum standards for quality, accuracy, accessibility, and timeliness of CAM-related information on the Internet.

Regardless of efforts to develop standards and ensure quality, consumers will always need to evaluate and validate information they receive from the Internet. Public education in using the Internet as a source of health information can help individuals search for knowledge and make decisions about their health. Internet users are concerned not only about the quality and accuracy of the information they are getting, but also about the information they may unwittingly be giving out. In a recent study, 85 percent of people seeking health information on the Internet said they are concerned about their employer or health insurance company tracking their site visits and using that information to change their insurance status or rates [7].

Unfortunately, privacy protections for people seeking health information on the Internet are limited. The Health Insurance Portability and Accountability Act of 1996 protects the privacy of consumer information collected by health plans, health care clearinghouses, and health care providers conducting electronic transactions, but it does not protect consumers seeking health information on the Internet. In 1998, Congress enacted the Children's Online Privacy Protection Act, which prevents the collection of personally identifiable information from young children without their parents' consent. The FTC has filed four civil penalty actions this year to enforce the act, and additional cases are under investigation. Congress should take steps to expand privacy protection for health information seekers on the Internet.

Recommendation 12: The quality and accuracy of CAM information on the Internet should be improved by establishing a voluntary standards board, a public education campaign, and actions to protect consumers' privacy.

Actions

12.1 The Secretary of Health and Human Services should form a public-private partnership to review new and existing websites and to develop voluntary standards promoting accuracy, fairness, comprehensiveness, and timeliness of information on CAM web sites, as well as the disclosure of sources of support and possible conflicts of interest. Sites reviewed and found in compliance with the standards could publicize the fact and display a logo denoting their merit.

12.2 Funding should be provided to the Department of Health and Human Services and the Department of Education to conduct a joint public education campaign that teaches consumers how to evaluate health care

information, including CAM information, on the Internet and elsewhere.

12.3 Congress should protect consumers' privacy by requiring all health information sites, including CAM sites, to disclose whether they track users and if so, how that information is used and stored, including whether it is sold to third parties.

Availability of Information on the Training and Education of Providers of CAM Health Services to Enhance Consumer Knowledge and Choice

Training, licensing requirements, certification, scope of practice, regulations, and even definitions of CAM practitioners can vary considerably. For example, traditional or lay naturopaths and naturopathic physicians have significantly different levels and types of training, yet most consumers are unaware of the difference. In some states, acupuncture can be practiced by professional acupuncturists who have spent several years in training or by practitioners of another health modality (e.g., a physician, dentist, podiatrist, physical therapist, or chiropractor) with less, limited, or no additional training or experience in acupuncture. Herbalists may have years of informal training and experience or no formal training and little experience. The situation is further complicated by state variations in licensing requirements and scope-of-practice regulations.

Navigating the maze of titles and certificates among the various types of practitioners is a challenge for consumers, most of whom are unfamiliar with the nuances of these professions. Information on a practitioner's qualifications should be readily available to help consumers make informed choices in their selection and use of a practitioner. Information on state regulations, requirements, and disciplinary actions should be readily available to help ensure consumers' safety.

CAM practitioners without any formal training may be reluctant to make that fact known. Moreover, consumers may not be able to distinguish between a degree or certificate obtained from an accredited organization and a degree or certificate purchased from an organization with no requirement that students meet appropriate educational standards. However, disclosure of such information will help consumers evaluate the qualifications of practitioners and make informed choices. In addition to practitioners, people such as vendors, retailers, and multi-level marketers of CAM products should disclose their qualifications for providing health-related information.

Recommendation 13: Information on the training and education of providers of CAM services should be made easily available to the public.

Actions

13.1 The Commission recommends that states require all persons providing CAM services to disclose information regarding their level and scope of training and to make it easily available to consumers.

13.2 The Commission recommends that states disclose information on state guidelines, requirements, licensure, certification, and disciplinary actions of health providers, including CAM providers, and make it easily accessible to the public.

Availability of CAM Products That Are Safe and Meet Appropriate Standards of Quality and Consistency

The availability and use of dietary supplements in the United States has grown significantly in the past several years. As a result, public interest in the safety and effectiveness of dietary supplements has also increased. Because they are regulated as foods rather than drugs, dietary supplements are regarded - from a regulatory perspective - as generally safe for human consumption. Yet problems with the composition and purity of some of these products have been reported and raise questions about their safety.

Some dietary supplements do not contain the ingredients or the amount of the ingredients declared on the label. For example, in laboratory testing of 25 separate Echinacea products, only 14 (56 percent) were found to have the amount and type of Echinacea and polyphenol (or marker compound) claimed on the label [8]. Testing of 13 SAMe (S-adenosyl-L-methionine) products showed that 5 had less than half the amount listed on the label and 1 had no detectable level at all [9]. An analysis of 25 ginseng products showed substantial variability in the concentration of marker compounds [10].

Some herbal preparations contain ingredients other than those listed on the label, including undeclared pharmaceuticals. Herbal products claiming to contain only natural ingredients were found to contain the prescription drugs glyburide and phenformin, which are used to treat diabetes [11]. Two other herbal products were found to contain warfarin and alprazolam, prescription drugs that can cause serious health effects if not taken under medical supervision[12]. Dietary supplements have been found to be contaminated with heavy metals, microorganisms, and pesticides, and toxic levels of mercury have been reported in some imported herbal products [13]. In April and May 2001, two manufacturers recalled several products as a result of Salmonella contamination [14].

Public concern with dietary supplements includes not only possible contamination and adulteration, but also active ingredients that may be toxic or cause unwanted side effects. For example, aristolochic acid, a naturally occurring

compound associated with cancer and renal failure, has been found in several herbal products, prompting a nationwide recall of products containing this substance[15]. Certain pyrrolizidine alkaloids, which are found in numerous plants used medicinally around the world, have been found to be harmful to the liver [16].

Such examples raise questions about whether current regulations are adequate to ensure the safety of dietary supplements and whether regulatory agencies can respond quickly when a problem is identified. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, a manufacturer is responsible for determining that the dietary supplements it produces or distributes are safe and that its claims are substantiated by adequate scientific evidence. However, DSHEA does not require manufacturers to disclose the source of the information they used to determine the safety of their products. The failure to require safety data weakens the current regulatory system, making it unable to provide consumers with sufficient and scientifically valid information.

Even though dietary supplements are regulated as foods, which are subject to the standards of Good Manufacturing Practices (GMP), DSHEA encouraged the FDA to develop separate GMPs for dietary supplements. The process of development has been an effective collaboration between many members of the dietary supplement industry and the Federal government. Implementation of GMPs for dietary supplements will help ensure the identity, purity, quality, strength and composition of these products. Formal publication and implementation of the GMPs are pending.

While implementation of GMPs for dietary supplements will address domestically produced products, finished products imported from some other countries may not meet these standards or the standards of responsible manufacturers. Such products may find their way into commerce. Appropriate government entities should work with manufacturers and importers to improve the monitoring of imported dietary supplements and prevent naturally or accidentally contaminated or adulterated products from entering the United States. Cooperation with appropriate international organizations should be encouraged in order to establish standards of quality for the ingredients in dietary supplements. These standards should include preventing the exploitation of endangered animal and plant species for the manufacture of dietary supplement products.

Since the passage of DSHEA in 1994, many new dietary supplements have been introduced into the United States. For many of these supplements, particularly botanicals, validated analytical methods have not been developed. Moreover, different analytic methods are used by different manufacturers, leading to varying test results regarding concentrations of active ingredients or other marker compounds.

Government, industry, and scientific organizations have begun developing analytical methods for botanicals and other dietary supplements so that

consensus can be reached regarding the chemical and physical standards for composition and quality. These efforts need to be accelerated. Congress has included language in the fiscal 2002 appropriation bill for the Department of Health and Human Services in support of the development of standards, and the Commission recommends that this progress be continued.
A framework for reviewing data on the safety of ingredients in dietary supplements is being developed by the Institute of Medicine. While this is an important step that will assist in improving the safety of specific ingredients of dietary supplements, the Commission believes that an independent review process is needed to evaluate the safety of dietary supplements, many of which contain multiple ingredients that can interact with drugs, foods, and other ingested products. An external review process was recommended by the Presidential Commission on Dietary Supplement Labels in 1997 [17] and more recently by a scientific conference [18]. Continuous, enhanced cooperation between government and industry is needed to make certain that dietary supplements are safe.

Recommendation 14: CAM products that are available to U.S. consumers should be safe and meet appropriate standards of quality and consistency.

Actions

14.1 The efforts of both the public and private sectors to ensure the development, validation, and dissemination of analytical methods and reference materials for dietary supplements should be accelerated.

14.2 The proposed Good Manufacturing Practices for Dietary Supplements should be published expeditiously, followed by a timely review of comments and completion of a final rule. The Food and Drug Administration should be provided with adequate resources to complete this task.

14.3 Adequate funding should be provided to appropriate Federal agencies, including U.S. Customs and Food and Drug Administration inspection authorities, to enforce current laws monitoring the quality of imported raw materials and finished products intended for use as dietary supplements.

14.4 Manufacturers should have on file and make available to the FDA upon request scientific information to substantiate their determinations of safety, and current statutory provisions should be periodically reexamined to determine whether safety requirements for dietary supplements are adequate.

14.5 An objective process for evaluating the safety of dietary supplement products should be developed by an independent expert panel.

Availability of Accurate Information on Potential Benefits, Risks, and Appropriate Use of Dietary Supplements and Other CAM Products

The regulation of products such as foods, drugs, vitamins, minerals, and botanicals is determined by the intended use of the product, and the label must conform to the laws and regulations governing the product's intended use. Thus, the same product can be marketed as a prescription drug, dietary supplement, or food, depending on the manufacturer's statements regarding the product's intended use.

Any product that claims to diagnose, prevent, mitigate, treat, or cure a disorder must be approved as a drug by the FDA; otherwise, such claims cannot be included on the label. Statements that a nutrient will reduce the risk of disease, such as "diets high in calcium may reduce the risk of osteoporosis" or "diets low in sodium may reduce the risk of high blood pressure" are known as health claims and must be approved under the provisions of the Nutrition Labeling and Education Act of 1990. This act applies to dietary supplements as well as conventional foods and it allows health claims to be made only after extensive FDA review of the scientific literature, using the "significant scientific agreement" standard to determine that the nutrient - disease relationship is well established.

Recent Federal legislation allows a product to claim a health benefit if the manufacturer provides evidence of an "authoritative statement" from a Federal agency or scientific organization such as the National Academy of Sciences. However, claims about treating, preventing, curing, or mitigating diseases are reserved only for drugs. Dietary supplements may make claims related to structure and function of the body, such as "improves immune function," or make no claim at all on the label.

Not having to undergo approval as drugs has greatly increased the accessibility of dietary supplements to the public, yet it has limited the availability of label information on potential risks, benefits, and appropriate use. For example, because it is distributed as a dietary supplement, glucosamine sulfate (2-amino-2-deoxyglucose), which has been shown in numerous scientific studies published in peer-reviewed journals to be effective in treating osteoarthritis [19], can claim only that it helps to maintain joint health. Likewise, numerous scientific studies, a monograph by the U.S. Pharmacopeia, and a meta-analysis published in the Journal of the American Medical Association show that Saw palmetto (Serenoa repens) is an effective treatment for benign prostatic hyperplasia [20]. This information cannot be included on the label because dietary supplements are limited to structure-function claims.

Manufacturers of products such as these have no incentive to petition the FDA for a health or drug claim because the products are not patentable and the manufacturers are therefore unlikely to recover the cost of additional research to

support the claim. This situation also acts as a deterrent to investment in research on risks, benefits, and appropriate conditions of use. Yet, even when such information is known, manufacturers are limited by current regulations as to what they can claim.

When information about substantial, documented risks does becomes available, as in the case of the potential interaction between St. John's Wort (Hypericum perforatum) and certain prescription drugs [21], it should be included on the label of both the prescription drug and the dietary supplement. Labels should provide information about significant interactions with prescription or over-the-counter drugs, foods, or other health products, as well as information about likely, significant risks to vulnerable populations such as children, the elderly, pregnant or nursing women, and those with certain health conditions or compromised immune systems.

Under current law, which holds the manufacturer responsible for ensuring the safety of products before marketing, the provision of such information is primarily the responsibility of the manufacturer. As with labeling for all products covered by the Federal Food, Drug, and Cosmetic Act, dietary supplement labels must include all facts that are material in light of consequences (such as potential risks and interactions) that may result from use of the product or representations made about it [22]. However, some manufacturers believe that insufficient scientific evidence is a justification for not informing the FDA of a potential problem. Greater emphasis should be placed on this important responsibility of manufacturers.

The public expects that products sold in the United States have been deemed safe. Most people are unaware of the complexities and implications of existing regulatory guidelines or recent court decisions that have upheld the right of commercial free speech in the advertising and labeling of dietary supplements. Since many dietary supplements are purchased without the knowledge or advice of an appropriately trained and credentialed provider, information on benefits, appropriate use, and potential risks should be made easily available to consumers at the time of purchase.

Although product labeling is of primary importance, labels have only limited space for information. Other options such as package inserts and point-of-sale information should be considered to ensure that consumers receive all pertinent information.

Some imported products have labels with information in a language other than English. Current regulations requiring information on labels to be in English should be enforced. This does not preclude another language from being used also, but it does ensure that the majority of consumers, providers, and regulators can understand the information.

Because the use of dietary supplements has grown so dramatically since the enactment of DSHEA, Federal and State regulatory agencies need more well-trained, highly skilled professionals with expertise in dietary supplements to safeguard the public. Expert staff are needed, particularly in the rapidly evolving area of botanicals, to help develop mutually supportive relationships between regulatory agencies and industry, thus engendering consumer confidence. Providing accurate information to consumers on CAM products is a complex technical, legal, and regulatory matter that requires ongoing participation by and consultation with the public.

Recommendation 15: Provisions of the Federal Food, Drug, and Cosmetic Act, as modified by the Dietary Supplement Health and Education Act of 1994, should be fully implemented, funded, enforced, and evaluated.

Actions

15.1 The Food and Drug Administration and other agencies with regulatory responsibilities should be provided with additional resources to 1) enforce the Dietary Supplement Health and Education Act's regulations regarding labeling of dietary supplements, 2) enforce current provisions requiring that dietary supplements be labeled in English, even if the same information is also included in another language, and 3) employ additional professionals with expertise in dietary supplements.

15.2 Current provisions requiring disclosure of material facts by manufacturers of CAM products should be enforced, and manufacturers should meet their responsibility to disclose material facts on the label, package, and/or package insert, so that the public will have information about known risks and well-documented significant interactions. Information on potential benefits of dietary supplements should also be made easily available at the time of purchase.

15.3 Congress should periodically evaluate the effectiveness, limitations, and enforcement of

---

The Dietary Supplement Health and Education Act of 1994, including its impact on public health, and take appropriate action to ensure the public's safety.

Advertising of Dietary Supplements and Other CAM Practices and Products

The FTC is responsible for ensuring that advertising is truthful, not misleading, and substantiated so that consumers can make informed decisions about the products being marketed. The FTC does this by enforcing laws that prohibit unfair or deceptive acts or practices in print and broadcast advertisements (including the Internet), catalogs, and similar direct-marketing materials.

Since the passage of DSHEA, the FTC has placed increased emphasis on monitoring the advertising of dietary supplements. More than 1,500 businesses in the United States manufacture dietary supplements [23] and an estimated $700 million was spent by these companies in 2000 to advertise their products on television and in print [24]. Almost $192 billion was spent on direct marketing of all health care products in 2000, including mail, catalogs, teleservices, and the Internet. This marketing is estimated to have generated $1.7 trillion in sales [25]. To help the dietary supplement industry conform to its standards of truthful and not misleading advertising, the FTC has produced a guide that provides detailed explanations and descriptions of acceptable statements [26]. Still, abuses have been identified, particularly on the Internet and in direct-mail advertising materials. Deceptive advertising by this small segment of the industry can not only hurt consumers, but also cause manufacturers and distributors that comply with current anti-deception and substantiation standards to lose market share and suffer financially.

Deceptive advertising comes in many forms. Some advertisements promise to treat or cure a disease or condition without scientific backing for the claim. Others claim to slow or reverse the aging process and increase longevity, energy, memory, and sexual function. Although some products may be beneficial for such conditions, others have no effect. In some cases, these products cause serious unintended effects, ranging from the consequences of delayed treatment to interactions with prescription drugs to increased risk of developing other conditions.

A recent Government Accounting Office (GAO) report and Senate hearing [27] highlighted the potential for physical and economic harm posed by certain dietary supplements marketed and advertised as anti-aging therapies. In addition to the potential medical consequences of these supplements, the GAO reports, 20 companies marketing the products have been targeted by law enforcement agencies and have cost consumers approximately $36 million [28].

Because of the proliferation of health fraud on the Internet, the FTC has established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims. Although Operation Cure.all is not aimed specifically at CAM- related sites, many of the fraudulent claims uncovered by the program are for CAM products and services to cure cancer, AIDS, and other chronic diseases. Although the FTC has identified hundreds of Internet sites with questionable or clearly fraudulent health claims and has sent out e-mail advisories to more than 500 of them, the agency has brought formal action against only 16 since 1997.

In addition to the Internet cases, the FTC has brought 40 enforcement actions since 1997 against companies for deceptive marketing of dietary supplements in other media, including radio, television, newspapers, magazines and direct mail.

The advertising challenged by the FTC promoted products for such conditions as attention deficit-hyperactivity disorder, colds and allergies, impotence, diabetes, vascular diseases, and obesity.

Current FTC efforts should be significantly expanded to decrease the amount of false or deceptive advertising, to solicit public comments on CAM advertising, and to expand the use of CAM experts in the process of examining advertisements.

Recommendation 16: Activities to ensure that advertising of dietary supplements and other CAM practices and products is truthful and not misleading should be increased.

16.1 Congress should provide additional support to the Federal Trade Commission to 1) expand efforts to identify false and deceptive advertising of CAM-related health services and products and take appropriate enforcement action when necessary, 2) use appropriate CAM experts in the process of examination of CAM-related advertising, 3) increase activities to help consumers distinguish useful and reliable information from deceptive and unsubstantiated advertising in all forms of marketing and advertising, including at the point of purchase; and 4) seek additional public comment on the benefits and potential problems in the advertising of CAM-related services and products.

Collection and Dissemination of Information on Adverse Events Stemming from the Use of Dietary Supplements

Most dietary supplements are likely to be safe for human consumption, yet, as with any biologically active substance, adverse events can and do occur. The rigorous pre-market testing and review process required for pharmaceuticals is not required for dietary supplements. Therefore, monitoring of adverse events after supplements reach the market is critical to understanding their effects and interactions and to responding quickly when problems do occur.

The FDA uses the Adverse Events Reporting system to identify emerging problems with specific products and general trends in illness and death related to dietary supplements. However, reporting is voluntary - manufacturers and distributors are not required to notify the FDA of adverse reactions that are reported to them. In April 2001, the Inspector General of the Department of Health and Human Services issued a report calling adverse event reporting for dietary supplements "an inadequate safety valve" [29]. The report identifies the limitations of the Adverse Events Reporting system in detecting serious adverse events and recommends ways of improving it.

Serious adverse events (as defined under Medwatch and the FDA's Standard Operating Procedures of 1999) related to dietary supplements need to be identified and, when necessary, contained in a timely manner to prevent unnecessary illness and death. Since manufacturers are not required to register themselves or their supplements with the FDA before producing or selling them, a potentially dangerous situation could be extremely difficult to contain. Manufacturers and suppliers should be required to register their products with the FDA so that the agency can quickly notify other manufacturers and suppliers and the public when a serious adverse event occurs. In addition, information from poison control centers needs to be linked with the Adverse Events Reporting system.

Recommendation 17: The collection and dissemination of information about adverse events stemming from the use of dietary supplements should be improved.

Actions

Congress should require dietary supplement manufacturers and suppliers to register with t the Food and Drug Administration, and the agency should encourage voluntary registration until such a requirement is in effect, so that manufacturers, suppliers, and consumers can be promptly notified if a serious adverse event is identified.

17.1 Recent congressional support for improving the Food and Drug Administration's adverse events reporting system should be enhanced by requiring dietary supplement manufacturers and suppliers to maintain records and report serious adverse events to the agency.

17.2 Additional resources and support should be provided to 1) the Food and Drug Administration to simplify the adverse events reporting system for dietary supplements, and to streamline the database for timely review and follow-up on received reports; and 2) the Food and Drug Administration, the Centers for Disease Control and Prevention, and other appropriate Federal agencies to increase outreach activities to consumers, health professionals (including poison control centers, emergency room physicians, CAM practitioners, and mid-level marketers) in order to improve both manufacturers' and the public's awareness of and participation in voluntary event reporting.

References

1 Coen Robert, The Insider's Report, Universal McCann, Dec 3, 2001. http://www.mccann.com/insight/bobcoen.html.

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

3 Survey of Consumer Use of Dietary Supplements, Prevention Magazine. Emmaus, Pennsylvania. 2000, p1-79.

4 P.L. 105 - 825, "Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year, 1999" Conference Report.

5 U.S.Department of Education, National Center for Educational Statistics. Adult Literacy and Education in America: Four Studies Based on the National Adult Literacy Survey, NCES 1999-469, U.S. Department of Education, National Center for Education Statistics, 2001. NCES 2001-534. 288p.

6 Newburger, EC, Current Population Reports: Home Computer s and Internet Use in the United States: August 2000. Census Bureau Report P23-207, September 2001.

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

8 Product Review: Echinacea, http://www.ConsumerLab.com, LLC, 2001.

9 Product Review: SAMe, http://www.ConsumerLab.com, LLC, 2000.

10 Harkey MR, Henderson GL, Gershwin ME, Stern JS, Hackman RM. Variability in commercial ginseng products: an analysis of 25 preparations. American Journal of Clinical Nutrition 2001, 73 (6):1101-1106.

11 California Department of Health Services, State Health Director Warns Consumers About Prescription Drugs in Herbal Products, February 2000. http://www.fda.gov/oc/po/firmrecalls/Herbal.html.

12 FDA Medwatch, February 2002. http://www.fda.gov/medwatch/SAFETY/2002/safety02.html.

13 Huggett DB, Khan IA, Allgood JC, Block DS, Schlenk D. Organochlorine Pesticides and Metals in Select Botanical Dietary Supplements, Bulletin of Environmental Contamination and Toxicology 2001, 66:150-155.

14 U.S. Food and Drug Administration, FDA News, "Solgar Vitamin and Herb Company Recalls Solgar's Digestive Aid 100's Dietary Supplements

Because of Possible Salmonella Contamination". FDA Talk Paper, Food and Drug Administration April 27, 2001. http://www.cfsan.fda.gov.

15 U.S. Food and Drug Administration, FDA News, "FDA Issues a Nationwide Alert on the Recall of Thirteen "Treasure of the East" Herbal Products Because of Possible Health Risk", FDA Talk Paper, Food and Drug Administration June 20, 2001. http://www.cfsan.fda.gov.

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

17 Report of the Commission on Dietary Supplement Labels, Report to the President, Congress, and Secretary of the Department of Health and Human Services, Nov 1997, Washington, DC.

18 Falk, M. Model for a Third-Party Review of the evidence Substantiating Food and Dietary Supplement Claims. Journal of Nutrition 131:2219-2223, 2001.

19 McAlindon T. Glucosamine and Chondroitin for Osteoarthritis?, Bulletin on the Rheumatic Diseases 2001 Jul; 50 (7): 1-4.

20 Wilt TJ, Ishani,A, Stark, G, MacDonald,R, et al. Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. Journal of the American Medical Society 1998; 280 (18):1604-9.

21 Ang-Lee M, Moss J, Yuan C. Herbal Medicines and Perioperative Care, Journal of the American Medical Association 2001, 286 (2): 208-216.

22 Federal Food, Drug, and Cosmetic Act, Sections 201(n) and 403(a)(1). http://www.fda.gov/opacom/laws/fdcact/fdctoc.html.

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

24 Dietary Supplement Market View 2 (10): 1-9; October 2000.

25 The WEFA Group. Economic Impact: U.S. Direct & Interactive Marketing Today, Direct Marketing Association, 2001.

26 Dietary Supplements - An Advertising Guide for Industry, Federal Trade Commission, Bureau of Consumer Protection, 1998.

27 Special Committee on Aging, U.S. Senate, September 10, 2001.

28 Health Products for Seniors; Potential Harm from "Anti-Aging Products, GAO-01-1139T, September, 2001.

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

Chapter 6: Access and Delivery

In Town Hall meetings across the country during the past two years, people voiced a number of concerns about access of the public to Complementary and Alternative Medicine (CAM) practitioners and products. Issues raised include 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 who testified, including those who have only limited access to "basic health care", expressed a desire for increased access to safe and effective CAM, along with conventional services.

As is true for 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. As with conventional care, access to CAM is more problematic for rural, uninsured, underinsured, and other special populations. The issue of access is further compounded by lack of scientific evidence regarding safety and effectiveness of many CAM practices and products.

A better understanding of how the public uses CAM is needed in order 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.

Most CAM practices have developed independently of the conventional health care system and are not uniformly regulated by the states or the Federal government. A variety of market mechanisms and other arrangements have developed to pay for these services, including out-of-pocket payments, discounted fees, insurance reimbursement, and donated services. Where the public has had access to CAM services it has often been with little assurance of safety, quality, or efficacy. Moreover, because most consumers have had to pay for CAM services directly, access often has been limited to those with higher discretionary income.[1] An overview of insurance coverage and reimbursement for CAM is presented in Chapter 7.

As interest in CAM grows and as CAM increasingly enters the mainstream of American health care, mechanisms that worked in the past to help ensure safety and quality may no longer be adequate. For example, if CAM practices become eligible for reimbursement through the health insurance system, issues that now confront the conventional health care system - including safety, fraud, and

practitioner malpractice or incompetence - will need to be addressed for CAM. In addition, if private health insurance reimbursement for CAM services increases, questions of equity arise for beneficiaries of Federal - and state- sponsored health care programs, the underinsured, and uninsured.

Some people believe that existing practice structures have worked well for those who use CAM and that no further action is required. But market demand for CAM is already reshaping the dynamics of health care delivery, requiring that some issues be addressed. For example, insurers and managed care plans are offering CAM options more frequently, and integrated medical clinics and private practices are spreading. As more evidence is published on the safety and effectiveness of CAM practices, they are more likely to be incorporated into health care treatment protocols.

Now is the time to look at policy options for the future and to design strategies for addressing potential issues of access and safety. Beyond these basic concerns, protecting the public, maintaining free competition in the provision of CAM services, and maintaining the consumer's freedom to choose appropriate health professionals are issues to be considered when developing strategies and policies. Moreover, 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 these issues.

If approached with both imagination and caution, the policy planning process could not only address these issues more effectively, but also a broader set of health issues affecting the nation, such as whether access to safe and effective CAM services can:

- Benefit vulnerable populations including those with chronic diseases, the terminally ill, and other populations with special needs;
- Lower health care costs and possibly increase access to conventional health care services for some segments of the population, such as the chronically and terminally ill; and,
- Help solve issues of equity and quality that do not set up a zero-sum struggle over limited resources.

The present state of evidence concerning the safety and effectiveness of various CAM practices precludes any final assessment of their contributions to and limitations in addressing these broader health issues. The process of gathering evidence is on-going, however, and as evidence increases concerning ways that various CAM approaches do or do not affect health, processes of living and dying, and costs for other care, access to and delivery of some CAM practices and services are likely to become more pressing public policy issues.

Meanwhile, public interest in CAM, and the market dynamics that have evolved in response to it, have brought issues of access to the forefront. Policy-makers

should begin to address these issues and examine the implications of different kinds of policy for consumers and practitioners, for clinics, hospitals and other organizational settings where health care is now delivered, and for the system as a whole.

CAM Practitioners and Public Safety

The public has expressed interest in maintaining easy access to CAM practitioners and in having sufficient information about them to make informed choices. Perceptions of the relative importance of being able to take responsibility for one's own health and health decisions, yet be protected from incompetent practitioners, underlie differences in consumers' response to possible state or Federal regulation of CAM. Public sentiment on the need for and degree of regulation ranges, with some calling for more regulation of CAM, to others who are opposed to any regulation. 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.

CAM practitioners have raised additional issues that are important to the public because they affect freedom of access to CAM providers. Some health care practitioners, both CAM and conventional, are concerned about liability and prosecution if the services they provide are not commonly accepted within conventional medical practice. Another concern of some CAM professionals is that they are licensed to practice in some states but not others, and that even where licensed, their scope of practice may vary across the country.

While some CAM professions endorse licensure requirements in order to participate fully in the health care delivery system, several people testified that licensure is not feasible for some categories of CAM practitioners, such as Native American and other traditional healers. Some CAM practitioners consider their disciplines to be educational (Alexander Technique) or spiritual (Reiki) and have expressed concerns about being licensed as health professionals. Some conventional health care practitioners who incorporate CAM modalities into their practices want to broaden the scope of practice laws to allow these modalities to be used.

Establishing legal authority to practice requires states to establish standards of practice, including training, education and continuing education requirements, as well as scope of practice. Some CAM professionals believe that to reorganize CAM on the conventional professional model, with the kind of licensure, registration, or exemption procedures that this implies, will damage the fundamental character of much of CAM. Some believe that in the past, legislation to "protect the public" was often used to restrict competition in the provision of services.

Five important issues of access and delivery concern both the public and practitioners:

- Protecting the public from the inappropriate practice of health care,
- Providing opportunities for appropriately trained and qualified health practitioners to offer the full range of services in which they are trained and competent,
- Maintaining competition in the provision of CAM and other health services,
- Preserving CAM styles and traditions that have been valued by both practitioners and consumers, and
- Determining the extent of the public's choice among health care modalities.

If addressed separately, these concerns can lead to very different public policies, and state legislation that affects access to CAM practices varies in its emphasis on these concerns. Therefore, when developing strategies to address problems of access to CAM practitioners, all of these criteria should be considered.

Evaluating State Approaches

Legislative and regulatory policies that affect conventional and CAM practitioners fall largely under the aegis of state governments, primarily through regulation of practice. In recent years, a few states have passed legislation and enacted regulations that affect access to CAM practitioners. These regulations provide a natural experiment for solutions to access and delivery of CAM. If properly documented and evaluated, these ventures could provide information that may guide other states and the Federal government in future policy development.

Minnesota provides almost unlimited freedom to practice. Unlicensed practitioners must inform clients of their education, experience, and intended treatments, as well as possible side effects or known risks of the treatments. Clients must sign an informed consent statement acknowledging the practitioner is unlicensed, that complaints may be filed with the Minnesota Department of Health if treatment is unsatisfactory, and that they have the right to seek licensed care at any time. Requirements for practice are minimal, but practitioners are not exempted from liability for untoward outcomes. Licensed health professionals also may provide CAM services, as long as their provision of the services is consistent with regulations governing their licensure. In short, the Minnesota law preserves maximum freedom for CAM practitioners and consumers and relies primarily upon informed consent for protection of health care consumers.

In contrast, Washington provides licensure, registration, or exemption for various categories of CAM professionals, based on their education and the extent to which their profession prepares practitioners to assume responsibility for the total health care of clients. Regulations delineate standards of practice, the scope of practice allowable, education and training requirements for licensure, registration,

or exemption, and required professional oversight. Four CAM professional groups (naturopathic physicians, acupuncturists, massage therapists, and chiropractors) are licensed and regulated.

The emphasis in Minnesota is placed on granting all CAM professionals the freedom to practice with minimal restrictions, while holding them accountable for outcomes. The Washington law emphasizes licensure as the route to protecting consumers and the practice rights of some CAM professionals. The Minnesota law preserves the range of CAM practices without distinguishing among them, whereas the Washington law requires CAM practitioners to fit into a professional model in order to receive the rights and responsibilities granted conventional health care professions.

Other states vary considerably in their regulatory approaches to licensure and scope of practice. For example, chiropractors are licensed in all states, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 40, 30, and 11 states, respectively. (Table 1 shows the distribution of CAM specialties by state.) These variations affect access to and delivery of CAM by limiting practitioners' ability to practice lawfully and to obtain malpractice insurance. On the Federal level, several bills have been introduced into recent sessions of Congress that could affect access to CAM, including some that allow greater latitude for unconventional treatments. Any Federal legislation drafted in the future should consider the experience states are acquiring through their various legislative initiatives.

A number of factors should be studied when evaluating state models of creating access and delivery and protecting the public. Health services research should document how different legal frameworks affect access to CAM and how this different access affects health outcomes. Other issues to be considered include how state regulations affect the supply and distribution of various CAM practices and practitioners over time, as well as competition and costs of services. Also important are the effects of different regulatory models on the safety of the population, problems that may arise from use of different models, and the impact on conventional health care practitioners. Changes in the amount of time and quality of interaction with consumers of CAM services might also be assessed through periodic surveys. As evidence becomes available about the impact each regulatory model is having, the lessons learned can help inform choices that other states and the Federal government will be making.

Authority to practice has real impact on access to and delivery of services. The Department of Health and Human Services should gather and assess information about effects of these laws on the public's health as well as on access to CAM and CAM practitioners.

Recommendation 18: The Department of Health and Human Services should evaluate current barriers to consumer access to safe and effective CAM practices and to qualified practitioners and should develop strategies for removing those barriers in order to increase access and to ensure accountability.

Actions

18.1 The Department of Health and Human Services should assist the states in evaluating the impact of legislation enacted by various states on access to CAM practices and on public safety.

18.2 The Department of Health and Human Services and other appropriate Federal agencies should use health care workforce data, data from national surveys on use of CAM, regional public health reports on CAM activities and other studies to identify current and future health care needs and the relevance of safe and effective CAM services for helping address these needs.

Regulatory Frameworks

States, in exercising their authority over health care practitioners, should consider where a regulatory infrastructure for CAM practitioners might be necessary in order to promote quality of care and patient safety. The primary mechanisms used by states to regulate health care practitioners are:

- Mandatory Licensure, which prohibits the practice of a profession without a license. Licensure denotes a high degree of professional development, including consensus within the profession concerning standards of education, training, and practice, and the ability to self-regulate.
- Title Licensure, which permits anyone to practice the modality, but allows only those granted a license to use the title. A demonstrable level of skill or training normally is required for title licensure.
- Registration, which is granted in some states to professionals such as dieticians and pharmacists upon completion of required training and exams, is in other states simply a requirement that a provider register his or her name, address, and training with a designated state agency. This type of registration prohibits non-registered individuals from practicing and gives the agency authority to receive consumer complaints and revoke registrations.
- Exemption, which accords special status to religious healers. Medical licensing statutes do not apply to these healers, provided they practice within the tenets of a recognized church.

State and Federal policy-makers and others with an interest in these issues should recognize three unique challenges that face regulation of CAM

practitioners. First, views vary among CAM practitioners regarding how much training should be required for licensure in any given field, the extent to which such training should be required for licensure, and whether and how such education and training can incorporate intuitive skills and individualized approaches to providing health care services. For many CAM providers, licensure presents a tension between the desire to increase standardization of CAM education, training, and practices across states and the desire to keep CAM practice flexible, non-standardized, and linked to subjective, interpersonal and intuitive aspects of care. While increased licensure of CAM may help facilitate research, ease referrals, enhance patient access, and increase consumer protection, it may decrease individualization of services, time spent per patient, and range of patient options, qualities of CAM practice valued by practitioners and patients alike.

Second, variation in what constitutes "CAM" makes any assessment of CAM as value-added services difficult. Disagreement also surrounds the nature and scope of various CAM professions. In 2001, the University of California, San Francisco Center for Health Professions published a report that addresses this issue[2]. Questions it raised include: How does the profession describe itself in terms of the types of care it provides, and the types of care that are beyond its professional scope? Are there differences of opinion within the profession about the range of care that is appropriate for the profession to provide? What interventions and modalities does the profession use? Answers to these questions will help define the various CAM professions.

A third, related concern involves the confusion and potential legal consequences that arise from the overlap of approaches and techniques used by CAM practitioners. For example, some states include homeopathy and acupuncture within the definition of the practice scopes for naturopathy or chiropractic, whereas others do not. Practitioners from states with a broad scope of practice who move to states with a more limited one may be unsure whether they risk state censure by providing these services. Confusion and legal risk can occur within a state if the legal authority to practice is not well defined or lacks clarity as to boundaries for practice. The potential for liability creates fear and uncertainty for some CAM practitioners. All providers, CAM and conventional, can be prosecuted if they are considered to have exceeded their scope of practice.

To address some of these issues the Pew Health Professions Commission, established in 1989, conducted an in-depth study of reform in the regulation of health care practitioners. They recognized that health care workforce reform would necessitate regulatory reform and created a task force to propose new approaches that would better serve the public's interest. In 1995, they published 10 recommendations for regulatory reform and offered policy options, hoping to stimulate debate and discussion by states.[3] The recommendations focus primarily on regulation of conventional health care practitioners but they are

applicable to CAM practitioners as well. Recommendations from the Pew Commission Taskforce are in Appendix B.

Recommendation 19: The Federal Government should offer assistance to states and professional organizations in 1) developing and evaluating guidelines for practitioner accountability and competence in CAM delivery, including regulation of practice, and 2) periodic review and assessment of the effects of regulations on consumer protection.

Actions

19.1 The Secretary of Health and Human Services should create a policy advisory committee, including CAM and conventional practitioners and representatives of the public, to address issues related to providing access to qualified CAM practitioners, provide guidance to the states concerning regulation possibilities, and provide a forum for dialogue on other issues related to maximizing access.

19.2 The Secretary of Health and Human Services, in collaboration with states, should assist CAM organizations that wish to develop consensus within their field of practice regarding standards of practice, including education and training. The conclusions reached by CAM professional groups concerning these matters should be considered by states and regulatory bodies in determining the appropriate status of these practitioners for such regulatory options as registration, licensure or exemption.

Recommendation 20: States should evaluate and review their regulation of CAM practitioners and ensure their accountability to the public. States should, as appropriate, implement provisions for licensure, registration, and exemption consistent with the practitioners' education, training, and scope of practice.

Actions

20.1 The Department of Health and Human Services' policy advisory committee, in partnership with state legislatures, regulatory boards, and CAM practitioners, should develop model guidelines or other guidance for the regulation and oversight of licensed and registered practitioners who use CAM services and products. This guidance should balance concerns regarding protection of the public from the inappropriate practice of health care, provide opportunities for appropriately trained and qualified health practitioners to offer the full range of services in which they are trained and competent, maintain competition in the provision of CAM and other health services, preserve CAM styles and traditions that have been valued by both practitioners and consumers, and determine the extent of the public's choice among health care modalities.

Hospitals, Nursing Homes, Hospice, Community Health Centers, and other Health Care Delivery Organizations

Hospitals and Other Conventional Health Care Settings

Because of the increased use of CAM, access and safety issues involving delivery of CAM in hospitals, hospices, nursing homes, community health centers, and other health delivery organizations are increasing. Patients sometimes bring CAM products and even CAM practitioners into inpatient settings. Health delivery organizations vary in their policies and procedures regarding such situations, and there is little monitoring of interactions between CAM and conventional health care in these settings.

Health care facilities credential practitioners who provide services at their facilities. The question of who may practice and under what conditions within health delivery facilities is not addressed consistently for CAM practitioners. In some facilities, CAM practitioners who are not credentialed are permitted to provide services to patients; in others, only practitioners already credentialed by the facility may provide services.

Issues of safety and quality of care also arise when conventional practitioners who are credentialed by a facility use CAM in their practice. An increasing number of physicians use CAM practices for their patients in both inpatient and outpatient settings.

One way to address the growing number of issues related to the use of CAM interventions in hospitals, nursing homes, hospices, other clinical settings, and home health care is through the initiatives and leadership of nationally recognized accrediting organizations, including those that accredit health care networks and managed care organizations. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), an independent nonprofit organization, surveys and accredits nearly 18,000 facilities, other health delivery settings, and health plans using professionally based standards to measure compliance. Other nationally recognized accrediting organizations include the National Committee for Quality Assurance and the American Accreditation HealthCare Commission. The efforts of these organizations to address CAM in all health care settings will contribute greatly to the public's safety. In addition, these efforts will assist state and Federal regulators of health delivery organizations and health plans, who often use accreditation as a proxy for government oversight.

One important initiative that national accrediting organizations may take is to review their standards, guidelines, and interpretations for areas that affect or are affected by trends in CAM. For instance, one JCAHO standard addresses "the

relationship of the hospital staff and its staff members to other health care providers, educational institutions, and payers." In this case, more specific guidance is needed as to how a facility can meet the standard when incorporating CAM interventions into hospital services, serving as a component of an integrated delivery system that includes CAM, or participating in collaborative treatment plans with CAM providers.

The work of national accrediting organizations includes not only a wide range of standards and guidance, but also measurement tools, quality and performance improvement initiatives, and surveys. The work usually is conducted by staff along with representatives of the health care industry, other industry experts, and consumers who serve on various committees and special working groups. It is important for national accrediting organizations to include CAM experts and representatives of CAM organizations on any group that addresses issues related to CAM.

Recommendation 21: Nationally recognized accrediting bodies should evaluate how health care organizations under their oversight are using CAM practices and should develop strategies for the safe and appropriate use of qualified CAM practitioners and safe and effective products in these organizations.

Actions

21.1 National accrediting bodies, in partnership with other public and private organizations, should evaluate present uses of CAM practitioners in health care delivery settings and develop strategies for their appropriate use in ways that will benefit the public.

21.2 Nationally recognized accrediting bodies of health care organizations and facilities should consider increasing on-going access to CAM expertise to ensure that processes to develop accreditation standards and interpretations reflect emerging developments in the health care field.

21.3 Nationally recognized accrediting bodies, using CAM experts, should review and evaluate current standards and guidelines to ensure the safe use of CAM practices and products in health care delivery organizations.

Community Health Centers, Hospices, Independent Centers and Other Programs

A growing number of Americans use community health centers and other public health programs to meet their health care needs, including help with mental health and substance abuse treatment. These centers and programs often emphasize patient-centered care. A few community health centers have begun to

use the services of CAM practitioners such as chiropractors, naturopathic physicians and acupuncturists. These centers might serve as models for the use of CAM practitioners by other community health centers and other public health service programs; however, they need to be evaluated to determine their impact on health care access and cost-benefits.

Hospice care for the terminally ill is another important model that should be evaluated further. Some hospice programs are beginning to include CAM practitioners on the treatment team. Some of the CAM practices they use are chiropractic, acupuncture, music therapy, meditation, and visualization. In some instances, these services are believed to help reduce anxiety and pain.

Some independent CAM centers, which may not have any direct hospital affiliation and may not have a physician on staff, also offer a variety of CAM services. These centers tend to be client-oriented with flexible hours and a broad spectrum of practitioners available. Many of the centers encourage patients to actively improve their health and concentrate on health maintenance rather than disease care and encourage coordination and collaboration among CAM practitioners who are seeing the same patient or client. More information is needed on who uses these centers, their impact on access and delivery, whether appropriate referral procedures are in place, and the quality of care provided. Only when more systematic data are available can the advantages and disadvantages of independent CAM centers be assessed.

Special and Vulnerable Populations

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. Efforts to address access to CAM need to be balanced with the need for access to conventional health care. Scarce resources need to be carefully allocated so that these populations are not denied opportunities available to others to access safe and effective conventional and CAM services.

Increased information on CAM use and barriers to access for these populations is needed. Although some studies have described CAM use among African Americans, Native Americans, Hispanics, and Asian Americans, reliable access and utilization data are largely lacking. In the case of Native Americans, information gathering is limited by their status as sovereign nations. Nonetheless, the Indian Health Service has a program to encourage communication with practitioners of traditional Indian medicine, which will help ensure safety when both Native American and conventional medical systems are used.

Surveys of CAM use in the general population indicate that it is being used disproportionately by highly educated, and upper-income Americans.[4] However,

early studies used telephone interviews with English speakers, thus providing little information about CAM use among those who do not speak or have limited ability in English, who have lower income, or who lack telephones.[5] Later studies corrected for these biases, but they did not use adequate statistical sampling to estimate the use of CAM in minority populations.[6, 7, 8, 9, 10, 11] Other surveys have focused on low-income and ethnic groups, but these studies frequently had small, unrepresentative samples.[12, 13, 14, 15] The National Center for Health Statistics is conducting a nationwide survey on access to and use of CAM among racial and ethnic minorities that is expected to provide statistically reliable estimates of CAM use in these groups.

In an October 2000 letter to community health centers and other public health programs, the Health Resources and Services Administration's Bureau of Primary Health Care (BPHC) endorsed the use of CAM in these centers where appropriate. [16] In 2001 they began surveying the use of CAM by persons receiving health services from BPHC-funded community health centers. Information being gathered includes participants' use of six modalities (acupuncture, manual healing, botanicals and herbs, homeopathy, traditional healing, and mind-body techniques); whether the CAM service was provided onsite or by referral, either with or without payment by the community health center; and demographic data. Results should be available in 2002 and will provide a significant, statistically reliable portrait of the use of a variety of CAM services and products by community health center clients, whose come disproportionately from rural, low-income, and minority populations. It is important to continue collecting this kind of information in the future.

Discussions are currently underway between BPHC and the National Center for Complementary and Alternative Medicine to include clients of community health centers in CAM clinical trials, in order to increase the relevance of findings for application to the health needs of minority populations.

Use of CAM is especially high among populations with potentially life-threatening diseases. Surveys show that people with cancer use CAM practices and products more frequently than the population as a whole, with CAM most often being used in conjunction with conventional therapies.[17, 18,19] Similarly, there is high use of CAM by people who are terminally ill and their care-takers. Many people in these vulnerable populations are using CAM services regardless of whether they have insurance coverage and sometimes without the knowledge or cooperation of their conventional physician.

The chronically and terminally ill consume more health care resources than the rest of the population. Approximately 75 percent of all health care spending in the U.S. currently is for the treatment of chronic disease [20], and 25 percent of Medicare spending is for costs incurred during the last year of life.[21] The great interest in CAM practices among the chronically ill, those with life-threatening conditions, and those at the end of their lives suggests that increased access to

some CAM services among these groups could have significant implications for the health care system. Health services research, demonstrations, and evaluations are needed to assess whether CAM services can improve care and quality of life for people in these groups, and possibly lessen the use of expensive technological interventions.

With the number of older Americans expected to increase dramatically over the next 20 years, alternative strategies for dealing with end-of-life processes will be increasingly important in public policy. This demographic shift should influence priorities for the kinds of research and demonstration projects that would be carried out in the near future. A more careful assessment of the potential and limitations of CAM approaches in the health care system as a whole might lead to more effective use of resources. For example, Congress could direct the Center for Medicare and Medicaid Services to develop a demonstration project to study evidence-based CAM interventions as part of comprehensive care of persons with chronic disease in both the Medicare and Medicaid programs. The demonstrations would assess health outcomes and total costs of care for beneficiaries in settings where physician leaders are committed to evidence-based medicine, high quality, client-centered care, and openness to CAM approaches. If evaluations show that some uses of CAM can lessen the need for more expensive conventional care in these populations, the economic implications for these Medicare and Medicaid could be significant.

If safe and effective CAM practices become more available to the general population, special and vulnerable populations should also have access to these services, along with conventional healthcare. CAM would not be a replacement for conventional health care, but would be part of the options available for treatment. In some cases, CAM practices may be an equal or superior option.

Evidence for assessing the potential of CAM interventions in treating vulnerable and special populations is still being gathered. While it is too early to judge the effectiveness of CAM in addressing their health care needs, CAM nonetheless offers the possibility of a new paradigm of integrated health care that could affect the affordability, accessibility, and delivery of health care services for millions of Americans.

Recommendation 22: The Federal government should facilitate and support the evaluation and implementation of safe and effective CAM practices to help meet the health care needs of special and vulnerable populations.

Actions

22.1 The Department of Health and Human Services and other Federal Departments should identify models of health care delivery that include safe and effective CAM practices, evaluate them, and then support those

models which are successful for use with special and vulnerable populations, including the chronically and terminally ill.

22.2 The Department of Health and Human Services should sponsor the development and evaluation of demonstration projects that integrate the use of safe and effective CAM services as part of the health care programs in hospices and community health centers.

22.3 The Department of Health and Human Services should identify ways to support the practice of indigenous healing in the United States and to improve communication among indigenous healers, conventional health care professionals, and CAM practitioners.

Table 1. Provider Licensing by State and Specialty

STATE	CHIRO-PRACTORS	ACUPUNCTURISTS				MASSAGE THERAPISTS				NATUR O-PATHS	DIETITIANS		
	Licensing Laws	Licensing Laws	Access Requires MD Referral and/or Prior Diagnosis	MD Supervision Required	May dispense TCHS	MD Supervision Required	Licensing Laws	Regulated	Licensing Laws Pending	Licensing Laws	Registration Laws	Licensing Laws	Certification Laws
Alabama	x						x				x	x	
Alaska	x	x						x		x	x	x	
Arizona	x	x			x			x		x	x		
Arkansas	x	x			x		x				x	x	
California	x	x			x			x			x		
Colorado	x	x			x			x			x		
Connecticut	x	x					x			x	x		x
Delaware	x						x				x		x
Florida	x	x			x		x				x	x	
Georgia	x	x			x			x			x	x	
Hawaii	x	x			x		x			x	x	x	
Idaho	x	x			x			x			x	x	
Illinois	x	x	x					x			x	x	
Indiana	x	x	x					x			x		x
Iowa	x	x					x				x	x	
Kansas	x							x			x	x	
Kentucky	x							x			x	x	
Louisiana	x	x		x		x	x				x	x	
Maine	x	x					x			x	x	x	
Maryland	x	x					x				x	x	
Massachusetts	x	x			x			x			x	x	
Michigan	x							x			x		
Minnesota	x	x			x			x			x	x	
Mississippi	x							x	x		x	x	
Missouri	x	x					x				x	x	
Montana	x	x			x			x		x	x	x	
Nebraska	x						x				x	x	
Nevada	x	x			x			x			x		
New Hampshire	x	x			x		x			x	x	x	
New Jersey	x	x	x		x		x				x		
New Mexico	x	x			x		x				x	x	
New York	x	x					x				x		x
North Carolina	x	x			x		x				x	x	
North Dakota	x						x				x	x	
Ohio	x	x	x	x		x	x				x	x	
Oklahoma	x							x			x	x	
Oregon	x	x			x		x			x	x	x	
Pennsylvania	x	x		x		x		x			x		
Rhode Island	x	x					x				x	x	
South Carolina	x	x	x	x		x	x				x		
South Dakota	x							x			x	x	
Tennessee	x	x					x				x	x	
Texas	x	x	x		x		x				x	x	
Utah	x	x					x			x	x		x
Vermont	x	x			x			x		x	x		x

References

1 Eisenberg, DM, Kestrel RC, Foster C, et al. Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use. New England Journal of Medicine 1993; 328(4): 246-252.

2 University of California, San Francisco. The Center for the Health Professions. Profiling the Professions: A Model for Evaluating Emerging Health Professions. 2001.

3 University of California, San Francisco. The Center for the Health Professions. Reforming Health Care Workforce Regulation Policy: Considerations for the 21st Century. 1995.

4 Eisenberg DM, Davis RB, Ettner SL, et al. Trends in Alternative Medicine Use in the United States, 1990-1997: Results of a Follow-up National Survey. Journal of the American Medical Association 1998; 280:1569-1575.

5 Wootton JC, Sparber A. Surveys of Complementary and Alternative Medicine: Part I. General Trends and Demographic Groups. Journal of Alternative and Complementary Medicine 2001; 7(2): 195-208.

6 Allen R, Cushman LF, Morris S, et al. Use of Complementary and Alternative Medicine Among Dominican Emergency Department Patients. American Journal of Emergency Medicine 2000; 18:51-54.

7 Cushman LF, Wade C, Factor-Litvak P, et al . Use of Complementary and Alternative Medicine Among African-American and Hispanic Women in New York City: Pilot Study. Journal of the American Medical Women's Association 1999; 54 (4): 193-195.

8 Keegan L. Use of Alternative Therapies Among Mexican-Americans in the Texas Rio Grande Valley. Journal of Holistic Nursing 1996; 14 (4): 277-294.

9 Kim C, Kwok YS. Navajo Use of Native Healers. Archives of Internal Medicine 1998; 158:2245-2249.

10 Ma GX. Between Two Worlds: The Use of Traditional and Western Health Services by Chinese Immigrants. Journal of Community Health 1999; 24(6): 421-437.

11 Risser AL, Mzur LJ. Use of Folk Remedies in a Hispanic Population. Archives of Pediatric Adolescent Medicine 1995; 149: 978-981.

12 Breunner CC, Barry PJ, Kemper KJ. Alternative Medicine Use by Homeless Youth. Archives of Pediatric Adolescent Medicine 1998; 152: 1071-1075.

13 Burg MA, Hatch RL, Neims AH. Lifetime Use of Alternative Therapy: a Study of Florida Residents. Southern Medical Journal 1998; 91(12): 1126-1131.

14 Johnson JE. Older Rural Women and the Use of Complementary Therapies. Journal of Community Health Nursing 1999; 16(4): 223-232.

15 Pourat N, Lubben J, Wallace SP, Moon A. Predictors of Use of Traditional Korean Healers Among Elderly Koreans in Los Angeles. Gerentologist 1999; 39(6): 711-719.

16 Program Assistance Letter, Bureau of Primary Health Care, October 2001 Friedman T, Slayton WB, Allen L, et al. Use of Alternative Therapies for Children with Cancer [abstr] Pediatrics 1997; 100(6) E1.

17 Kelly KM, Jacobson JS, Kennedy DD, et al. Use of Unconventional Therapies by Children with Cancer at an Urban Medical Center. Journal of Pediatric Hematology and Oncology 2000; 22(5): 412-416.

18 Wyatt GK, Friedman LL, Given CW, et al. Complementary Therapy Use Among Older Cancer Patients. Cancer Practice 1997; 7(3): 136-144.

19 Hoffman C, Rice D, Sung HY. Persons with Chronic Conditions: Their Prevalence and Costs. Journal of the American Medical Association 1996; 276(18): 1473-1479.

20 Hogan C, Lunney J, Gabel J, et al. Medicare Beneficiaries' Costs of Care in the Last Year of Life. Health Affairs 2001; 20: 188-195.

Chapter 7: 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 and will continue to play a crucial role in shaping the health care system in this country. Likewise, policies influencing coverage of and reimbursement for non-conventional health care therapies will play an increasingly important role in the future of complementary and alternative medicine (CAM), as well as the future structure of the nation's health care system.

Today, coverage of CAM is evolving in benefit design, type and number of interventions offered, and availability. Consumers and health care providers may use available coverage for a CAM therapy as a principal intervention or as an integral part of the treatment of certain health conditions, such as acupuncture for management of chronic pain. The direction taken by health plan coverage of CAM in the future will shape consumer access to CAM services, the degree of integration of CAM and conventional medicine, and the philosophical foundation of the nation's health care system.

Although a considerable segment of the U.S. population is uninsured -- a significant public policy issue in itself -- health care coverage is widely available in this country. Recent census data indicate that 86 percent of the population had some type of health insurance during the year.[1] Included in that number are 32 million people (11 percent of the population) covered by Medicare, the federal insurance program for the elderly and for eligible persons who are disabled or who have end-stage renal disease. Other significant sources of health care coverage include private employer and sponsors of benefits, the Office of Personnel Management (OPM) for Federal employees, State and other public employers, the Department of Defense (DOD) for the military community, the Department of Veterans Affairs (VA) for veterans, and Federal and State programs providing Medicaid and other health coverage for the economically disadvantaged. Researchers estimate that, in 2001, Federal and State programs (i.e., Medicare, Medicaid, and the State Children's Health Insurance Program) accounted for 44 percent of the nation's health expenditures and that insurers and other private sources were responsible for 40 percent.[2] The entities, whether public and private, that pay for or bear most of the cost of coverage are the purchasers of health care.

With some exceptions (e.g., fee-for-service Medicare), purchasers obtain health care coverage for their employees or eligible persons by "buying" health plans in the private market. Less commonly, purchasers directly contract with, or employ, health care providers.

The remainder, or approximately 14 percent of national health expenditures, were paid out-of-pocket.

The entities that sell health plan coverage to purchasers are insurance and managed care companies, which include preferred provider organizations (PPOs) and health maintenance organizations (HMOs). These companies undertake all the tasks associated with operating health plans, including marketing, enrollment, paying or operating networks of thousands of providers (physicians, hospitals, clinics, nursing homes, therapists, and so on), and bearing -- or sometime sharing with providers -- most of the financial risk of health care coverage. That is, they shift the potential for financial loss from purchaser to themselves. Even federally sponsored programs such as Medicare, and Federal sponsors such as DOD (for the military, retirees, and dependents), have in place special programs that shift not only delivery of care but financial risk to managed care companies. Some purchasers, including a number of employers, self-insure and assume the risks inherent in providing health care coverage, although these purchasers are the exception rather than the rule.

Consumers are sheltered from most of the costs associated with conventional health care, as well as from the risks of future, unknown expenses because purchasers, insurers, and managed care companies shoulder them. In contrast, most fees for CAM services and products are paid by consumers. This direct financial relationship between provider and consumer has the merit of enhancing the consumer's interest and participation in his or her treatment. Furthermore, some CAM practitioners feel that their ability to control fees -- and to avoid time-consuming claims payment and network participation requirements -- enables them to spend more time with clients and to maintain a high level of individualized care. On the other hand, without insurance coverage, access to CAM services is limited by the consumer's ability to pay. Many consumers are unable, or perhaps unwilling, to obtain CAM treatments or to or integrate them into their care because the treatments are not covered under their health plan.

Coverage of CAM

In the last several years, a number of health plans have begun to cover certain CAM services, although the prevalence of this coverage is relatively low, compared to coverage of conventional therapies. Information on this trend is available from an annual survey of employer-sponsored health plans that recently began to include questions regarding a few specific CAM services offered in benefit packages. In 1998, 49 percent of survey respondents indicated that chiropractic was covered; by 2000, the number had risen to 70 per cent. Over the same time period, coverage of acupuncture rose from 12 per cent to 17 percent, and coverage of massage therapy increased from 10 percent to 12 percent. The survey also found that large employers (those with more than 20,000 employees) were more likely to offer CAM benefits than medium and smaller employers. PPOs and indemnity insurers were more likely than HMOs to offer health plans that include CAM benefits.[3]

Insurance and HMO coverage of CAM will very likely have an impact on use of CAM services. It has been reported that fully covered persons made twice as many visits to chiropractors as individuals with no health plan coverage or those required to pay 25 percent of costs.[4] In a recent survey of over 2,000 households, health insurance coverage was found to be the strongest correlate for frequent use of CAM practitioners.[5]

Even where there is health plan coverage, it is often limited. For example, the CAM benefit may cover only one or a few CAM services as the data above indicates. Other limitations include ceilings on the number of visits covered, restrictions on clinical applications, and fixed qualifications for the type of practitioner; for example, ten acupuncture visits might be covered for pain management provided by a medical doctor, and thus would not be covered if provided by a professionally-trained acupuncturist.

Why have employers begun to ask their health insurance and managed care companies to cover CAM benefits? Surveys indicate that they do so primarily in response to employee requests. Other reasons cited in the findings include: 1) attracting and retaining employees, 2) State mandates, and 3) the potential medical benefits of CAM. Although most respondents anticipated increasing their coverage of CAM programs in the future, they cited a number of obstacles to such increases, including inadequate research, regulatory concerns (e.g., licensure), lack of understanding and knowledge about CAM, and lack of data on utilization and costs.[6] A recently published survey of health plans new to offering CAM benefits supports these findings: The plans are offering CAM benefits in response to market research, consumer demand, to attract and retain enrollees, and at the request of purchasers.[7]
At present, CAM is being offered as part of a health plan in several ways, including:

- As a rider, or supplement, to the basic benefit package, often with controls on usage, such as copayments, benefit limits (e.g., visit limits, annual limits), or use of an approved network of CAM providers.
- As a discount program whereby covered employees (or members) pay out-of-pocket but are eligible for discounts off professional CAM fees and CAM products (discounted fees are usually tied to an approved network of CAM practitioners).
- As a defined, core benefit. This benefit is managed by limiting the type of CAM services covered (e.g., only chiropractic, or only chiropractic and acupuncture), requiring a preauthorization or a referral by a primary care physician, or setting visit or dollar limits and higher co-payments than for routine physician visits.
- As a CAM benefit account, typically an annual dollar amount.

Employers also may offer prevention, wellness, or health promotion programs, on-site or off-site. These typically include smoking cessation, weight control,

stress reduction, yoga, health club memberships, and other special programs. More recently, employers have become interested in educational programs to help employees with chronic diseases manage their conditions. Employers who have introduced such programs do so to decrease absenteeism, improve productivity and morale, and achieve some cost savings. Like health benefit coverage, employer-based programs to promote health are often limited in scope and restricted to certain modalities.

Overcoming Barriers to Coverage of Safe and Effective CAM

Health care interventions known to be safe and beneficial should be reviewed and considered for coverage under health benefit programs, regardless of whether the interventions are considered conventional medicine or CAM. Such consideration has not occurred often for CAM interventions, and may continue to occur infrequently because of numerous barriers inherent in the health care industry. The Commission believes that these barriers to coverage and reimbursement of CAM should be addressed. Doing so does not imply that CAM should be treated differently from conventional medicine -- on the contrary, CAM should be held to the same standards as conventional medicine.

The fundamental barriers to coverage and reimbursement identified by the Commission are addressed in the remainder of this chapter. They are clustered into two broad issue areas that must be addressed as purchasers, insurers, managed care organizations, Federal agencies, States, and others respond to consumers' increasing use of CAM interventions. The first area involves the need for health services research to test the benefits and cost-effectiveness of CAM interventions, and to effectively communicate the findings. The second area is the need for equivalent and impartial consideration of safe, effective CAM interventions, especially in developing coverage policy.

Testing the Benefits and Cost-Effectiveness of CAM Services and Products, and Communicating the Findings

Effectiveness of CAM Therapies

A growing body of evidence shows that many CAM interventions are effective in treating or helping to treat a range of health conditions. However, insurance and managed care executives have indicated to the Commission that CAM services and products are not covered, or receive limited coverage, because there is not enough evidence of "medical effectiveness." [8, 9, 10]

Understandably, decision-makers for organizations that purchase health plans or for the health plans themselves are concerned that their limited dollars be spent on care that has been shown to be safe and efficacious. In the face of ever-rising health care costs and the vicissitudes of the economy, purchasers and payers

also want value and accountability for their investment. The addition of State-mandated benefits, as well as the constant stream of new technologies, drugs, and treatment protocols, has left these parties cautious about expanding any health care benefits.

At the operational level, government agencies like the Centers for Medicare and Medicaid Services (CMS), insurers, and managed care organizations invest significant time and resources to determine which benefits are covered, for how long, which practitioners are authorized to perform the services, and how payment will be made. Except for chiropractic and, increasingly, acupuncture and massage therapy, much of CAM is not covered. The services that are covered are often accompanied by limitations, such as global visit limits that are unrelated to individual patient needs or course of treatment.

With the rising cost of health care and heightened sensitivity to price in the market place, the addition of new benefits is a major undertaking. Taken together, economic and market forces, as well as pressures to manage the use of services in today's health insurance world, are creating the need for more evidence of the clinical effectiveness of CAM interventions. Evidence of clinical effectiveness in the treatment of illnesses and injuries will form the basis for sound coverage and reimbursement policies for CAM.

The Commission strongly supports more health services research to establish the medical and clinical efficacy of CAM therapies. Because research dollars are limited, cooperative efforts between the public and private sectors are needed to identify and resolve methodological issues that challenge health services research and to establish research priorities.

In addition to research on safety and efficacy, health services research is needed to evaluate the outcomes of CAM interventions in improving health status, treating acute and chronic conditions such as with heart disease, diabetes, and HIV infection, and supporting the care of persons with life-threatening diseases such as cancer. Research and demonstrations are needed to develop and test models of providing CAM (including integrative and collaborative programs), to compare conventional and CAM approaches for the same condition, to test the effectiveness of individual and combined CAM interventions, to test CAM offered in conjunction with conventional therapies, and to conduct population-based studies. Likewise, research is needed on whether CAM, health promotion programs, and prevention efforts increase worker morale, reduce stress, lessen the incidence of workplace disabilities and workmen's compensation claims, shorten treatment duration for illness and injuries, and improve productivity.

To maximize resources, vested parties should be brought together to develop a comprehensive, cohesive agenda. The parties would, at a minimum, identify priority questions for research and demonstrations, issues in applying common research methodologies, data needs, and ways in which the public and private

sectors could coordinate their efforts. The parties will need to commit to carrying out this agenda and invest financial resources to build the needed research base. Participants should include the Department of Health and Human Services (DHHS), including the Agency for Health Research and Quality (AHRQ), the National Institutes of Health (NIH), CMS, the Health Resources and Services Administration (HRSA), DOD, VA, private research and other foundations, health industry associations, medical associations and experts, CAM associations and experts, and representatives for employers, States, and consumers.

Lifestyle Modification and Heart Disease

- Comprehensive lifestyle changes have been used successfully as an alternative to coronary artery bypass surgery and coronary angioplasty in treating heart disease. The lifestyle modification program tested includes exercise, a low-fat plant-based diet, stress management, and group support. A Mutual of Omaha study with 333 patients (194 followed the lifestyle changes, and 139 were a control group) demonstrated that lifestyle changes can be used to avoid invasive interventions for at least 3 years without increasing the risk of a heart attack, stroke, or death. In addition, savings were estimated at $29,500 per patient.[11]

- Preliminary findings of the Highmark Blue Cross Blue Shield lifestyle modification program include significant decreases in cholesterol, blood pressure, weight, stress and depression. Cost savings range from 30 to 60 percent, and actuaries estimate that Highmark will save over $16,000 on each person who might have required bypass surgery or angioplasty. In another study, Highmark compared claims of individuals before and after entering the program. Results show that claims dropped from an average of $546 per member to $273 in the year after entering the lifestyle modification program.[12]

- A meta-analysis of the literature concluded that " -- all the available evidence suggests that the comprehensive lifestyle program is highly likely to be cost saving, and extremely unlikely to be cost increasing."[13]

Cost Effectiveness and CAM

Public pressure to make CAM more accessible is increasing, yet without adequate information on the use, costs and overall cost-effectiveness of CAM benefits, lawmakers, health plans, and employers are ill-equipped to make decisions about offering CAM services. Costs and cost-effectiveness of health care interventions are important factors in any consideration of changes in coverage. There is growing evidence of cost-savings from CAM interventions, such as massage therapy and the use of mind-body medicine in a variety of

clinical situations.[12] For example, researchers in two randomized trials found that pre-term babies who received massage and comforting touch had greater weight gain and were discharged earlier than babies who did not receive this care. Hospital stays were shortened by 5 to 6 days, and savings averaged more than $10,000 per infant.[13] While research like this is encouraging, further evidence needs to be gathered regarding CAM interventions, especially those that are widely used by consumers or where clinical and cost effectiveness is promising.

Cost Effectiveness and Mind/Body Medicine: A Sample

- Researchers have found that a self-management course designed to help arthritis patients handle disability, pain, depression, and anxiety resulted in positive outcomes. Clinical improvement was found to correlate with a positive outlook and a strong sense of control over their disease. The best predictor of clinical improvement was the patient's belief in his or her improvement. The cost of the course was $54 per person. After 4 years, physician visits had decreased 43%, for a saving of $648 for persons with rheumatoid arthritis and $189 for those with osteoarthritis.[15,16]

- Researchers placed 109 patients with chronic pain into a group intervention program where they received information about pain and behavioral treatment approaches, as well as yoga, relaxation techniques, and life coping skills. They found that the program, while not eliminating the pain, reduced anxiety, depression, and hostility. The clinic's estimated savings from reduced clinic visits were $110 per patient the first year, and $210 per patient in the second year. Estimates did not include savings in the area of prescription drugs or diagnostic tests.[17]

- In another randomized trial, researchers found that an audiotape providing guided imagery for diminished blood loss and rapid healing had significant results. Patients using this tape lost 43% less blood and were discharged at least a day earlier.[18]

More information is needed on the cost-effectiveness of specific CAM interventions for various conditions, different models of CAM practice, the clinical and financial impact of integrating CAM with conventional medicine, and the relative costs of CAM treatments and conventional medical treatments. Information is also needed regarding whether CAM interventions reduce the use of conventional medical services and pharmaceuticals by people with heart disease, cancer, chronic pain, or other chronic illnesses, as well as by the terminally ill. The short- and long-term costs and benefits of wellness programs and self-care need to be studied, as does the impact of CAM practices on the short- and long-term health status of men, women, and children. Likewise,

employers and other purchasers need to know more about the impact of CAM and health promotion programs on workplace costs, including productivity, workmen's compensation and disability costs, and recruitment and retention. Finally, Congress, the Executive Branch, and decision makers in both the public and private sectors need information about the impact of CAM on patterns and costs of health care in the United States.

The information needed by purchasers, insurers, and managed care organizations can be obtained only through health services research, demonstrations, and evaluations in the areas of cost, cost-benefit, and cost-effectiveness of CAM practices and products. These studies, which ideally should stem from the research agenda discussed earlier, will require the support of the Federal government, States, employers, private research organizations, the insurance and managed care industries, and other entities. Participants in building cost-effectiveness research are the same as those identified above for research into the clinical effectiveness of CAM.

Cost is not always a threshold for coverage. Health plans cover a number of costly conventional medical interventions, including heart and lung transplants. The Comission believes that the cost of CAM services and products should not in itself pose a barrier to coverage. Rather, cost should be approached in the same manner as the costs of conventional interventions.

Coding for CAM Interventions

On an operational level, insurers and managed care organizations need data bases to design health benefit plans, set premiums, conduct actuarial analyses, perform quality-of-care studies, manage provider networks, and manage the costs and use of health services. Policy makers and health researchers need data bases to conduct the clinical and health services research in which public policy and programs are grounded. Much of the data used by health plans, researchers, and policy makers are drawn from claim, or transaction, forms, such as the CMS/HCFA 1500 or the UB-92.

A number of the information fields on claim forms are assigned standardized, nationally accepted codes for data management purposes. The use of such codes has helped create powerful data bases that drive much of health care. Standard coding has become even more critical now that the Secretary of Health and Human Services is implementing administrative requirements stemming from the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These requirements impact heavily on the electronic filing of claims; in particular, the act contains a provision that fines practitioners and insurance companies up to $10,000 per code for incorrectly submitting and processing claims. Practitioners are charged for miscoding, and insurance companies are fined for paying fraudulent claims.

Government agencies, insurance companies and managed care organizations use uniform coding systems -- such as the International Classification of Disease to denote diagnosis, Common Procedural Terminology (CPT) to denote medical procedures, dental codes for dentistry, national drug codes for prescriptions, and the CMS/HCFA Common Procedure Coding System for supply items and some procedures -- as part of the electronic record of information about items and services used. Because coding has evolved along with conventional health care, including reimbursement trends, these systems have limited capability to capture CAM practices and products. For example, CPT codes, a set of more than 8,000 procedure codes developed by the American Medical Association for use throughout conventional health care, provides for a few CAM services including two codes for acupuncture.

More recently, a coding system for CAM procedures, services and products (as well as nursing services) has been developed and is being used in a number of settings. This system, ABCcodes developed by Alternative Link, contains 4,000 codes and captures a large amount of detail regarding specific CAM interventions. For example, it has 37 codes reflecting acupuncture services.

Currently, there is some variation regarding which coding system is used in CAM practice settings. Some practitioners use CPT, some use ABCcodes, and some use both. As part of their reimbursement policies, insurance companies may require the use of CPT codes. There is concern that the use of conventional coding systems, such as CPT, in limits the data that can be generated for CAM interventions.

If not resolved, limited coding capability will present a barrier to health services research on the safety, benefits, and cost-effectiveness of CAM interventions, as well as on the efficiency of models of integration and collaboration, where claims data are needed by researchers. In addition, the absence of nationally recognized, standardized codes for use in claims filing creates a significant challenge for CAM practitioners as HIPAA transaction requirements move toward implementation. To address these issues, any coding system for CAM that may be adopted by the Secretary of Health and Human Services should reflect the nature and scope of identified CAM interventions, and should allow for modifications to the coding system over time. If these issues cannot be addressed in line with HIPAA implementation dates and compliance requirements, then the Secretary should consider alternative strategies that would allow CAM practitioners to comply with the law.

Supporting Coverage of CAM Through Information

Purchasers, insurers, managed care organizations, and other sponsors of health care coverage need access to timely, reliable information about safe, efficacious,

and cost-effective CAM practices and products. Such information will promote equitable consideration of safe and effective CAM interventions in developing health benefit packages, supporting executive decision-making, and guiding policy-makers.

Those who help develop benefit packages, including health benefits consultants, have well-established methods and processes for making such changes in coverage. At the same time, there are many barriers to changing the status quo, including concerns about the financial impact of a health benefit not previously offered to the public or for which few data exist. Cost estimates for a new benefit are often low because it is difficult to estimate the number of persons who will qualify for or need the new service, or who actually use the service. Purchasers and providers are willing to respond to consumer demand but find it difficult to make significant changes to benefit packages without sufficient, reliable information.

The paucity of clinical and health services research, together with publication and dissemination issues discussed in the chapter on research, have created an information vacuum. Insurers, managed care organizations, public purchasers, employers, and other sponsors are increasingly willing to consider coverage of CAM interventions, but they need an adequate base of information in order to make decisions.

Federal support is needed to bridge this information gap. The National Center for Complementary and Alternative Medicine in NIH, for example, could consider making more health services research findings available electronically. Such information is used by employers, other purchasers, insurance and managed care industries, health benefits experts, health care associations, health education institutions, health policy bodies, foundations, professionals, and consumers.

There is a need also for Congress and other government leaders to understand the use of CAM within Federal programs, as well as impediments to the coverage of safe and effective CAM interventions. Reports may be necessary from DHHS (particularly Medicare, Medicaid, and community health centers), DOD, VA, and OPM.

More generally, there appears to be a need for the health care industry to become more informed about CAM, research on CAM modalities, and the international experience with such modalities. To meet this need, the Commission encourages health care associations and provider groups to include CAM topics at annual and other pertinent health care meetings. Government leaders and Federal agencies with health care programs also need more information about CAM and are encouraged to help management and staff become more informed. These informational needs may merit or even require

Federal support and leadership to develop informational programs on the broad and complex field of CAM.

Recommendation 23: Evidence should be developed and disseminated regarding the safety, benefits, and cost-effectiveness of CAM interventions, as well as the optimum models for complementary and integrated care.

Actions

23.1 The Secretary of Health and Human Services should convene a joint public and private task force to identify and set priorities for researching health services issues related to CAM and to help purchasers and health plans make prudent decisions regarding coverage of and access to CAM.

23.2 Federal agencies, States, and private organizations should increase funding for health services research, demonstrations, and evaluations related to CAM, including outcomes of CAM interventions, coverage and access, effective sequencing and integration with conventional therapies, effective models for service delivery, and the use of CAM in underserved, vulnerable, and special populations.

23.3 Federal, State, and private entities should fund health services research on the costs, cost-benefits, and cost-effectiveness of CAM interventions and wellness programs.

23.4 Secretary of Health and Human Services and the National Committee for Vital and Health Statistics should authorize a national coding system that supports standardized data for CAM. This system should make possible the collection of data for clinical and health services research on CAM, and support compliance with the electronic claims requirements of the Health Insurance Portability and Accountability Act.

23.5 The National Center for Complementary and Alternative Medicine, through its clearinghouse, should provide information on health services research, demonstrations, and evaluations of CAM services and products.

23.6 Public agencies and private organizations should support the development of informational programs on CAM targeted to health plan purchasers and sponsors, health insurers, managed care organizations, consumer groups, and others involved in the provision of health care services.

23.7 Congress should request periodic reports from appropriate Federal departments on coverage of and reimbursement for CAM practices and products for Federal beneficiaries, Medicaid beneficiaries, Federal employees, military personnel, veterans, and eligible family members and

retirees, as well as any legislative, regulatory, or programmatic impediments to covering safe and effective CAM interventions.

Equitable and Impartial Consideration of Safe, Effective CAM Interventions

Coverage Policies and Processes

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, current methods, standards, and processes used to gather evidence and make decisions regarding coverage for conventional medicine should be extended to CAM. These methods, standards, and processes should not be prejudiced toward any philosophy of health care, but give equitable consideration to safe and efficacious interventions for both conventional health care and CAM. The Commission's intent, in general, is that conventional medicine and CAM be considered in a similar manner with adjustments to accommodate differences in philosophical approach, not to unilaterally propel CAM into the conventional model. This challenge should be met by private employers and sponsors of health coverage, insurers, managed care organizations, and Federal purchasers including DHHS, DOD, VA, and OPM. Within DHHS, it is particularly important for CMS and HRSA to address CAM throughout their policies and procedures, and to identify statutory and regulatory issues.

The Medicare Coverage Process

The Medicare law has 55 defined benefit categories. Within these categories, services and products must be "reasonable and necessary" in order to be covered. CMS, which administers the program, has coverage regulations and maintains coverage manuals that contain definitions, criteria for determining what is reasonable and necessary, and other guidance regarding benefits. Coverage questions not addressed by law, regulations, or manuals are answered through two methods:

- Decisions by contractors who pay claims for the Medicare program. These contractors have their own processes, and may issue their own coverage rulings, called Local Medical Review Policies (LMRPs), which are not applicable outside the contractor's area. About 90 percent of Medicare coverage decisions are made this way.

- The formal, labor-intensive, and lengthier national coverage policy process. This process is managed by CMS and is used mostly for significant advancements in treatment, expensive interventions, and situations in which there is wide disagreement or inconsistency among contractors.

Medicare Coverage Issues for CAM

- Definitional constraints: Medicare benefit and practitioner categories contain restrictions. For example, Medicare can reimburse for acupuncture if provided by a physician but not if provided by a professionally trained acupuncturist because acupuncturists are not recognized in the law.

- Expert consultation: CAM experts have not participated in coverage advisory groups at CMS or in Medicare fiscal intermediary and carrier decisions.

- Same-day billing: For office or clinic settings, Medicare requires that many services provided on the same day be bundled and billed together. This helps the program avoid paying for services which are unnecessarily fragmented in order to maximize Medicare payment. This policy, however, poses a hardship for many patients who use conventional and CAM services at integrated clinics, requiring them to make additional trips for services that may be billed separately.

- Anti-kickback rules: The restrictions on referrals and other aspects of these rules pose problems and unresolved issues for physicians and CAM practitioners in integrated practice settings.

Adequate evidence as to safety and efficacy already exist for considering coverage of some CAM interventions. Where there is such evidence, CAM practices and products should be considered for coverage and reimbursement through processes similar to those already in use, modified only to the extent necessary to accommodate the fundamental differences in philosophy and treatment approach that underpin CAM. For example, private health insurance and managed care companies conduct a number of activities that contribute to the benefit design process, including cost-benefit comparisons between current and proposed packages; appraisals of the competition; review of long-term corporate goals; estimates of potential financial liability and losses; and assessments of key factors such as employer and customer requests, potential revenues from redesigned packages, and trends in the economy and market place.

The often-engrained viewpoints within both conventional medicine and CAM may hamper efforts to modify coverage processes to consider including CAM interventions. Each health care industry has knowledge gaps and negative perceptions about the other. For example, those who are skeptical about CAM may oppose coverage on the basis that CAM interventions are not backed by

valid, reliable research. Those who support CAM may be more willing to accept preliminary research findings as persuasive evidence that CAM services should be covered. Such differences in perspective may be overcome through cooperative efforts and working relationships between CAM and conventional health care experts. The public and private sectors offer many opportunities for CAM and conventional health care experts to work together, for example, advisory committees and other workgroups related to health services research and coverage.

Determining When to Pay For or Provide CAM

Once health insurers, managed care companies, and government agencies have decided to cover a benefit, additional procedures must be followed before arriving at a decision to approve or pay for it in a particular situation. The procedures commonly include two questions: 1) Are the circumstance for use of the service or product investigational, and 2) Is use of the service or product medically necessary in the current situation? For example, a health insurance company may decide to add acupuncture to its benefit, but may limit coverage to situations in which acupuncture is no longer considered investigational, such as control of nausea during cancer treatment and treatment of certain pain conditions. In addition, the company will review each request to approve or pay for the service on a case-by-case basis to determine whether acupuncture was indeed medically necessary in that situation.

A health care service or product is considered no longer investigational if it has been proven through scientific methods to be safe and effective at improving health outcomes, or if, in cases where the scientific evidence is still unfolding, expert consensus regarding its safety and efficacy is established. Various parties, such as a national professional association, a government agency such as CMS, or an organization hired to advise a health insurance or managed care company may make such a determination. In the private health care market, insurers and managed care companies often follow one another's lead in determining whether a service or product as safe and beneficial.

The process of determining what is medically necessary is critical to controlling use of and spending on health care services, determining the cost estimates on which premiums are based, and maintaining the financial soundness of the insurance and managed care industries. Decisions are usually made by practitioners on the basis of criteria that have been developed by bodies of experts, including professional organizations, academic medical institutions, private companies, and, in some circumstances, the insurers and managed care companies themselves. Often, the criteria are developed from studies sponsored by or the work of advisory groups for government agencies, such as AHRQ, CMS, and NIH. Government-funded programs, like Medicare develop their own

coverage criteria and offer guidance either nationally or at the local level through Medicare payment contractors.

Insurers and HMOs rely heavily on medical necessity criteria to define the extent of a benefit, manage the use of it, and make claims payment decisions. Controlling health care use and expenditures is fundamental to managing a company's insurance risk and to the financial stability of managed care and third-party reimbursement systems.

Methods of determining investigational status and medical necessity work for CAM as long as interventions fit the conventional medical model, but they often restrict the integration of, and the complementary use of, "alternative" services and products. At this time, few criteria are available to guide practitioners in deciding the medical or, more generally, the clinical necessity of CAM interventions. New medical and health services research on CAM, when published, will help to fill this need. Agencies of DHHS (including NIH, AHRQ, and CMS) could convene groups of experts and hold conferences to assess the state-of-the-science of a particular CAM approach or treatment, and develop consensus statements, guidance for clinical use, and coverage policy. Other government bodies and nongovernmental organizations could sponsor similar efforts.

Federal leadership is needed to help guide changes in health plan coverage for safe and effective CAM services and products and to develop criteria for the use of CAM interventions. The Secretary of Health and Human Services, preferably through a centralized CAM office, should work with insurance companies, health care and professional associations, health insurers and managed care companies and associations, employers, other Federal departments, States, CAM professionals and associations, benefits experts, and others to accomplish these goals.

To make coverage of CAM more readily available to consumers, private and public entities should develop clinical necessity criteria or clinical appropriateness criteria for circumstances in which CAM is proven to be safe and effective. Such circumstances could include preventing a condition or the progress of a condition, allaying symptoms or side-effects of conventional treatments such as pain or nausea, and helping patients, particularly with life-threatening illnesses, cope with their conditions.

Coverage and the Need for Authority to Practice

Coverage of and reimbursement for most health care services are linked to a provider's ability to furnish services legally within the scope of their practice. This legal authority to practice is given by the State in which services are provided. Thus, even if insurers, managed care organizations, employers, and other health

plan sponsors are interested in covering safe, cost-effective CAM interventions, they cannot do so unless there are properly licensed (or otherwise legally authorized) practitioners in a State. State laws and processes that establish professional standing protect the public by ensuring that covered health benefits are provided by qualified practitioners whose services should meet recognized standards of care. Moreover, in the absence of such laws, health insurers, managed care organizations, and any other entities that provide services would be at increased risk of liability if an adverse event occurred.

CAM practitioners qualified to furnish safe, beneficial services for which purchasers, insurance companies, managed care organizations, and other payers are willing to pay should have the ability to practice legally in their State, just as conventional practitioners do.

Other Issues

The Internal Revenue Code allows employers and other health plan sponsors to deduct the costs of providing accident and health insurance. Although the Federal code includes chiropractic and acupuncture as deductible medical expenses, the current policy approach is weighted heavily toward conventional medical care and physician direction of services. This approach could be modified to allow purchasers, health insurers, and managed care companies to develop health benefit packages that include safe and beneficial CAM interventions that qualify fully for favorable tax treatment under the law and regulations. In addition, Federal policy-makers are encouraged to monitor evidence on the benefits and cost-effectiveness of CAM interventions and health promotion programs with an eye to possible modifications of the tax code in the future.

Recommendation 24: Insurers and managed care organizations should offer purchasers the option of health benefit plans that incorporate coverage of safe and effective CAM interventions provided by qualified practitioners.

Actions

24.1 Health insurance and managed care companies should modify their benefit design and coverage processes in order to offer purchasers, for their consideration, health benefit plans that include safe and effective CAM interventions.

24.2 Health insurance and managed care companies should make use of CAM expertise in the development of benefit plans that include safe and effective CAM interventions.

24.3 Health insurers, managed care organizations, CAM professional associations,

CAM experts, private organizations that develop medical criteria, and Federal agencies are encouraged to develop appropriate clinical criteria and guidelines for the use of CAM services and products.

Recommendation 25: Purchasers, including Federal agencies and employers, should evaluate the possibility of covering benefits or adding health benefit plans that incorporate safe and effective CAM interventions.

Actions

25.1 Employers, Federal agencies, other purchasers and sponsors should enhance the processes they use to develop health benefits and give consideration to safe and effective CAM interventions.

25.2 Public purchasers such as the Centers for Medicare and Medicaid Services and the Department of Defense, employers, other health benefit sponsors, and health industry organizations should include CAM practitioners and experts on advisory bodies and workgroups considering CAM benefits and other health benefit issues.

25.3 The Secretary of Health and Human Services, preferably through the Federal CAM coordinating office when established, should maintain a list of opportunities for CAM experts to participate on advisory committees and other workgroups.

25.4 The Secretary of Health and Human Services should direct agencies under his authority to convene workgroups and conferences to assess the state-of-the-science of CAM services and products and to develop consensus and other guidance on their use.

25.5 State governments should consider, as part of evaluating and reviewing their regulations, how regulation of CAM practitioners could affect third-party coverage of safe and effective CAM interventions.

References

1. Current Population Survey. Annual Demographic Survey, March Supplement. A Joint Project Between the Bureau of Labor Statistics and the Bureau of the Census. Available on-line at http://ferret.bls.census.gov/macro/032001/health/h01_001.htm.

2. Centers for Medicare and Medicaid Services, Office of the Actuary. National Health Expenditure Projections. Available on-line at: http://www.hcfa.gov/stats/NHE-Proj/proj2000/tables/t3.htm.

3. Data provided by William M. Mercer, Inc. Mercer/Foster Higgins National Survey of Employer-Sponsored Health Plans, 1998, 1999, 2000.

4. Shekelle PG, Rogers WH, Newhouse JP. The Effect of Cost Sharing on the Use of Chiropractic Services. Medical Care 1996; 34:863-872.

5. Wolsko PM, Eisenberg DM, Davis RB, et al. Insurance Coverage, Medical Conditions, and Visits to Alternative Medicine Providers. Archives of Internal Medicine 2002; 162:281-287.

6. International Society of Certified Employee Benefit Specialists. Health Benefits for Alternative Medicine: Is There a Fit? Census Survey of Certified Employee Benefit Specialists, 1999. Available on-line at: http://www.ifebp.org/knowledge/recen99a.asp.

7. Pelletier KR, Astin, JA. Integration and Reimbursement of Complementary and Alternative Medicine by Managed Care and Insurance Providers: 2000 Update and Cohort Analysis. Alternative Therapies in Health and Medicine 2002; 8(1): 38-48.

8. Korn A. Testimony before the White House Commission on Complementary and Alternative Medicine Policy, May 2001.

9. Kelly J. Testimony before the White House Commission on Complementary and Alternative Medicine Policy, May 2001.

10. Francis M. Testimony before the White House Commission on Complementary and Alternative Medicine Policy, May 2001.

11. Ornish DM. Avoiding Revascularization with Lifestyle Changes: The Multicenter Lifestyle Demonstration Project. American Journal of Cardiology 1998; 82:72-76.

12. Silberman A. unpublished data of Lifestyle Advantage, Highmark Blue Cross Blue Shield, Pittsburgh; 2001 and 2002.

13. Eddy DM. Assessment of Intensive Lifestyle Changes for the Treatment of Coronary Artery Disease, 2000.

14. Sobel DS. The Cost-Effectiveness of Mind-Body Medicine Interventions. In: Mayer EA, Saper CB, eds. The Biological Basis of Mind Body Interactions: Progress in Brain Research 2000; 122: 393-412.

15. Kruger JM, Helmick CG, Callahan LF, et al. Cost-Effectiveness of the Arthritis Self-Help Course. Archives of Internal Medicine 1998; 158:1245-1249.

16. Lorig KR, Sobel DS, Stewart AL, et al. Evidence Suggesting That a Chronic Disease Self-Management Program Can Improve Health Status While Reducing Hospitalization. Medical Care 1999; 37:5-14.

17. Caudill M, Schnabel R, Zuttermeister P, et al. Decreased Clinic Use by Chronic Pain Patients: Response to Behavioral Medicine Interventions. Journal of Clinical Pain 1991; 7(4): 305-310.

18. Bennett HL. A Comparison of Audiotaped Preparation for Surgery: Evaluation and Outcomes. Paper presented at the annual meeting of the Society for Clinical and Experimental Hypnosis. Reported in H Dreher. Mind-Body Interventions for Surgery: Evidence and Exigency. Advanced Mind-Body Medicine 1998; 14:207-222.

Chapter 8: CAM in Wellness and Health Promotion

In recent years, people have come to recognize that a healthy lifestyle can promote wellness and prevent illness and disease, allowing them to enjoy a long, high-quality life. To achieve this goal, many people have used various approaches, including complementary and alternative medicine (CAM).

Wellness is defined in many different ways, but all agree that it is more than the absence of disease. For some it is the achievement of one's fullest potential, for others it is an integration of body, mind, and spirit. Wellness can include a broad array of activities and interventions that focus on the physical, mental, spiritual, and emotional aspects of one's life.

Since the publication of Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention in 1979,[1] the U.S. Public Health Service has led an initiative to define goals and objectives for the health of the U.S. population and to direct resources for improving the Nation's health. The goals and objectives are updated periodically, along with a progress report on their attainment, and have been published as Healthy People 2000[2] and 2010.[3] Long-range goals and objectives for Healthy People 2020 are currently being developed.

As the Healthy People 2000 and 2010 reports illustrate, approaches to improving health and wellness, preventing illness and disease, and managing disabilities and chronic conditions require the involvement of a wide range of disciplines and social institutions. 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 optimal health. People with better health habits have been shown to survive longer and to postpone and shorten disability.[4] CAM practices such as acupuncture, biofeedback, yoga, massage, 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.

Helping people achieve a healthy, meaningful, and long life is the fundamental purpose of all health care systems. In the United States, great strides have been made in conquering disease and extending life, and the health care system reflects these remarkable scientific advances. Yet in the quest to conquer illness and disease, national wellness and prevention efforts have been focused primarily on immunizations, disease screening and monitoring (e.g., pap smears blood pressure checks), and services offered in response to an already identified illness or condition (e.g., physical therapy after stroke, nutritional counseling for diabetics). With some notable exceptions, wellness and health promotion have, for the most part, been left to the initiative and discretion of the individual. The

Commission believes that it is time for wellness and health promotion to be a national priority and for the role of CAM in these efforts to be explored further. The concomitant rise of interest in CAM and in wellness and prevention presents many new and exciting opportunities for the health care system. There is evidence that certain CAM practices, when administered by properly trained practitioners, may be beneficial. Evaluating safe and effective CAM practices and products to determine their applicability to wellness and health promotion activities presents new and exciting areas to explore in the quest to improve health outcomes and quality of life.

The Role of Safe and Effective CAM Practices and Products in Promoting Wellness and Helping to Achieve the Nation's Health Promotion and Disease Prevention Goals

The most recent Federal government report on the health status of the nation, Healthy People 2010, is designed to further two overarching goals: 1) increasing the quality and years of healthy life and 2) eliminating disparities in health. These goals and objectives are the blueprint for the nation's health promotion and disease prevention activities, and they influence data collection, national health policy, and program development and implementation. Healthy People 2010 addresses clinical, behavioral, environmental, and health system issues that affect health, and it emphasizes on health education and changing the health-related behaviors of individuals and communities.

The principles that underlie CAM practices are consistent with the two overarching goals of Healthy People 2010. Several CAM practices have shown promise in addressing some of the specific objectives outlined in Healthy People 2010, such as massage therapy to reduce the limited activity caused by chronic low back pain (Objective 2-11), meditation or biofeedback to reduce high blood pressure (Objectives 12-9 through 12-12), and tai chi to increase physical activity and flexibility (Objectives 22-1 through 22-5). These and other CAM practices and products that have been shown to be safe and effective should be evaluated to determine their potential for helping to achieve the nation's health promotion and disease prevention goals and objectives.

The Healthy People Consortium, which includes over 600 Federal, state, and national organizations, should form a working group to evaluate the potential impact of safe and effective CAM practices and products on the nation's leading health indicators (physical activity, overweight and obesity, tobacco use, substance abuse, responsible sexual behavior, mental health, injury and violence, environmental quality, immunization, and access to health care). Strategies, including demonstration projects, should be developed to incorporate CAM practices and products found to have potential benefit to address these indicators and promote healthy lifestyles.

Wellness and Health Promotion for Children

For no other group is the learning and adoption of healthy behaviors and lifestyle choices more important than for children and young people. Although many programs address some of the pressing issues facing American youth, the statistics remain sobering, with unintentional injuries, homicides, and suicides accounting for the majority of deaths between the ages of 1 and 24.3 Serious, chronic conditions are beginning earlier in life, as shown by the recently released The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity.[5] This report highlights many of the health issues facing children who are overweight, including heart disease, diabetes, and depression, and states that risk factors for heart disease (e.g., high cholesterol and high blood pressure) occur with increased frequency among overweight children. Numerous reports have cited the dramatic increase of Type II diabetes in children and adolescents in recent years, which is also strongly associated with being overweight.[6,7]

- Added sugar and discretionary fat make up 40 percent of the total energy intake of children in the United States, and only about 1 percent of children are meeting the recommendations of the Department of Agriculture's Food Guide Pyramid,8 despite research showing that poor nutrition can have lasting effects on children's behavior, school performance, and overall cognitive development.[9]

- Daily participation in physical education classes by high school students dropped from 42 percent in 1991 to 29 percent in 1999, even though physical activity is known to have many beneficial effects on health, including reduced anxiety and stress and increased self-esteem.[10]

- By the time they are 7 years old, almost 13 percent of children are seriously overweight.[11] Studies have shown that obese children and adolescents are more likely to become obese adults.[12]

- Despite public health efforts to curb smoking, 36 percent of high school students smoke and 70 percent have tried cigarettes.[13]

- Seventeen percent of high school students have carried a weapon in the past month, and 19 percent have seriously considered suicide in the past year.[14]

- Among children age five to 14, the leading causes of death are unintentional injuries, cancer, and homicide, respectively. In the 15-24 age group, the leading causes of death are unintentional injuries, homicide, and suicide, respectively.[3] Behavioral and mental health problems, especially depression and attention deficit disorder, are widespread, and substance abuse continues to be a problem, including the so-called performance-enhancing drugs used in sports.

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 early in life. Poor dietary habits, lack of exercise, smoking, suicide, substance abuse, homicide, and depression are a silent epidemic among young people and should be considered a national priority.

While many individual programs address these problems, safe and effective CAM principles and practices should be evaluated to determine their potential role in transforming the unhealthy behavior responsible for U.S. youths' dismal health statistics. Those CAM principles and practices that have been shown to be appropriate for children and young people should be included as part of a national effort and involve all sectors of the community, especially the schools.

Parents, schools, communities, businesses, influential individuals, and the media should become part of a national campaign to heighten children's interest in and awareness of health issues, including how their behavior affects their life and environment and how they can establish good habits for coping with life's stresses. This effort could be similar to other national initiatives, such as those to increase seat belt use, decrease alcohol consumption when driving, and modify other behaviors that impact on public health.

Schools are a particularly important part of any strategy. Schools provide activities and services to promote students' physical, emotional, and social development and they usually require that some form of health education be taught. The teaching of safe and effective CAM practices in schools to improve nutrition, reduce stress, resolve conflicts, and develop healthy lifestyles should be evaluated to determine if it can complement the efforts already under way to improve the health and well-being of young people. School programs are locally designed and implemented, and what works in one community may not work in another. Therefore, it is essential that members of the local community (children, parents, teachers, school boards, and others) be involved in these activities.

The Centers for Disease Control and Prevention has developed guidelines for schools to use to increase physical activity, promote healthy eating, prevent tobacco use and addiction, and prevent HIV infection.[14] The Health Resources and Services Administration, in conjunction with the American Academy of Pediatrics, is developing guidelines for schools that address comprehensive physical and mental health and safety programs. Other Federal organizations, such as the Department of Agriculture, also produce information to assist schools in promoting health. A public-private working group should be established to evaluate the applicability of safe and effective CAM practices and products to existing guidelines. In addition to representatives from Federal organizations, CAM professionals, and parent and teacher groups should be included, and the guidelines should reflect the cultural diversity in school systems. Innovative programs that are successfully addressing wellness promotion and disease

prevention in schools should be identified so that other schools can learn from them and, if appropriate, adapt them for use in developing their own programs. For example, a group of middle schools in the Minneapolis-St. Paul metropolitan area has developed school nutrition advisory councils to promote the nutritional health of students. This is part of the Teens Eating for Energy and Nutrition at Schools (TEENS) program, which encourages adolescents to adopt good dietary habits to reduce their risk of cancer risk.[15] Some elementary, middle, and high schools in New York and California are offering yoga classes as part of their health or physical education curricula. The reported benefits include increased concentration, reduced impulsive behavior, and increased self-esteem.[16]

Wellness and Health Promotion in the Workplace

Most adults in the United States spend a large part of their lives in the workplace, and employers spend an average of $2,400 per employee for single coverage and $6,900 for family coverage annually.[17] Premiums rose an average of 11 percent from 2000 to 2001, with small firms bearing a disproportionate share of that increases.[17] Data consistently show that high levels of stress, excessive body weight, and multiple risk factors are associated with increased health care costs and absenteeism, and that health promotion programs in the workplace can lower health care and insurance costs and decrease absenteeism.[18]

- One study showed an average decrease of $129 in health care costs per year for each employee who shifted from a high-risk to a low-risk status by increasing safety belt use, reducing blood pressure, and reducing cholesterol.[19] In another study, a health promotion program for retirees was introduced at a cost of $30 per person, resulting in a $164 per person decrease in insurance claims.[20]

- A national manufacturing company reported a decrease of over 12 percent in illness days for employees in a health promotion program.[21] Some health promotion programs have yielded an eightfold return on investment in the form of reduced health care costs and absenteeism.[22]

The Department of Health and Human Service's Division of Federal Occupational Health helps Federal organizations improve the health, safety, and productivity of their workforce. It provides comprehensive medical, nursing, and wellness and fitness services at Federal workplaces around the country and serves more than 300 agencies with 1.6 million employees. Other Federal organizations may offer their employees wellness programs as well.

Many health promotion programs in the workplace focus on reducing risk factors for illness by encouraging weight loss, smoking cessation, and stress reduction. Studies have shown that stress reduction techniques such as yoga and

meditation are beneficial. Evaluations should be conducted to determine the role of safe and effective CAM practices and products in the workplace, and incentives should be developed to encourage those found to be beneficial.

Incentives to include CAM in wellness programs and health coverage will vary with the size of the business. For example, larger companies that negotiate health plans through a union will require a different set of incentives than small companies that may only offer limited or no coverage. Some incentives currently exist but have not been evaluated for their effectiveness. Any additional programs or services will have start-up costs that may deter some companies from offering them.

Recommendation 26: The Department of Health and Human Services and other 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 to promote wellness and help achieve the nation's health promotion and disease prevention goals. Demonstration programs should be funded for those determined to have benefit.

Actions

26.1 The Healthy People Consortium should evaluate the role of safe and effective CAM practices and products in addressing the[10] leading health indicators and develop strategies, including demonstration programs, to encourage the use of CAM practices and products found to be beneficial in addressing these indicators.

26.2 Questions on the extent and use of CAM products and practices should be included in national surveys and other assessment tools including the National Health Interview Survey, the National Health and Nutrition Examination Survey, and the Medical Expenditure Panel Survey. Where appropriate, information from these sources should be incorporated into the Healthy People 2020 goals and objectives.

26.3 The Department of Health and Human Services, as part of the Healthy People 2010 initiative, should support the development of a national campaign to teach and encourage behaviors that focus on improving nutrition, promoting exercise, and teaching stress management for all Americans, especially children. This campaign should include safe and effective CAM practices and products where appropriate.

26.4 The Federal government, in partnership with public and private organizations, should evaluate safe and effective CAM practices and products to determine their applicability to improving nutrition, promoting exercise, and teaching stress management to children. Demonstration programs should be funded for those found to be applicable to children.

26.5 The Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Department of Agriculture, the Department of Education, and other Federal agencies that develop school health guidelines should evaluate the potential applicability of safe and effective CAM practices and products to these school health guidelines. Those found to have benefits should be included in the guidelines.

26.6 Federal agencies, in partnership with the business community, should develop incentives for schools to make lunches and snacks healthful, and to limit the sale-and eliminate the advertising-of high-fat snacks, soft drinks, and other products that do not contribute to healthy lifestyles

26.7 The Department of Health and Human Services and the Department of Labor should evaluate safe and effective CAM practices and products to determine their potential role in workplace wellness and prevention activities, and include them in Federal workplace wellness and health promotion programs and Federal health coverage plans when appropriate.

26.8 Federal agencies, in conjunction with the business community, should develop incentives for employers to include CAM practices and products found to be beneficial in wellness and prevention activities in their workplace wellness programs and health coverage.

The Role of Safe and Effective CAM Practices and Products in Health Care Delivery Systems and Health-Related Programs to Help Promote Wellness and Health and Prevent Disease

Federal/State Programs and Systems

The Federal government funds many programs that serve vulnerable populations. Among them are Head Start; Meals on Wheels; Special Supplemental Nutrition Program for Women, Infants and Children; Healthy Mothers/Healthy Babies; the State Children's Health Insurance Program, and programs for people with disabilities. These programs have a direct impact on the health and quality of life of the people they serve and 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 these programs and fund demonstration programs for those found to be applicable. An example of CAM practices and products that might be considered is teaching children in Head Start programs to breathe deeply as a relaxation technique. The State Children's Health Insurance Program might consider whether chiropractic

services would be appropriate for this population, and Meals on Wheels might re-evaluate the type of food being served. Appropriately trained CAM providers should be part of the evaluation and decision-making process.

Federally funded health care delivery programs should also evaluate the applicability of CAM wellness and prevention activities into their services. This includes the Department of Veterans Affairs, which has 172 hospitals and more than 500 other health care facilities serving 25 million persons; the Indian Health Service, serving 1.5 million American Indians and Alaskan Natives; community and migrant health centers, serving more than 10 million people who otherwise would not have access to care; maternal and child health programs; and school health programs. Demonstration programs should be funded for those CAM practices and products found to benefit these populations.

Public and Private Programs and Systems

Much of the research, education, training, services, reimbursement, and information development and dissemination activities of the health care system is directed toward identifying and treating diseases and conditions. Although many hospitals have begun to offer community programs that focus on wellness and prevention, these activities often occur outside the system of primary health care and rely upon consumers' knowing that these activities exist, belief in their potential benefit, ability to pay for them out-of- pocket, and ability to access them.

Public and private health care programs and systems should evaluate safe and effective CAM practices and products to determine their role in wellness and prevention activities for individuals and communities. The Department of Health and Human Services should help bring together organizations from the private and public sectors for this purpose and help to develop strategies to promote the use of those found to be beneficial. Representatives of national, state, and local organizations of clinicians, administrators, health plans, pharmacists, nurses, mental health professionals, consumers, and others from hospitals, long-term care facilities, and programs serving the aging, the dying, and those with disabilities or chronic illness should be included with CAM professionals and institutions in this process.

Recommendation 27: Federal, state, public, and private health care delivery systems and programs should evaluate CAM practices and products to determine their applicability to programs and services that help promote wellness and health. Demonstration programs should be funded for those determined to be beneficial.

Actions

27.1 The Secretaries of Health and Human Services, Agriculture, Veterans Affairs, and Defense and the Commissioner of the Administration for Children and Families, should evaluate safe and effective CAM practices and products that contribute to wellness and health and determine their applicability to Federal health systems and programs.

27.2 The Secretary of Health and Human Services should facilitate the bringing together of public and private health care organizations to evaluate safe and effective CAM practices and products that contribute to wellness and health and determine their applicability to health systems and programs, especially in the nation's hospitals and long-term care facilities and in programs serving the aging, those with chronic illness, and those at the end of life.

27.3 CAM and conventional health professional training programs should consider offering training and educational opportunities for students in self-care and lifestyle decision-making to improve practitioners' health and to enable practitioners to impart this knowledge to their patients or clients.

The Role of Safe and Effective CAM Practices and Products in Wellness and Health Promotion and the Application of CAM Principles and Practices to the Management of Chronic Disease

Although a significant percentage of people who use CAM practices and products do so to prevent disease and promote health, more information is needed on how CAM approaches can improve wellness and promote health. A related but largely unexplored area is the application of CAM wellness and prevention practices to the management of chronic disease. 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.

The core philosophy and orientation of many CAM systems is to support and stimulate the inherent healing capacities of the individual. For example, Traditional Chinese Medicine practitioners focus on maintaining the flow of "qi" and "blood" to balance "yin" and "yang" for the maintenance of good health. Ayurvedic medicine emphasizes early detection and balancing of "doshas" to prevent disease and pathology. Other CAM modalities, such as chiropractic and naturopathic medicine, seek to enhance the body's natural healing system to prevent, treat, and cure disease. A significant portion of the adult population takes supplements and herbs to maintain health.

Although many CAM systems and practitioners emphasize the health-promoting nature of their approaches and interventions, research is needed to determine

which ones are or might be useful for improving overall health and preventing disease. A systematic review of research to evaluate CAM approaches to health promotion would help identify promising areas for further research and development. In addition to the Federal government, private organizations such as the Institute of Medicine and the American Public Health Association should provide leadership in this area, including assistance in determining how CAM may contribute to the goals of Healthy People 2010 and the development of Healthy People 2020.

Recommendation 28: Research on the role of CAM in wellness and health promotion, the application of CAM principles and practices, and the role of CAM practitioners in the management of chronic disease should be expanded.

Actions

28.1 The Department of Health and Human Services 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.

28.2 The Federal government and private health organizations should evaluate CAM practices and products that are currently being used for wellness and health promotion to determine their effectiveness and applicability to the management of chronic disease. Funding should be provided for demonstration projects in the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs, the Department of Defense, the Health Resources and Services Administration, and other Federal agencies for those CAM practices and products found to have benefit in the management of chronic disease, end of life such as hospice.

References

1 U.S. Department of Health, Education, and Welfare, Public Health Service. Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention. DHEW (PHS) Publication No. 79-55071. U.S. Government Printing Office, 1979.

2 U.S. Department of Health and Human Services, Public Health Service. Healthy People 2000: National Health Promotion and Disease Prevention Objectives. DHHS (PHS) Publication No.91-50213. U.S. Government Printing Office, 1990.

3 U.S. Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. (2nd.ed. 2 vol). Washington, D.C.:

U.S. Government Printing Office, 2000.

4 Vita A, Terry R, Hubert H, Fries J. Aging, health risks, and cumulative disability. New England Journal of Medicine 1998;338:1035-41.

5 U.S. Department of Health and Human Services. The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity. 02NLM: WD-210-S9593. Washington, D.C.:U.S. Government Printing Office, 2001

6 Deckelbaum R, Williams C. Childhood obesity: The health issue. Obesity Research 2001;9(Suppl.4):239S-43S.

7 American Diabetes Association. Type 2 diabetes in children and adolescents. Diabetes Care 2002:22(12):381.

8 Munoz K, Krebs-Smith S, Ballard-Barbash R, Cleveland L. Food intakes of US children and adolescents compared with recommendations. Pediatrics 1997:100(3): 323-329.

9 Center on Hunger, Poverty, and Nutrition Policy. Statement on the Link between Nutrition and Cognitive Development in Children. Medford, MA: Tufts University School of Nutrition, 1995

10 Centers for Disease Control and Prevention. Guidelines for school and community programs: Promoting lifelong physical activity. Morbidity and Mortality Weekly Report 1997;46: 1-36

11 Centers for Disease Control and Prevention. Update: prevalence of overweight among children, adolescents, and adults - United States 1988-1994. Morbidity and Mortality Weekly Report 1997; 46:199-202.

12 1Guo SS, Roche AF, Chumlea WC, Gardner JD, Siervogel RM. The predictive value of childhood body mass index values for overweight at age 35 years. American Journal of Clinical Nutrition 1994; 59:810-819

13 Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. Guidelines for School Health Programs: Preventing Tobacco Use and Addiction. February 2000.

14 Centers for Disease Control and Prevention, School Health Guidelines to Prevent Unintentional Injuries and Violence, Morbidity and Mortality Weekly Report, Vol 50: 1-46, December 7, 2001.

15 Kubik MY, Lytle LA, Story M. A practical, theory-based approach to establishing school nutrition advisory councils. Journal of the American

Dietetic Association 2001 Feb; 101 (2):223-8

16 Yoga in schools. Yoga Inside Foundation. Available on-line at: http://www.yogainside.org/who/school.html

17 Cost of Health Insurance - Employer Health Benefits 2001 Annual Survey. Kaiser Family Foundation, 2001.

18 Aldana SG. Financial impact of health promotion programs: A comprehensive review of the literature. American Journal of Health Promotion 2001;15(5):296-320.

19 Edington, DW, Tze-ching Yen L, Witting P. The financial impact of the changes in personal health practices. Journal of Occupational and Environmental Medicine 1997;39(11):1037-46

20 Fries JF, Bloch DA, Harrington H, Richardson N, et al. Two-year results of a randomized controlled trial of a health promotion program in a retiree population. American Journal of Medicine 1993;94(5):455-462.

21 Bertera R. Behavioral risk factors and illness day changes with workplace health promotion. American Journal of Health Promotion 1993;7(5):365-373.

22 Aldana SG. Financial impact of worksite health promotion and methodological quality of the evidence. Art of Health Promotion 1998; 2(1):1-8.

Chapter 9: Coordinating Federal CAM Efforts

In the course of Commission meetings, it became clear that a wide cross-section of the population wants the Federal government to take the lead in integrating safe and effective complementary and alternative health care practices and products into the nation's health care system. Consumers, complementary and alternative medicine (CAM) and conventional practitioners, and product manufacturers testified about the need for a coordinated Federal effort to achieve this goal. This view is consistent with the findings of other groups as well. At the "Second Annual Integrative Medicine Industry Leadership Summit," held in May 2001, a major recommendation was the establishment of a Federal office of CAM and integrative health care and the selection of an advisory committee to the office.[1,2] Similarly, the creation of a Federal CAM/integrated health care office was a key recommendation of the "National Policy Dialogue to Advance Integrated Health Care: Finding Common Ground" held at Georgetown University in late 2001.[3]

Proper integration of safe and effective CAM practices and products into the nation's health care system will require an ongoing, coordinated Federal presence. The most effective means of accomplishing this goal is to establish a centralized office that would include the full range of CAM perspectives in the dialogues that guide policy formulation and implementation. Several possible locations of the office were proposed, each of which has advantages and disadvantages.

If located in the White House, the new office could be either a freestanding entity in the Executive Office of the President, following the precedent of the Office of National AIDS Policy and the Office of Faith-Based and Community Initiatives, or it could be placed in an existing office, such as the Office of Domestic Policy. A White House location would provide an opportunity to influence Federal policy, but it would not provide a permanent presence in the Federal sector. If located in the Department of Health and Human Services (DHHS), the office could be created in the Secretary's Office of Public Health and Science (OPHS), following the lead of the Office of Minority Health and the Office on Women's Health, or it could be placed within one of the 13 existing program offices that make up the OPHS-in particular, the Office of the Surgeon General. Locating it under the Surgeon General could provide links to other important public health activities, such as Healthy People 2010. While a DHHS location would provide a permanent Federal presence, it would limit the office's influence mainly to DHHS policy.

The National Center for Complementary and Alternative Medicine (NCCAM) is an example of effective Federal coordination of CAM research that evolved from an office established within DHHS. It began as the Office of Alternative Medicine in the National Institutes of Health with a $2 million budget in fiscal year 1992 and

became a national research-coordinating center with a $104.6 million budget in fiscal year 2002. The presence and focus of NCCAM in the Federal government has stimulated research well beyond the reach of its budget, with private and public organizations also contributing to increased efforts in CAM research, education, and practice in the United States and around the world.

Office of Complementary and Alternative Health Care Coordination

Three options for creating an office of complementary and alternative health care coordination are possible. First, the President could establish the office in the White House through an executive order. Second, the Secretary of Health and Human Services could establish the office in OPHS or one of its component program offices by an administrative action. Third, Congress could create the office and determine the most appropriate location through legislation, which would provide permanence, a legislative mandate, and budget appropriations.

Responsibilities of the Office

Responsibilities should include the following:

- 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 Federal point of contact for CAM 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;
- Exploring additional and emerging topics not included in the Commission's Executive Order.

Coordinating Federal CAM Activities

Coordinating Federal CAM activities requires that the office be placed at the highest possible and most appropriate level in the Federal Government. If located in DHHS, the office would work closely with all DHHS Agencies in a manner similar to that of the minority health and women's health offices. For example, the new office would collaborate with NCCAM, the National Cancer Institute's Office of Cancer Complementary and Alternative Medicine, the Office of Dietary Supplements at the National Institutes of Health, and other appropriate Federal Departments and Agencies.

Once established, the office will need to coordinate CAM activities all Federal CAM activities. It should form a trans-departmental CAM coordinating committee that includes representation from all Federal Departments and Agencies to facilitate its mission. Because the extent of Federal CAM activities has not been identified fully, the office should conduct a baseline survey of activities, by collecting data through the trans-departmental committee. Results of the survey could form the basis for coordinating Federal CAM activities. Because of its value to the Secretary, Administration, and Congress, this type of report on Federal CAM activities could be generated periodically to assist in making ongoing policy decisions.

Serving As a Federal CAM Policy Liaison

Another significant role of the office would be to serve as a Federal CAM policy liaison with conventional health care and CAM professionals, organizations, educational institutions, and commercial ventures. These activities are described in the recommendations and actions in the Education and Training, Information Development and Dissemination, Wellness, Access and Delivery, Coverage and Reimbursement, and Coordination of Research chapters of this report.
An important activity of the new office would be to establish an advisory council similar to NCCAM's. This group should bring together the various parties interested in CAM to develop a strategic plan that reflects public opinion. Therefore, the advisory council should include consumers and other members from outside the Federal government. The membership also should include the directors of NCCAM, the Office of Cancer Complementary and Alternative Medicine, and the Office of Dietary Supplements. In addition, it should include representatives from the Departments of Agriculture, Defense, Education, Energy, and Veterans Affairs, as well as the Centers for Medicare and Medicaid Services, the Food and Drug Administration, the White House Office of Domestic Policy, and other appropriate Federal entities.

Planning, Facilitating, and Convening Conferences, Workshops, and Necessary Advisory Groups

Public testimony stressed the importance of creating sustainable, collaborative environments in which issues of mutual concern to CAM and conventional health care can be raised, discussed, and resolved. The new office would bring together interested parties from CAM and conventional health care to design and undertake activities to meet the needs identified by the advisory council, the trans-departmental CAM coordinating committee, and the results of the survey of Federal CAM activities. By planning, facilitating, and convening conferences, workshops, and advisory groups, the new office would create unique opportunities to explore CAM issues, such as those involving product safety, licensure, or coverage and reimbursement.

Acting as a Centralized Federal Point of Contact for CAM

As a centralized Federal point of contact for CAM, the office would develop and implement a system to direct inquiries from the public, CAM practitioners, conventional health care providers, and the media to the appropriate person at the Departmental or Agency level. The office would carry out this responsibility through a network of information officers or other persons with known expertise. To transmit information readily to the public, CAM practitioners, and conventional health care providers, the office should create a website that includes information about the office and its responsibilities, a CAM events calendar, and links to Federal and other appropriate CAM websites.

Not everyone has access to the Internet, so information must be developed and made readily available to these consumers as well. Since NCCAM has a Congressional mandate "to establish a clearinghouse to exchange information with the public about alternative medicine," the new office should not undertake activities that would duplicate NCCAM's. However, additional information is needed consumes if they are to make informed decisions about CAM. The office would collaborate with Federal Departments and Agencies and the private sector to develop reliable information for dissemination through the NCCAM clearinghouse and other means that are not dependent upon the Internet.

Facilitating Implementation of Commission Recommendations and Actions

Considerable time and resources were spent in soliciting specific recommendations from the public, and this advice helped form the basis of the Commission's recommendations and actions. However, without legislative authority, staff, and a budget, the likelihood of their being successfully implemented is diminished significantly. Therefore, one of the most important roles of the new office is to facilitate implementation of the Commission's recommendations and actions.

This role would include interactions with Administration officials, members of Congress and their staffs, and relevant Departments and Agencies. Particularly encouraging is language in the Conference Report that accompanied the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2002 (Public Law 107-116), which urged the Secretary of Health and Human Services to form a coordinating unit to review the Commission's report and implement ways of improving coordination of the DHHS's many CAM-related activities.

Exploring additional and emerging topics not included in the Commission's Executive Order

Despite the comprehensive nature of the Commission's Executive Order, additional and emerging topics beyond the scope of this report will need to be addressed, and the new office would be in a position to do this. For example, the office could provide technical assistance on CAM to individual States when requested.

Recommendation 29: The President, Secretary of Health and Human Services, or Congress should create an office to coordinate Federal CAM activities and to facilitate the integration into the nation's health care system of those complementary and alternative health care practices and products determined to be safe and effective.

Actions

29.1 The office should be established at the highest possible and most appropriate level in the Department of Health and Human Services and should be given sufficient staff and budget to meet its responsibilities.

29.2 The office should charter an advisory council. Members should include CAM and conventional practitioners with expertise, diverse backgrounds, and necessary training, as well as representatives of both the private and public sectors, to guide and advise the office about its activities.

29.3 The office's responsibilities should include, but not be limited to, coordinating Federal CAM activities; serving as a Federal CAM policy liaison with conventional health care and CAM professionals, organizations, institutions, and commercial ventures; planning, facilitating, and convening conferences, workshops, and advisory groups; acting as a centralized Federal point of contact regarding CAM for the public, CAM practitioners, conventional health care providers, and the media; facilitating implementation of the Commission's recommendations and actions; and exploring additional and emerging topics not considered by the Commission.

References

1 Areas of agreement and proposed action among industry stakeholders. The Integrator for the Business of Alternative Medicine. June 2001; 5(9):2-3.

2 Weeks J. Integrative medicine industry leadership summit 2001. Accepted for publication, Alternative Therapies in Health and Medicine. March/April

2002; 8(2).

3 Zablocki E. National policy dialogue sparks discussion, finds consensus. The Integrative Medicine Consult. February 2002;4(2):13,19,23.

Chapter 10: Recommendations and Actions

COORDINATION OF RESEARCH

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 make these activities, including available technical assistance, known to CAM and conventional researchers and practitioners. 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 scope of scientific, practice, and public interest and needs regarding CAM that are relative to their missions, examine their portfolios, and develop funding distribution strategies to address these interests and needs.

1.3 The Agency for Health Care Research and Quality together with The National Center for Complementary and Alternative Medicine 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) complex compounds/mixtures frequently found in CAM products, (2) clinical interventions consisting of multiple treatments, (3) how patient-practitioner interactions affect treatment outcomes, and (4) individualizing treatments.

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.

Recommendation 2: Congress and the Administration should consider enacting legislative and administrative incentives to stimulate private sector investment in CAM research on products that may not be patentable.

Actions

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

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

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

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.

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

Actions

4.1 The National Center for Complementary and Alternative Medicine, assisted by the Institute of Medicine of the National Academy of Sciences, should develop guidelines for establishing research priorities in CAM.

4.2 The National Science Foundation, in collaboration with The National Center for Complementary and Alternative Medicine, should examine

frontier 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 The National Center for Complementary and Alternative Medicine, working with the World Health Organization, should examine investigative approaches for studying the traditional systems of medical practice from a variety of cultures.

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 follow the same requirements as in conventional medical research. They should develop, or partner with a research institution to develop, a scientifically valid research protocol and obtain Institutional Review Board 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 Institutional Review Boards where possible, and guide their colleagues and members to utilize the Institutional Review Board process, which is required to conduct clinical research.

5.3 Institutional Review Boards that review CAM research studies should include the expertise of qualified CAM professionals in the review.

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

Recommendation 6: The Commission recommends that state professional regulatory bodies 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 Institutional Review Boards,
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.

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

Actions

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

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

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

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

7.5 The nonprofit sector and the private sector should create funding partnerships, whether independently or with Federal agencies, to augment support for CAM research, research infrastructure and training, research conferences, and information dissemination.

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

7.7 To benefit patients and future research protocol development and to add to our knowledge about the use of CAM, Institutional Review Boards should consider requiring that all 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.

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 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 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 The National Center for Complementary and Alternative Medicine-supported centers and the National Center for Research Resources' General Clinical Research Centers should be utilized to increase opportunities to conduct clinical research and training on CAM and examine the inclusion of CAM into the clinical setting.

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

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-benefit of CAM practices and products.

Actions

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

9.2 The National Center for Complementary and Alternative Medicine 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.

EDUCATION AND TRAINING OF HEALTH CARE PRACTITIONERS

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.

Actions

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

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

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.

10.4 Increased Federal, state, and private sector support should be made available to expand and evaluate CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

10.5 Expansion of eligibility of CAM students at accredited institutions for existing of loan programs should be explored.

10.6 The Department of Health and Human Services should conduct a feasibility study to determine whether appropriately educated and trained CAM practitioners enhance and/or expand health care provided by primary care teams.* This feasibility study could lead to demonstration projects to identify: 1) the type of practitioners, 2) their necessary education and training, 3) the appropriate practice settings, and 4) the health outcomes attributable to the addition of these practitioners and services to comprehensive care.

10.7 The Department of Health and Human Services and other Federal Departments and Agencies should convene conferences of the leaders of CAM, conventional health, public health, evolving health professions, and the public; of educational institutions; and of appropriate organizations to facilitate establishment of CAM education and training guidelines. Subsequently, the guidelines should be made available to the states and professions for their consideration.

10.8 Feasibility studies of postgraduate training for appropriately educated and trained CAM practitioners should be conducted to determine the type of

practitioners, practice setting, and their impact on clinical competency, quality of health care, and collaboration with conventional providers.

10.9 Practitioners who provide CAM services and products should complete appropriate CAM continuing education programs that include critical evaluation of CAM to enhance and protect the public's health and safety.

CAM Information Development and Dissemination

Recommendation 11: The Federal government should make available accurate, useful, and easily accessible information on CAM practices and products, including information on safety and effectiveness.

Actions

11.1 The Secretary of Health and Human Services should establish a task force to facilitate the development and dissemination of CAM information within the Federal government and to eliminate existing gaps in CAM information. The task force should include consumers, CAM providers, scientists, and conventional health care practitioners. Resources should subsequently be provided to close identified gaps and improve the availability, coordination, and dissemination of information.

11.2 Federal Departments and agencies with missions or activities relevant to CAM should 1) develop informational materials about CAM that are easy to understand and use, and 2) support and collaborate with national and local community leaders and CAM leaders and organizations to identify strategies for enhancing the development, availability, and accessibility of information on the safety and effectiveness of CAM practices and products.

11.3 Increased funding should be provided to the National Library of Medicine and the American Library Association to expand training of librarians to include helping consumers find information on CAM.

11.4 The Secretary of Health and Human Services should direct resources to streamline the process of identifying and making available relevant, high-quality CAM information from other countries and in other languages.

Recommendation 12: The quality and accuracy of CAM information on the Internet should be improved by establishing a voluntary standards board, a public education campaign, and actions to protect consumers' privacy.

Actions

12.1 The Secretary of Health and Human Services should form a public-private partnership to review new and existing websites and to develop voluntary standards promoting accuracy, fairness, comprehensiveness, and timeliness of information on CAM web sites, as well as the disclosure of sources of support and possible conflicts of interest. Sites reviewed and found in compliance with the standards could publicize the fact and display a logo denoting their merit.

12.2 Funding should be provided to the Department of Health and Human Services and the Department of Education to conduct a joint public education campaign that teaches consumers how to evaluate health care information, including CAM information, on the Internet and elsewhere.

12.3 Congress should protect consumers' privacy by requiring all health information sites, including CAM sites, to disclose whether they track users and if so, how that information is used and stored, including whether it is sold to third parties.

Recommendation 13: Information on the training and education of providers of CAM services should be made easily available to the public.

Actions

13.1 The Commission recommends that states require all persons providing CAM services to disclose information regarding their level and scope of training and to make it easily available to consumers.

13.2 The Commission recommends that states disclose information on State guidelines, requirements, licensure, certification, and disciplinary actions of health providers, including CAM providers, and make it easily accessible to the public.

Recommendation 14: CAM products that are available to U.S. consumers should be safe and meet appropriate standards of quality and consistency.

Actions

14.1 The efforts of both the public and private sectors to ensure the development, validation, and dissemination of analytical methods and reference materials for dietary supplements should be accelerated.

14.2 The proposed Good Manufacturing Practices for Dietary Supplements should be published expeditiously, followed by a timely review of comments and completion of a final rule. The Food and Drug

Administration should be provided with adequate resources to complete this task.

14.3 Adequate funding should be provided to appropriate Federal agencies, including U.S. Customs and Food and Drug Administration inspection authorities, to enforce current laws monitoring the quality of imported raw materials and finished products intended for use as dietary supplements.

14.4 Manufacturers should have on file and make available to the FDA upon request scientific information to substantiate their determinations of safety, and current statutory provisions should be periodically reexamined to determine whether safety requirements for dietary supplements are adequate.

14.5 An objective process for evaluating the safety of dietary supplement products should be developed by an independent expert panel.

Recommendation 15: Provisions of the Federal Food, Drug, and Cosmetic Act, as modified by the Dietary Supplement Health and Education Act of 1994, should be fully implemented, funded, enforced, and evaluated.

Actions

15.1 The Food and Drug Administration and other agencies with regulatory responsibilities should be provided with additional resources to 1) enforce the Dietary Supplement Health and Education Act's regulations regarding labeling of dietary supplements, 2) enforce current provisions requiring that dietary supplements be labeled in English, even if the same information is also included in another language, and 3) employ additional professionals with expertise in dietary supplements.

15.2 Current provisions requiring disclosure of material facts by manufacturers of CAM products should be enforced, and manufacturers should meet their responsibility to disclose material facts on the label, package, and/or package insert, so that the public will have information about known risks and well-documented significant interactions. Information on potential benefits of dietary supplements should also be made easily available at the time of purchase.

15.3 Congress should periodically evaluate the effectiveness, limitations, and enforcement of the Dietary Supplement Health and Education Act of 1994, including its impact on public health, and take appropriate action to ensure the public's safety.

Recommendation 16: Activities to ensure that advertising of dietary supplements and other CAM practices and products is truthful and not misleading should be increased.

Actions

16.1 Congress should provide additional support to the Federal Trade Commission to 1) expand efforts to identify false and deceptive advertising of CAM-related health services and products and take appropriate enforcement action when necessary, 2) use appropriate CAM experts in the process of examination of CAM-related advertising, 3) increase activities to help consumers distinguish useful and reliable information from deceptive and unsubstantiated advertising in all forms of marketing and advertising, including at the point of purchase; and 4) seek additional public comment on the benefits and potential problems in the advertising of CAM-related services and products.

Recommendation 17: The collection and dissemination of information about adverse events stemming from the use of dietary supplements should be improved.

Actions

17.1 Congress should require dietary supplement manufacturers and suppliers to register with the Food and Drug Administration, and the agency should encourage voluntary registration until such a requirement is in effect, so that manufacturers, suppliers, and consumers can be promptly notified if a serious adverse event is identified.

17.2 Recent congressional support for improving the Food and Drug Administration's adverse events reporting system should be enhanced by requiring dietary supplement manufacturers and suppliers to maintain records and report serious adverse events to the agency.

17.3 Additional resources and support should be provided to 1) the Food and Drug Administration to simplify the adverse events reporting system for dietary supplements, and to streamline the database for timely review and follow-up on received reports; and 2) the Food and Drug Administration, the Centers for Disease Control and Prevention, and other appropriate Federal agencies to increase outreach activities to consumers, health professionals (including poison control centers, emergency room physicians, CAM practitioners, and mid-level marketers) in order to

improve both manufacturers' and the public's awareness of and participation in voluntary event reporting.

Access and Delivery

Recommendation 18: The Department of Health and Human Services should evaluate current barriers to consumer access to safe and effective CAM practices and to qualified practitioners and should develop strategies for removing those barriers in order to increase access and to ensure accountability.

Actions

18.1 The Department of Health and Human Services should assist the States in evaluating the impact of legislation enacted by various States on access to CAM practices and on public safety.

18.2 The Department of Health and Human Services and other appropriate Federal agencies should use health care workforce data, data from national surveys on use of CAM, regional public health reports on CAM activities and other studies to identify current and future health care needs and the relevance of safe and effective CAM services for helping address these needs.

Recommendation 19: The Federal Government should offer assistance to states and professional organizations in 1) developing and evaluating guidelines for practitioner accountability and competence in CAM delivery, including regulation of practice, and 2) periodic review and assessment of the effects of regulations on consumer protection.

Actions

19.1 The Secretary of Health and Human Services should create a policy advisory committee, including CAM and conventional practitioners and representatives of the public, to address issues related to providing access to qualified CAM practitioners, provide guidance to the states concerning regulation possibilities, and provide a forum for dialogue on other issues related to maximizing access.

19.2 The Secretary of Health and Human Services, in collaboration with states, should assist CAM organizations that wish to develop consensus within their field of practice regarding standards of practice, including education and training. The conclusions reached by CAM professional groups concerning these matters should be considered by states and regulatory

bodies in determining the appropriate status of these practitioners for such regulatory options as registration, licensure or exemption.

Recommendation 20: States should evaluate and review their regulation of CAM practitioners and ensure their accountability to the public. States should, as appropriate, implement provisions for licensure, registration, and exemption consistent with the practitioners' education, training, and scope of practice.

Action

20.1 The Department of Health and Human Services' policy advisory committee, in partnership with state legislatures, regulatory boards, and CAM practitioners, should develop model guidelines or other guidance for the regulation and oversight of licensed and registered practitioners who use CAM services and products. This guidance should balance concerns regarding protection of the public from the inappropriate practice of health care, provide opportunities for appropriately trained and qualified health practitioners to offer the full range of services in which they are trained and competent, maintain competition in the provision of CAM and other health services, preserve CAM styles and traditions that have been valued by both practitioners and consumers, and determine the extent of the public's choice among health care modalities.

Recommendation 21: Nationally recognized accrediting bodies should evaluate how health care organizations under their oversight are using CAM practices and should develop strategies for the safe and appropriate use of qualified CAM practitioners and safe and effective products in these organizations.

Actions

21.1 National accrediting bodies, in partnership with other public and private organizations, should evaluate present uses of CAM practitioners in health care delivery settings and develop strategies for their appropriate use in ways that will benefit the public.

21.2 Nationally recognized accrediting bodies of health care organizations and facilities should consider increasing on-going access to CAM expertise to ensure that processes to develop accreditation standards and interpretations reflect emerging developments in the health care field.

21.3 Nationally recognized accrediting bodies, using CAM experts, should review and evaluate current standards and guidelines to ensure the safe use of CAM practices and products in health care delivery organizations.

Recommendation 22: The Federal government should facilitate and support the evaluation and implementation of safe and effective CAM practices to help meet the health care needs of special and vulnerable populations.

Actions

22.1 The Department of Health and Human Services and other Federal Departments should identify models of health care delivery that include safe and effective CAM practices, evaluate them, and then support those models which are successful for use with special and vulnerable populations, including the chronically and terminally ill.

22.2 The Department of Health and Human Services should sponsor the development and evaluation of demonstration projects that integrate the use of safe and effective CAM services as part of the health care programs in hospices and community health centers.

22.3 The Department of Health and Human Services should identify ways to support the practice of indigenous healing in the United States and to improve communication among indigenous healers, conventional health care professionals, and CAM practitioners.

COVERAGE AND REIMBURSEMENT

Recommendation 23: Evidence should be developed and disseminated regarding the safety, benefits, and cost-effectiveness of CAM interventions, as well as the optimum models for complementary and integrated care.

Actions

23.1 The Secretary of Health and Human Services should convene a joint public and private task force to identify and set priorities for studying health services issues related to CAM and to help purchasers and health plans make prudent decisions regarding coverage of and access to CAM.

23.2 Federal agencies, States, and private organizations should increase funding for health services research, demonstrations, and evaluations related to CAM, including outcomes of CAM interventions, coverage and access, effective sequencing and integration with conventional therapies, effective models for service delivery, and the use of CAM in underserved, vulnerable, and special populations.

23.3 Federal, State, and private entities should fund health services research on the costs, cost-benefits, and cost-effectiveness of CAM interventions and wellness programs.

23.4 The Secretary of Health and Human Services and the National Committee for Vital and Health Statistics should authorize a national coding system that supports standardized data for CAM. This system should make possible the collection of data for clinical and health services research on CAM, and support compliance with the electronic claims requirements of the Health Insurance Portability and Accountability Act.

23.5 The National Center for Complementary and Alternative Medicine, through its clearinghouse, should provide information on health services research, demonstrations, and evaluations of CAM services and products.

23.6 Public agencies and private organizations should support the development of informational programs on CAM targeted to health plan purchasers and sponsors, health insurers, managed care organizations, consumer groups, and others involved in the provision of health care services.

23.7 Congress should request periodic reports from appropriate Federal departments on coverage of and reimbursement for CAM practices and products for Federal beneficiaries, Medicaid beneficiaries, Federal employees, military personnel, veterans, and eligible family members and retirees, as well as any legislative, regulatory, or programmatic impediments to covering safe and effective CAM interventions.

Recommendation 24: Insurers and managed care organizations should offer purchasers the option of health benefit plans that incorporate coverage of safe and effective CAM interventions provided by qualified practitioners.

Actions

24.1 Health insurance and managed care companies should modify their benefit design and coverage processes in order to offer purchasers, for their consideration, health benefit plans that include safe and effective CAM interventions.

24.2 Health insurance and managed care companies should make use of CAM expertise in the development of benefit plans that include safe and effective CAM interventions.

24.3 Health insurers, managed care organizations, CAM professional associations, CAM experts, private organizations that develop medical criteria, and Federal agencies are encouraged to develop appropriate clinical criteria and guidelines for the use of CAM services and products.

Recommendation 25: Purchasers, including Federal agencies and employers, should evaluate the possibility of covering benefits or adding health benefit plans that incorporate safe and effective CAM interventions.

Actions

25.1 Employers, Federal agencies, other purchasers and sponsors should enhance the processes they use to develop health benefits and give consideration to safe and effective CAM interventions.

25.2 Public purchasers such as the Centers for Medicare and Medicaid Services and the Department of Defense, employers, other health benefit sponsors, and health industry organizations should include CAM practitioners and experts on advisory bodies and workgroups considering CAM benefits and other health benefit issues.

25.3 The Secretary of Health and Human Services, preferably through the Federal CAM coordinating office when established, should maintain a list of opportunities for CAM experts to participate on advisory committees and other workgroups.

25.4 The Secretary of Health and Human Services should direct agencies under his authority to convene workgroups and conferences to assess the state-of-the-science of CAM services and products and to develop consensus and other guidance on their use.

25.5 State governments should consider, as part of evaluating and reviewing their regulations, how regulation of CAM practitioners could affect third-party coverage of safe and effective CAM interventions. CAM in Wellness and Health Promotion

---

Recommendation 26: The Department of Health and Human Services and other 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 to promote wellness and help achieve the nation's health promotion and disease prevention goals. Demonstration programs should be funded for those determined to have benefit.

Actions

26.1 The Healthy People Consortium should evaluate the role of safe and effective CAM practices and products in addressing the10 leading health indicators and develop strategies, including demonstration programs, to encourage the use of CAM practices and products found to be beneficial in addressing these indicators.

26.2 Questions on the extent and use of CAM products and practices should be included in national surveys and other assessment tools including the National Health Interview Survey, the National Health and Nutrition Examination Survey, and the Medical Expenditure Panel Survey. Where appropriate, information from these sources should be incorporated into the Healthy People 2020 goals and objectives.

26.3 The Department of Health and Human Services, as part of the Healthy People 2010 initiative, should support the development of a national campaign to teach and encourage behaviors that focus on improving nutrition, promoting exercise, and teaching stress management for all Americans, especially children. This campaign should include safe and effective CAM practices and products where appropriate.

26.4 The Federal government, in partnership with public and private organizations, should evaluate safe and effective CAM practices and products to determine their applicability to improving nutrition, promoting exercise, and teaching stress management to children. Demonstration programs should be funded for those found to be applicable to children.

26.5 The Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Department of Agriculture, the Department of Education, and other Federal agencies that develop school health guidelines should evaluate the potential applicability of safe and effective CAM practices and products to these school health guidelines. Those found to have benefits should be included in the guidelines.

26.6 Federal agencies, in partnership with the business community, should develop incentives for schools to make lunches and snacks healthful, and to limit the sale-and eliminate the advertising-of high-fat snacks, soft drinks, and other products that do not contribute to healthy lifestyles

26.7 The Department of Health and Human Services and the Department of Labor should evaluate safe and effective CAM practices and products to determine their potential role in workplace wellness and prevention activities, and include them in Federal workplace wellness and health promotion programs and Federal health coverage plans when appropriate.

26.8 Federal agencies, in conjunction with the business community, should develop incentives for employers to include CAM practices and products found to be beneficial in wellness and prevention activities in their workplace wellness programs and health coverage.

Recommendation 27: Federal, State, public, and private health care delivery systems and programs should evaluate CAM practices and products to determine their applicability to programs and services that help promote wellness and health. Demonstration programs should be funded for those determined to be beneficial.

Actions

27.1 The Secretaries of Health and Human Services, Agriculture, Veterans Affairs, and Defense and the Commissioner of the Administration for Children and Families, should evaluate safe and effective CAM practices and products that contribute to wellness and health and determine their applicability to Federal health systems and programs.

27.2 The Secretary of Health and Human Services should facilitate the bringing together of public and private health care organizations to evaluate safe and effective CAM practices and products that contribute to wellness and health and determine their applicability to health systems and programs, especially in the nation's hospitals and long-term care facilities and in programs serving the aging, those with chronic illness, and those at the end of life.

27.3 CAM and conventional health professional training programs should consider offering training and educational opportunities for students in self-care and lifestyle decision-making to improve practitioners' health and to enable practitioners to impart this knowledge to their patients or clients.

Recommendation 28: Research on the role of CAM in wellness and health promotion, the application of CAM principles and practices, and the role of CAM practitioners in the management of chronic disease should be expanded.

Actions

28.1 The Department of Health and Human Services 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.

28.2 The Federal government and private health organizations should evaluate CAM practices and products that are currently being used for wellness and health promotion to determine their effectiveness and applicability to the management of chronic disease. Funding should be provided for demonstration projects in the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs, the Department of Defense, the Health Resources and Services Administration, and other Federal agencies for those CAM practices and products found to have benefit in the management of chronic disease, end of life such as hospice.

COORDINATING FEDERAL EFFORTS

Recommendation 29: The President, Secretary of Health and Human Services, or Congress should create an office to coordinate Federal CAM activities and to facilitate the integration into the nation's health care system of those complementary and alternative health care practices and products determined to be safe and effective.

Actions

29.1 The office should be established at the highest possible and most appropriate level in the Department of Health and Human Services and should be given sufficient staff and budget to meet its responsibilities.

29.2 The office should charter an advisory council. Members should include CAM and conventional practitioners with expertise, diverse backgrounds, and necessary training, as well as representatives of both the private and public sectors, to guide and advise the office about its activities.

29.3 The office's responsibilities should include, but not be limited to, coordinating Federal CAM activities; serving as a Federal CAM policy liaison with conventional health care and CAM professionals, organizations, institutions, and commercial ventures; planning, facilitating, and convening conferences, workshops, and advisory groups; acting as a centralized Federal point of contact regarding CAM for the public, CAM practitioners, conventional health care providers, and the media; facilitating implementation of the Commission's recommendations and actions; and exploring additional and emerging topics not considered by the Commission.

List of Acronyms

AAMC: Association of American Medical Colleges

AACOM: American Association of Colleges of Osteopathic Medicine

AANP: American Association of Naturopathic Physicians

AER: Adverse Events Reporting System

AHRQ: Agency for Healthcare Research and Quality

AMA: American Medical Association

BHPr: Bureau of Health Professions

BPHC: Bureau of Primary Health Care

CDCP: Centers for Disease Control and Prevention

CME: Continuing Medical Education

CMS: Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration)

CSPC: Consumer Product Safety Commission

D.C.: Doctor of Chiropractic

DOD: Department of Defense

D.O.: Doctor of Osteopathy

DOEd: Department of Education

DSHEA: Dietary Supplement Health and Education Act

GSA: General Services Administration

FDA: Food and Drug Administration

FSMB: Federation of State Medical Boards

FTC: Federal Trade Commission

GAO: Government Accounting Office

GMP: Good Manufacturing Practices

HIPAA: Health Insurance Portability and Accountability Act

HMO: Health Maintenance Organization

HRSA: Health Resources & Services Administration

IHS: Indian Health Service

IOM: Institute of Medicine

L.Ac: Licensed Acupuncturist

M.D.: Medical Doctor

MEPS: Medical Expenditure Panel Survey

MSOP: Medical Schools Objectives Project

NAS: National Academy of Sciences

NASA: National Aeronautics and Space Administration

NCCAM: National Center for Complementary and Alternative Medicine

NCI: National Cancer Institute

N.D.: Naturopathic Doctor

NHSC: National Health Services Corps

NIH: National Institutes of Health

NLEA: Nutrition Labeling and Education Act

NLM: National Library of Medicine

NSF: National Science Foundation

ODS: Office of Dietary Supplements

OIG: Office of the Inspector General

OMB: Office of Management and Budget

OMH: Office of Minority Health

OSTP: Office of Science and Technology Policy

OWH: Office of Women's Health

PHS: Public Health Service

PPO: Preferred Provider Organization

SAMSHA: Substance Abuse and Mental Health Services Administration

SBA: Small Business Administration

SBIR: Small Business Innovative Research Program

STTR: Small Business Technology Transfer Research Program

USDA: United States Department of Agriculture

USP: United States Pharmacopeia

VA: Department of Veterans Affairs

WHCCAMP: White House Commission on Complementary and Alternative Medicine Policy

WHO: World Health Organization

APPENDICES

Appendix A – Executive Order and Commission Charter

Executive Order 13147

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release March 7, 2000

EXECUTIVE ORDER 13147
WHITE HOUSE COMMISSION ON COMPLEMENTARY
AND ALTERNATIVE MEDICINE POLICY

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to establish the White House Commission on Complementary and Alternative Medicine Policy, it is hereby ordered as follows:

Section 1. Establishment. There is established in the Department of Health and Human Services (Department) the White House Commission on Complementary and Alternative Medicine Policy (Commission). The Commission shall be composed of not more than 15 members appointed by the President from knowledgeable representatives in health care practice and complementary and alternative medicine. The President shall designate a Chair from among the members of the Commission. The Secretary of Health and Human Services (Secretary) shall appoint an Executive Director for the Commission.
Sec. 2. Functions. The Commission shall provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine. The recommendations shall address the following:

(a) the education and training of health care practitioners in complementary and alternative medicine;

(b) coordinated research to increase knowledge about complementary and alternative medicine practices and products;

(c) the provision to health care professionals of reliable and useful information about complementary and alternative medicine that can be made readily accessible and understandable to the general public; and

(d) guidance for appropriate access to and delivery of complementary and alternative medicine.

Sec. 3. Administration. (a) To the extent permitted by law, the heads of executive departments and agencies shall provide the Commission, upon request, with such information and assistance as it may require for the purpose of carrying out its functions.

(b) Each member of the Commission shall receive compensation at a rate equal to the daily equivalent of the annual rate specified for Level 1V of the Executive Schedule (5 U.S.C. 5315) for each day during which the member is engaged in the performance of the duties of the Commission. While away from their homes or regular places of business in the performance of the duties of the Commission, members shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701-5707).

(c) The Department shall provide the Commission with funding and with administrative services, facilities, staff, and other support services necessary for the performance of the Commission's functions.

(d) In accordance with guidelines issued by the Administrator of General Services, the Secretary shall perform the functions of the President under the Federal Advisory Committee Act, as amended (5 U.S.C. App.), with respect to the Commission, except that of reporting to the Congress.

(e) The Commission shall terminate 2 years from the date of this order unless extended by the President prior to such date.

WILLIAM J. CLINTON
THE WHITE HOUSE,
March 7, 2000.

# # #

Amendment to Executive Order 13147

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release September 15, 2000

EXECUTIVE ORDER
AMENDMENT TO EXECUTIVE ORDER 13147, INCREASING THE MEMBERSHIP OF THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to increase the membership of the White House Commission on Complementary and Alternative Medicine Policy from not more than 15 members to up to 20 members, it is hereby ordered that the second sentence of section 1 of Executive Order 13147 of May 7, 2000, is amended by deleting "not more than 15" and inserting "up to 20" in lieu thereof.

WILLIAM J. CLINTON
THE WHITE HOUSE,
September 15, 2000.

# # #

Commission Charter

The Commission Charter is only available in hardcopy format.

Appendix B – 10 Rules for Health Care Reform, 28 Focus Areas of Healthy People 2010 and PEW Taskforce Recommendations

10 Rules for Health Care Reform

---

1. **Care based on continuous healing relationships.** Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This rule implies that the health care system should be responsive at all times (24 hours a day, every day) and that access to care should be provided over the internet, by telephone, and by other means in addition to face-to-face visits.

2. **Customization based on patient needs and values.** The system of care should be designed to meet the most common types of needs but have the capability to respond to individual patient choices and preferences.

3. **The patient as the source of control.** Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decisionmaking.

4. **Shared knowledge and the free flow of information.** Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.

5. **Evidence-based decision making.** Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.

6. **Safety as a system property.** Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.

7. **The need for transparency.** The health care system should make available to patients and their families information that allows them to make informed decisions when selecting a health plan, hospital, or clinical practice or when choosing among alternative treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.

8. **Anticipation of needs.** The health system should anticipate patient needs rather than simply reacting to events.

9. **Continuous decrease in waste.** The health system should not waste resources or patient time.

10. **Cooperation among clinicians.** Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

28 Focus Areas of Healthy People 2010

---

1. Access to Quality Health Services
2. Arthritis, Osteoporosis, and Chronic Back Conditions
3. Cancer
4. Chronic Kidney Disease
5. Diabetes
6. Disability and Secondary Conditions
7. Educational and Community-Based Programs
8. Environmental Health
9. Family Planning
10. Food Safety
11. Health Communication
12. Heart Disease and Stroke
13. HIV
14. Immunization and Infectious Diseases
15. Injury and Violence Prevention
16. Maternal, Infant, and Child Health
17. Medical Product Safety
18. Mental Health and Mental Disorders
19. Nutrition and Overweight
20. Occupational Safety and Health
21. Oral Health
22. Physical Activity and Fitness
23. Public Health Infrastructure
24. Respiratory Diseases
25. Sexually Transmitted Diseases
26. Substance Abuse
27. Tobacco Use
28. Vision and Hearing

PEW Taskforce Commission Recommendations for Regulation of the Health Care Workforce

---

1. States should use standardized and understandable language for health professions regulation and its functions to clearly describe them for consumers, provider organizations, businesses, and the professions.

2. States should standardize entry-to-practice requirements and limit them to competence assessments for health professions to facilitate the physical and professional mobility of the health professions.

3. States should base practice acts on demonstrated initial and continuing competence. This process must allow and expect different professions to share overlapping scopes of practice. States should explore pathways to allow all professionals to provide services to the full extent of their current knowledge, training, experience and skills.

4. States should redesign health professional boards and their functions to reflect the interdisciplinary and public accountability demands of the changing health care delivery system.

5. Boards should educate consumers to assist them in obtaining the information necessary to make decision about practitioners and to improve the board's public accountability.

6. Boards should cooperate with other public and private organizations in collecting data on regulated health professions to support effective workforce planning.

7. States should require each board to develop, implement and evaluate continuing competency requirements to assure the continuing competence of regulated health care professionals.

8. States should maintain a fair, cost-effective and uniform disciplinary process to exclude incompetent practitioners to protect and promote the public's health.

9. States should develop evaluation tools that assess the objectives, successes and shortcomings of their regulatory systems and bodies to best protect and promote the public's health.

10. States should understand the links, overlaps and conflicts between their health care workforce regulatory systems and other systems which affect the education, regulation and practice of health care practitioners and work to develop partnerships to streamline regulatory structures and processes

Appendix C – Commission Meetings

Schedule of Commission Meetings and Material Subjects Reviewed

Commission Meetings
July 13-14, 2000 - Planning Meeting

- Discussion of Vision, Issues and Concerns of the Commission Members on Issues Presented in Executive Order
- Development of Meeting Schedule
- Discussion of Website Development and Content

October 5-6, 2000 - Coordination of CAM Research & Achievements, Opportunities, Obstacles and Solutions

- Public Input and Research Priorities
- Federal Support for CAM Research
- Academic Centers and Support for CAM Research
- Research Support and Collaborations at the NIH
- Facilitating CAM Research and Regulatory Challenges
- Research in the Regulatory Framework
- Outcomes Research - Interface between CAM Research and Regulatory Agencies
- Outcomes Research - CAM Research and Experimental Study Design
- Guiding Principles of CAM Perspectives and Practices
- Support for CAM Research - The Not-for-Profit Sector
- Support for CAM Research - The Private Sector
- Support for CAM Research - Federal Agency Support

December 4-5, 2000 - Access and Delivery of CAM Services

- Utilization of CAM Services and Products
- Cost Effectiveness of Selected CAM Services
- Clinical Effectiveness of Selected CAM Services
- Use of CAM for Selected Health Conditions
- Issues in Integrating CAM in Service Delivery
- Meeting Public Needs: Systems of CAM Delivery at Community Health Clinics, in Private Practice and Hospital-based Centers, in Hospice Care, at Academic Research Centers and in Managed Care Organizations.

February 22-23, 2001 - Training, Education, Credentialing and Licensing of CAM Practices

- CAM Education and Training: Establishing Educational Programs

- Continuing CAM Education and Training - Building Knowledge and Skills
- CAM Credentialing and Licensure - Assuring Quality and Accountability in CAM Practices

March 26-27, 2001 - Development and Dissemination of CAM Information

- CAM in the Media - Newspapers, Magazines, Television and Radio
- CAM in the Media - The Internet
- Evaluation of available CAM Information
- Marketing and Advertising of CAM Services and Products

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities
- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

- Not-for-Profit Support for CAM Research
- Investigating the Scientific Bases of CAM Practices
- Approaches to Evaluating CAM Research Literature
- Challenges of CAM Research and Research Training
- Peer Reviews of CAM Research Results in the Published Literature

May 15-16, 2001 - Coverage and Reimbursement of CAM Services

- Health Care Financing in the United States
- Federal Purchasers
- State Perspectives
- Employer Coverage
- The Underinsured, Uninsured and Minorities
- Health Plans and CAM Benefits
- Healthcare Insurance - Providers Perspectives
- Evolving Health Care Systems

July 2-3, 2001 - Discussion of Interim Progress Report

October 4-6, 2001 - Discussion of Draft Recommendations

December 6-7, 2001 - Discussion of Draft Final Report and Recommendations

February 21-22, 2002 - Discussion of Draft Final Report, Recommendations, and Actions

---

Town Hall Meetings

September 8, 2000 - San Francisco, CA

October 30-31, 2000 - Seattle, WA

January 23, 2001 - New York City, NY

March 16, 2001 - Minneapolis, MN

Topics Discussed

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems
- Dietary Supplements and Herbal Products
- Education of CAM Providers
- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

The transcripts, agendas, and other information pertaining to all Commission Meetings and Town Hall Meetings are available on the Commission's website, http://whccamp.hhs.gov.

Appendix D – General and Town Hall Meeting Participants

Planning Meeting
July 13-14, 2000

Peter Reinecke
Senator Tom Harkin's Office

Karen Santoro
National Institute of Allergy and Infectious Diseases

September 8, 2000
Town Hall Meeting
San Francisco, California

Marilyn Schlitz
Institute for Noetic Sciences
CA Pacific Medical Center

Beverly Rubik
Institute for Frontier Science

Catherine Dower
UCSF Center for Health Professions

May Loo
Stanford Medical Center

Deborah Kesten
CA Pacific Medical Center

Corinne Giantonio
Kaiser Permanente

Savely Savva
Monterey Institute for the Study of Alternative Healing

Adam Burke
San Francisco State University

Dana Ullman
Homeopathic Education Services

Craig Little
American Chiropractic Association

Millie Tseng
Santa Clara County Employee Wellness

Lixin Huang
American College of Traditional Chinese Medicine

Bruce Shelton
Arizona Board of Homeopathic Medical Examiners

Kenneth Sancier
Qigong Institute

Peg Jordan
Integrative Health Circles

Michael Mayer
The Bodymind healing Center

Lynn Murphy
Feingold Association of the US

Karen Scott
Progress in Medicine

Stephen Bent
UCSF OSHER Center for Integrative Medicine

Bradley Jacobs
UCSF OSHER Center for Integrative Medicine

Sita Ananth
Health Forum/American Hospital Association

Jan Dederick
East Bay Shen Center

Brian Fennen
Council of Acupuncturists and Oriental Medicine

Carol Ceresa
California Dietetic Association

Anne Kilker

SFVA

Andea Garen
California Dietetic Association

Veny Zamora
Administration on Aging

Cynthia Copple
Lotus Holistic Health

Alex Feng
University of California at Berkeley

Richard Pavek
Shen Therapy Institute

Nicola Henriques
Institute of Classical Homeopathy

Adrian Lowe
Lamas Qigong Association

George Wedemeyer
National Council of Field Labor

Michael Traub
American Association of Naturopathic Physicians

Jay Azarow
Stanford University School of Medicine

Antonio Martinez
American Speciality Health, Inc.

Deane Hillsman
Union of American Physicians and Dentists

Sally Lamont
CA Association of Naturopathic Physicians

Evelyn Lee
Richmond Area Multi-services

Jennifer Bolen
JURIMED

Richard Hansen
Advanced health Research Institute

Ricki Pollycobe
CA Pacific Medical Center

Roy Upton
American Herbal Pharmacopocia

James Underdown
Center for Inquiry

Marc Halpern
California College of Ayurveda

Carla Wilson
Quan Yin Healing Arts Center

Howard Moffet
American College of Traditional Chinese Medicine

Perfecto Munoz
Health Plan of San Joaquin

Len Saputo
Health Medicine forum

Burton Goldberg
Alternative Medicine.com

Karen Ehrlich
CA Association of Midwives

Mitchell Katz
Health Department, City of San Francisco

Harriett Ishimoto
Office of Congresswoman Nancy Pelosi

Catherine Dodd
Department of Health and Human Services, Region X

Steven Ottenstein
Department of Health and Human Services, White House Liason

October 5-6, 2000
Research

Leon Rosenberg
Princeton University

Jeffrey White
Office of Cancer Complementary and Alternative Medicine

Claude Lenfant
National Heart, Lung, Blood Institute, NIH

Marvin Cassman
National Institute of General Medical Sciences

Steven Hausman
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH

Paul Coates
Office of Dietary Supplements, OD/NIH

Alfred Fishman
University of Pennsylvania

Daniel Federman
Harvard Medical School

Joseph Pizzorno
Bastyr University

William Meeker
Palmer Center for Chiropractic Research

Stephen E. Straus
National Center for Complementary and Alternative Medicine, NIH

Janet Woodcock
Center for Drug Evaluation and Research, FDA

David Feigal
Center for Devices and Radiological Health, FDA

Joseph A. Levitt
Center for Food Safety and Applied Nutrition, FDA

Christine Lewis
Office of Nutritional Products Labeling and Dietary Supplements, FDA

David Dorsey
Food and Drug Administration (FDA)

Floyd Leaders
Botanical Enterprises, Inc

Robert McCaleb
Herb Research Foundation

Anthony Rosner
Foundation for Chiropractic Education and Research

James Winn
Federation of State Medical Boards of the United States, Inc.

Richard Gonzalez
Private Practice

Ann McCombs
Private Practice

Devi Nambudripad
Private Practice

Jeffrey White
Office of Cancer Complementary and Alternative Medicine, NCI, NIH

John Templeton
The John Templeton Foundation

Dyanne M. Hayes
Conrad N. Hilton Foundation

Daniel Callahan
The Hastings Center

Teri Ades
American Cancer Society

Randy Burkholder
Advanced Medical Technology Association

Raymond Ruddon

Johnson and Johnson

Frank C. Sciavolino
Pfizer, Inc.

Mark Blumenthal
American Botanical Council

Annette Dickenson
Scientific and Regulatory Affairs Council for Responsible Nutrition

Elaine Cramer
National Center for Environmental Health, Centers for Disease Control

Leanna Standish
Bastyr University Research Institute

Lydia Segal
Complementary and Alternative Medicine, Kaiser Permanente (Mid-Atlantic)

Douglas Llyod
Association of Schools of Public Health

John G. Demakis
Health Services Research and Development ServiceVeterans Affairs

William Dietz
Division of Nutrition and Physical Activity, CDC

Michael Trujillo
Indian Health Service

October 30-31, 2000
Town Hall Meeting
Seattle, Washington

Richard Kelley
Department of Health and Human Services, Region X

Robert Harkins
Office of the Insurance Commissioner

Greg Nickels
King County Council, WA

Maggi Fimia

King County Council, WA

Kent Pullen
King County Council, WA

Richard Lyons
US Public Health Service

Dorothy Wong
International Communtiy Health Centers

Gail Zimmerman
WA Department of Health

Henry Ziegler
Private Practice

Kathy Abascal
Botanical Medicine Academy

Lori Bielinski
Office of the Insurance Commissioner

Alonzo Plough
Seattle-King County Health Department

Maggi Fimia
King County Council, District 1

Tom Trompeter
Community Health Centers of King County

Judy Featherstone
Kent Community Health Center

Kathy Lynn Boulanger
Washington Reflexology Association

Pamela Snider
Bastyr University

Leanna Standish
Bastyr University Research Institute

Jeffrey Bland
Institute for Functional Medicine

Richard Hammerschlag
Oregon College of Oriental Medicine

William Dallas
Western States Chiropractic College

Robert D. Mootz
Washington State Labor & Industries

Clyde Jensen
National College of Natural Medicine

Jim Taylor
University of Washington

Karen Sherman
Northwest Institute of Acupuncture and Oriental Medicine

Suzzanne Meyer
Bastyr University

Jacqueline Obando
Mercy Vet PLLC

William E. Lafferty
University of Washington

Charles Simpson
Complementary Healthcare Plans, Inc.

Arlene Darby
Citizens for Alternative Health Care

Nicole Ellis
Personal

Rose Eng-Lum
Dai Wai Association

Jayne Leet
Birdsong Ranch

Daniel J. Labriola
WA State Department of Health

Gay Koopman
Personal

Kathy McVay
WA State Profesioanl Loan Repayment and Scholarship Program

Fred Bomonti
Washington State Chiropractic Association

Laurence M. DeShields
Community Health Center

Tracy Turner
Personal

John Stephen Huber
Highline Community College

M. Jacobson
Personal

Laura Patton
Group Health Cooperative of Puget Sound

Elizabeth Goldblatt
Commission on Colleges, A/OM Accrediting Agency

JoAnne Myers-Ciecko
Seattle Midwifery School

Susan Haeger
Citizens for Health (National)

Michelle Simon
Personal

Julie Chinnock
Personal

Chris LePisto
Personal

Don Taylor
Personal

Cindy Breed

Community Health Centers of King County

Jane Guiltinan
Natural Medicine Clinic, Bastyr University

Fernando Vega
Seattle Healing Arts Clinic

Judith Aileen Kaufman
Emerald City Healing Arts

Stan Lippmann
Natural Medicine Party

Valerie Sasson
Puget Sound Birth Center

Scott Barnhart
University of Washington

Leah Kliger
Evergreen Community Health Center

Brenda Loew
Japanese Acupuncture Center

Robert A. May
Alternare Health Services

Terry Courtney
Bastyr University

Sue Vlasuk
DABCO

Diana Thompson
Private Practice

Houston LeBrun
American Message Therapy Association

Heike Doyle
Puget Sound Midwives & Birth Center

Jerri Fredin
Citizens for Alternative Healthcare

Don Sloma
Private Practice

Robert Nicoloff
WA State Department of Health

Richard Whitten
Washington Health Care Authority

Andrew John Brunskill
Uniform Medical Plan, Health Care Authority

Karl D. Peterson
NW Naturopathic Physicians Convention

Pat Prinz
U WA School of Nursing

Kay Lahdenpera
Personal

Jane Bernice Nelson
North Bend Elementary

Sheila Kennedy Rhodes
Mt. Baker Care Center

Vera Ridderbusch
Private Practice

Katherine R. Schmidt
Bellevue Massage School

Ronald Schneeweiss
University of Washington

Paul Saunders
Office of Natural Health Products

Karta Purkh Khalsa
Personal

Jennifer Jacobs
American Institute of Homeopathy

Emma Bezy
Spirituality Program, Bastyr University

Tom Shepherd
Bastyr University

Robert Arthur Anderson
American Board of Holistic Medicine

Charlotte Coon
Hellerwork International

Jeffrey Goin
Coalition for Natural Health

Barbara Mitchell
Standards Management, Inc.

Mark Tomski
Washington Chapter of the AAMA

Christa Louise
North American Board of Naturopathic Examiners

Todd L. Richards
University of Washington

Lise Alschuler
Bastyr University

Jeff Novack
Bastyr University

Sevak S. Kroesen
Integrative Health Care Center, Inc.

Robert Shook
Northwest Institute for Acupuncture & Oriental Medicine

Tommy Lewis
Northwest Indian College

Ralph Forquera
Seattle Indian Health Board

Graham Patrick

Seattle University School of Nursing

Wayne William Topping
Topping International Institute, Inc.

Wendy J. Weber
Personal

Heida Brenneke
Brenneke Massage School

Paul Reilly
WANP, AANP

John Daley
Private Practice

Eileen Stretch
American Whole Health Network

Jennifer Booker
American Association of Naturopathic Physicians

Victoria M. Taylor
Quality Midwifery Associates

Austin McMillin
Private Practice

Susan Rosen
American Massage Therapy Association

Sheila Quinn
King County Integrated Health Care 2010

David Matteson
Pacific Solutions

James K. Rotchford
Medical Acupuncture Research Foundation

Mitch Stargrove
Integrated Body/Mind Information System

Bradford S. Weeks
Well Mind Association

David A. Butters
Personal

Christopher Huson
Acupuncture Association of Washington

December 4-5, 2000
Access and Delivery

William Meeker
Palmer Center for Chiropractic Research

Konrad Kail
Private Practice

Patricia Culliton
Hennepin County Medical Center

Joyce Frye
National Center for Homepathy

Tiffany Field
University of Miami School of Medicine

Dennis Awang
Medi Plant Consulting Services

Christopher Hobbs
Institute for natural Products Research

Alan Gaby
Bastyr University

Patsy Brannon
College of Human Ecology, Cornell University

Harley Goldberg
Kaiser Permanente, Northern California

Francine Butler
Association for Applied Psychophysiology and Biofeedback

Nancy Dolores Kolenda
Center for Frontier Sciences

Diana Chambers
Friends of Health

Rustum Roy
University of Arizona-PIM

David Murray Blalwas
Maryland Acupuncture Society

Kathleen Golden
Acupuncture Society of New York

Natalia Egorov
California Oriental Medical Association

David Edgar Molony
American Association of Oriental Medicine

Elaine Marie Wallzer
Henry M. Jackson Foundation

Bhavna P Bhut
OJAS Cancer Care Institute

Neeta Kunai Suryavanshi
Aspen Systems

Salvatore A D'Onofrio
Natural Health Practitioners Board

Howard Josepher
Private Practice

Denise Drayton
Personal

Jeanne Andrews
Personal

Richard Collins
Allegent Health Heart Institute

Walter Czapliewicz
Personal

J. Donald Schumacher
The Center Hospice and Palliative Care

Richard Miles
Health Frontiers

Berkley Bedell
The National Foundation for Alternative Medicine

Paul Kurtz
State University of New York-Buffalo

Donald Kendall
National Guild of Acupuncture and Oriental Medicine

Candace Campbell
American Preventive Medical Association

Michele Forzley
Forzley and Company

Robert Atkins
Atkins Center for Complementary Medicine

Charlotte Eliopoulos
American Holistic Nurses Association

Mort Rosenthal
Wellspace, Inc.

Dannion Brinkley
Compassion in Action

Tom Trumpeter
Community Health Centers of King County

Sylver Quevedo
Center for Integrative Medicine

Woodson Merrell
Continuum Center for Health and Healing

James Dillard
Oxford Health Plans

Lori Bielinksi

Office of the Washington State Insurance Commissioner

Anna Silberman
Lifestyle Advantage

Robert Schneider
Maharishi University of Management

Tori Hudson
A Woman's Time

Robert Duggan
Traditional Acupuncture Institute

Bruce Nordstrom
American Chiropractic Association

Neal D. Barnard
Physicians Committee for Responsible Medicine

Doreen Chen
Chinese Medicine Council, AAOM

Gary Sandman
Integrative Medicine, LLC

Danny Freund
Pennsylvania State University

Melinna Giannini
Alternative Link

Jane Hersey
Feingold Association

Boyd Landry
The Coalition for Natural Health

Lawrence Auburn Plumlee
National Coalition for the Chemically Injured

Michael John Rohrbacher
Certification Board for Music Therapists, Inc.

Andrew L. Rubman
American Association of Naturopathic Physicians

Marshall H. Sager
American Academy of Medical Acupuncture

Alan Trachtenberg
Substance Abuse and Mental Health Administration

Bridget Duffy
Medtronic

Milton Hammerly
Catholic Health Initiatives

January 23, 2001
Town Hall Meeting
New York, New York

Ansel R. Marks
New York State Department of Health Board of Professional Medical Conduct

Margaret B. Buhrmaster
NYS Department of Health, Office of Regulatory Reform

Caroline V. Rider
Personal

Stephen Lee Lockwood
Lockwood & Golden, Esqs.

Simone Charlop
Personal

Martin Rossman
Academy for Guided Imagery

Grace Marie Arnett
The Galen Institute

Camilla R. G. Rees
Strategic Communications Counsel

Joseph Loizzo
Columbia Presbyterian Eastside

Kevin Chen
UMDNJ - New Jersey Medical School

Leo Galland
Foundation for Integrated Medicine

Fredi Kronenberg
Rosenthal Center for Complementary and Alternative Medicine

Elaine Stern
Personal

Kerri Ann Gruninger
Rosenthal Center

Frank Lipman
Personal

Faye Shenkman
The New York College for Wholistic Education and Research

Carole Sherri Margalit
SHARE

Ann E. Fonfa
The Annie Appleseed Project

Cecile Schey
Personal

Johanna Frances Antar
Personal

David E Molony
American Association of Oriental Medicine

David Yens
NY College of Osteo Medicine

Prabhat Jumar Pokhrel
New York College for Wholistic Health , Education and Research

Jennifer Daniels
Family Medicine, Solo Practice

Charles E. Gant

Personal

Serafina Corsello
Corsello Centers for Alternative Medicine

Arnold Gore
Consumers Health Freedom Coalition

Edna Fishman
Personal

Helen Choat
Personal

Janet Susan O' Faolain
New York State Reflexology Association

Vera C. Smith
Personal

Monica Miller
Foundation for the Advancement of Innovative Medicine (FAIM)

Phillip Shinnick
Personal

Patricia Connolly
Personal

Gary Wadler
Physician/Author for Peak Performance Issues

Renate Siekmann
Personal

Sheldon Lewis
for Healers.com

Sally Kimball Ekaireb
NYNHC

Jordana Sontag
Personal

James Navarro
Personal

Jordi Ross
Documentary Filmaker

Robert Schiller
Beth Israel Medical Center

Ellen Paula Tattleman
Albert Einstein College of Medicine

David Katz
Yale School of Medicine

William Prensky
Mercy College

Kenneth Steven Gorfinkle
Columbia University/New York

Constance Park
Columbia University College of
Physicians and Surgeons

Mark L. Hoch
American Holistic Medical Association

Fran Catherine Starr
American Holistic Nurses Association

Sally Bishop
Mt. Sinai Hospital

Bhaswati Bhattacharya
American Public Health Association

Pamela Miles
Institute for the Advancement of Complementary Therapies

Brian J. MacNamara
Personal

Andrew L. Rubman
University of Bridgeport

Mark W. Garber
Greenwich Hospital

Bronner Handwerger
University of Bridgeport

Jonathan A. Daniel
Pacific College of Oriental Medicine

Steven Schenkman
The New York College for Wholistic Health Education and Research

Michael Charles Gaeta
New York College for Wholistic Education and Research

Kathleen Ann Golden
Acupuncture Society of NY

Donald D'Angelo
American Society of Acupuncture

Tsao-Lin E. Moy
Tri-State College of Acupuncture

Huaihai Shan
University of Medicine & Dentistry of New Jersey

Christopher Kent
Council on Chiropractic Practice

James Dillard
Columbia University College of Physicians and Surgeons

Barrie R. Cassileth
Memorial Sloan-Kettering Cancer Center

Raymond Y. Chang
Institute of East-West Medicine

Janice Pingel
Personal

Joan Framo Runfola
Cancer Care

Barbara Sarah
Benedictine Hospital

Virginia Mae Langley
The Coalition for Natural Health

Robb Burlage
National Council of Churches

Swami Sada Shiva Tirtha
Ayurveda Holistic Center

Ellen H. Schaplowsky
Traditional Chinese Medicine World Foundation

Ming Jin
MingQi Natural Healthcare

Thomas Leung
Association of Chinese Herbalist

Sezelle Gereau-Haddon
The Riverside Church Wellness Center

Frances L Brisbane
School of Social Welfare
Ora J. Bouey
SUNY at Stony Brook, School of Nursing

Elsie Owens
School of Social Welfare

Eliza Townsend
Private Practitioner

Charles L Robbins
School of Social Welfare

Dan Kamofsky
Care for the Homeless

Maria Josepher
Exponents Inc

John Tribbie
Greyston Health Services

Anthony Vera
Betances Health Center

Anne Markowitz
Center for Victim Support, Harlem Hospital

Pamela A. Maurath
Midwifery Task Force

Sharon S. Reilly
Friends of Midwives in Connecticut

FeiLong Qi
World Shaolin Chanmigong Association

Yi Lin Hu
United Alliance of New York State

David KM Lew
The Acupuncture Center

Ding Peng
T.C.M.A.

Phyllis W. Tan
BMK International Inc.

Ruth Hillman
New York Oriental HealthCare Center

Victor Fuhrman
Independent Reiki Master

Ellen Louise Kahne
Rejki University-Reiki Peace Network, Inc.

Robbie Fian
American Association of Oriental Medicine

Missy Vineyard
American Society for the Alexander Technique

Martha Hart Eddy
International Somatic Movement Education and Therapy Assocation

Jodi Danielle Sherman
SUNY Downstate

Bruce L. Erickson
B. L. Erickson & Associates

Cassandra Lockwood
International Somatic Movement Education and Therapy Assocation

Patrick Gentempo
Chiropractic Leadership Alliance

Peter Bruce Flaum
T-CAM

Ken Frey
The Upledger Institute

Sidney Safron
Natural Medicine Practice

James H. Budd
Personal

Karen Fuller
Personal

Martin Vincent McCarthy
The Health Accord

Kathleen Ann Lukas
New York Natural Health Coalition

Rachel Lee Chaput
Green Party

Kimberleigh Nystrom
Resonance Homeopathic Study Group

Anthony G. Bloch, BA
Personal

Lawrence Galante
Lawrence Galante's School of Tai Chi Chuan

Jeffrey R. Goin
Coalition for Natural Health

Ulises Vargas

Coalition for Natural Health

Ridgely Ochs
Newsday

Ellen J. Schutt
Nutraceuticals World

Peter Chowka
Publick Occurrences.com

Chao Chyan Pai
AcuMD.COM

Hannah Vance Bradford
CAM Communications and Reports

Diane McEnroe
Sidley & Austin - National Nutrional Foods Association

Theresa Marie Warner
World Childrens Wellness Foundation

Stuart Peter Warner
World Childrens Wellness Foundation

Belinda Arocho
Personal

Francis Lane Rosenbluth
Personal

Yvonne R. Secreto
The Respit Foundation and Wholistic Professionals Inc.

Pauline Ness
The Respit Foundation and Wholistic Professionals Inc

Judy Schneider
Feingold Association of the United

Kathleen Bratby
Feingold Association

Sandra Ehrenkranz
Feingold Association

Ludwig Duarte Anaya
Association of the Homeopathy in Colombia, South American

Diego E. Sanchez
AOBTA

Magnolia Goh
Highbridge Woodycrest Center

Pierre Rene Fontaine
New York Natural Health Coalition

February 22-23, 2001
Education and Training

Louis H. Orzack
Rutgers University

Jennifer Engstrom
Case Western University
Deborah Danoff
Association of American Medical Colleges

Peter Scoles
National Board of Medical Examiners

Alfred Fishman
University of Pennsylvania

Polly Bednash
American Association of Colleges of Nursing

Neil Sampson
Health Resources and Services Administration

Sara Collina
National Breast Cancer Coalition

Joseph Helms
American Academy of Medical Acupuncture

Lixing Lao
Institute of Traditional Chinese Medicine

Mark Blumenthal
American Botanical Council

Denise Murray . Edwards
Center for Health and Well-Being

Susan South
University of Arizona

Murray Kopelow
Accreditation Council of Continuing Education

Michael Cohen
Center for Alternative Medicine Research and Education

Boyd Landry
Coalition for Natural Health

Sharon Hall
Washington Casualty Company

Steven Olson
American Massage Therapy Association

Clement Bezold
Institute for Alternative Futures

James Winn
Federation of State Medical Boards

Susan Silver
George Washington Center for Integrative Medicine

Margaret Huddleston
Harvard Divinity School

Robert Scholten
Beth Israel Deaconess Medical Center

Rustum Roy
Pennsylvania State University

Diane Miller
National Health Freedom Coalition

Susan Bonfield Herschkowitz
Self Representation

Colleen Smethers
Progress in Medicine Foundation

Michele Forzley
Attorney at Law

Victoria Mary Goldsten
Washington Institute of Natural Health

Brenda Jasper
Association of Physician Assistant Programs

Emily WhiteHorse
Association of Physician Assistant Programs

Ingrida Lusis
American Chiropractic Association

Brian McAulay
Sherman College of Straight Chiropractic

David Molony
American Association of Oriental Medicine

Kathleen Quain
Foundation for Health and the Environment

Shula Edelkind
Progress in Medicine Foundation

Karen Scott
Progress in Medicine Foundation

Christina Walker
Schenk Human Energetic Institute

Chi Chow
New York Institute of Chinese Medicine

George Krutz
Feldenkrais Guild of North America

March 16, 2001
Town Hall Meeting
Minneapolis, Minnesota

Frank Bernard Cerra
University of Minnesota

Chris Foley
HealthEast

Roger Chizek
Medtronic

James Woodburn
Blue Cross Blue Shield of MN

Patricia Culliton
Alternative Medicine Clinic

Lynn M. Lammer
Homeopathic Consultants, Inc

Sharon Norling
Mind Body Spirit Clinic, Fairview Health Systems

Julie Schmidt
Woodwinds Health Campus

Timothy P. Culbert
Children's Hospitals and Clinics

Carolyn Joyce Torkelson
Bush Fellowship Program of Study

Kathy Ann Schurdevin
President, MN Natural Health Legal Reform Project

Matthew Yavner Wood
American Herbalists Guild

Jodi A Chaffin
MN Pharmacists Association and HealthPartners

Richard Leon Kingston
UoMN/PROSAR Intl Poison Center

John Mastel
Natural Foods Store

R. William Soller
Consumer Healthcaree Products Association

Margery A. Wells
American Association of Oriental Medicine

Val Ohanian
Northwestern Academy of Homeopathy

Jackson Petersburg
Director: Center Point

Barbara York
Minnesota Touch Movement Network

Rose Haywood
MN College of Acupuncture and Oriental Medicine of Northwestern Health Sciences University

Michael Green
Personal

Mary Jo Kreitzer
University of Minnesota

Bill David Manahan
Center for Spirituality and Healing

Erin Colleen O'Fallon
University of Minnesota Medical School

Patricia Cole
Director of Family Practice Residency: Hennepin County Medical Center

Mary Buntrock Johnson
St. Olaf College

Janet Dahlem
Wholistic Nurses Association, University of St. Catherine's

Robert Patterson
University of Minnesota

Janice E. Post-White
University of Minnesota

Christopher James Hafner
Cloud River

Mary Ellen Kinney
United Hospital

Milton Seifert
Eagle Medical

Frank Dennis Wiewel
People Against Cancer

Okokon Udo
Center for Cross-Cultural Health

Michele Denize Strachan
Powderhorn-Phillips CulturalWellness Center

Thupten Dadak
Tibetan American Foundation of Minnesota

Chunyi Lin
Founder: Spring Forest QiGong, Inc.

Jose Reyes
Itzamatul Itolixtli Danzantes

Sabina Pello
American Association of Immigrants from the former USSR (IL Branch)

Tom R Hiendlmayr
Minnesota Department of Health

Michael Myers
University of South Dakota

Michael Morris Kleiner
University of Minnesota

Rob Leach
Executive Director: Board of Medical Practice

Marillyn Beyer
Natural Health Coalition

Rebecca Frost
International Somatic Movement Education and Therapy Association

Diane Miller
National Health Freedom Coaltion

Lynda Boudreau
A Representative of the Minnesota House of Representatives

Ms. Brekken
Minnesota Board of Nursing

Stephen T. Bolles
NW Health Sciences University

Helen Catherine Healy
Minnesota Association of Naturopathic Physicians

Jerri Johnson
MN Natural Health Coaltion

Susan Marie Hageness
Children's Hospitals and Clinics

Pamela Lou Ahrens
Children's Hospitals and Clinics

Bob Michael Barron
Wellness Educators

Kate S. Birch
Minnesota Homeoapthic Assosiation

Ann Catherine Richtman
Northland Natural Health Resources, Inc.

Tenby Owens
St. Luke's Center for Holistic HealthCare

Howard Fidler
American Chiropractic Association

John E. Toft

Functional Medicine Chiropractic Center

Marilynn Rose Anderson
The Feldenkrais Guild of North America

Chu Yongyuan Wu
Hmong Shaman Research Project

Jeffrey Dusek
Mind/Body Medical Institute

Richard Rainbow Pavek
The SHEN Therapy Institute

Larry Paul Caldwell
Acupunture Association of Minnesota

Zhaoping Li
MN College of Acupuncture and Oriental Medicine
Northwestern Health Sciences University

Changzhen Gong
American Academy of Acupuncture

Jennifer Blair
Acupuncture Association of MN

Ike Rodman
College of Acupuncture and Oriental Medicine
Northwestern Health Sciences University

Gregory Vernon Schmidt
MN Natural Health Legal Reform Project

Leo Bernard Cashman
MN Natural Health Legal Reform Project

Amrit Devgun
Santulan Health Center

Gayle Bowler
Minnesota Natural Health Coalition

Jeanne Hollingsworth
Minnesota Natural Health Coalition

Nancy Gay Hone
Minnesota Natural Health Coalition

March 26, 2001
Information Dissemination and Wellness

Irene Liu
National Institute of Health

Sheldon Kotzin
National Library of Medicine

Dale Ogar
University of California

Burton Goldberg
Alternative Medicine.com
Peter Chowka
Natural Health Line

Andrew Weil
Ask Dr. Weil

Craig Stoltz
Washington Post

Sara Altshul
Prevention Magazine

Christine Gorman
Time Magazine

Susan Schiller
CBS Evening News

Joe Neel
National Public Radio

Elmer Huerta
Prevencion

Harrison Rainie
Pew Internet and American Life Project

Susan Detwiler
The Detwiler Group

V.Srini Srinivasan
U.S. Pharmacopeia

Lucinda Maine
American Pharmaceutical Association

David Schardt
Center for Science in the Public Interest

Christopher Hendel
Consumer Reports

Michelle Rusk
Federal Trade Commision

Christine Lewis
U.S. Food and Drug Administration

Sarah Taylor
Covington & Burling

William Soller
Consumer Healthcare ProductsAssociation

Mark Land
Boiron Homeopathic Products

John Astin
University of Maryland

Adrian Sandler
American Academy of Pediatrics

Marc Micozzi
College of Physicians, Philadelphia

David Larson
National Institute of Healthcare Rearch

Walter Willett
Harvard School Public Health

Kate Gordon
American Dietetic Association

Michio Kushi
Kushi Institute

Jeffrey Bland
Metagenics

Mark Hyman
Canyon Ranch

Frances Brisbane
SUNY at Stony Brook School of Social Welfare

Cathy Moxley
Marriott International, Inc.

Karen Prestwood
University of Connecticut Health Center

Christina Puchhalski
George Washington University School
of Medicine

Michael Zeng
International Institute of Chinese Medicine

David Edgar Molony
American Association of Oriental Medicine

Marcellus Andre Walker
africanamericanhealth.com

Diana Chambers
Friends of Health

Robert Miller
First Church of Christ, Scientist

Kathleen Mary Quain
Foundation for Health and the Environment

Donald Epstein
Association for Network Care

Paula Kim
Pancreatic Cancer Action Network

Jennifer Roe
American Association of Naturopathic Physicians

Scott Lamp
American Message Therapy Association

George Krutz
Feldenkrais Guild of North America

John Philip Adams
Self

Bruce Nordstrom
American Chiropractic Association

John D. Melnychuk
California Health Freedom Coalition

May 14-16 2001
Reimbursement

Michael O'Grady
Project Hope, Center for Health Affairs

John Whyte
Health Care Financing Administration

Abby Block
Office of Personnel Management

Joy Johnson Wilson
National Conference of State Legislators

Merilyn Francis
American Association of Health Plans

Alan Korn
Blue Cross and Blue Shield Association

Tom Sawyer
William M. Mercer, Incorporated

Kathleen King
Washington Business Group on Health

Judith MacPherson
CACI International Inc.

Derrick Gallion
Blue Cross Blue and Shield of South Carolina

John Kelly
Aetna/U.S. Healthcare

John Weeks
Integration Strategies for Natural Health Care

Nathan Stinson
Office of Minority Health
Dorianne Miller
The Robert Wood Johnson
Foundation

Daniel Hawkins
National Association of Community Health Centers, Inc., Suite 122

Melinna Giannini
Alternative Link, Inc.

Linda Bedell-Logan
Solutions in Integrative Medicine

Wayne Sickles

Max Heirich
University of Michigan

Coordination of Research

David Eisenberg
Harvard Medical School and Beth Israel Deaconess Medical Center

M. Bridget Duffey
Medtronic USA, Inc. and Medtronic Foundation

Dorianne Miller
The Robert Wood Johnson Foundation

Susan Braun

Susan G. Komen Breast Cancer Foundation

Ronald Chez
Samueli Institute for Information Biology

Donald A. Lindberg
National Library of Medicine, NIH

Douglas B. Kamerow
Agency for Healthcare Policy and Research

Brian Berman
University of Maryland School of Medicine

William M. London
The National Council Against Health Fraud,Inc.

Simeon Margolis
Johns Hopkins School of Medicine

Arthur P. Grollman
State University of New York at Stony Brook

John A. Chabot
New York Presbyterian Hospital

Marcia Angell
Harvard Medical School

Jennifer Jacobs
University of Washington

B. Alex White
Kaiser Permanente Center for Health Research

Bruce Rabin
University of Pittsburgh Medical Center

Nancy Pearson
National Center for Complementary and Alternative Medicine

Neal West
National Center for Complementary and Alternative Medicine

Robert H. Blanks
University of California, Irvine

Russell Phillips
Harvard Medical School

Richard Hammerschlag
Oregon College of Oriental Medicine

Edward W. Campion
New England Journal of Medicine

Jackie C. Wootton
Journal of Alternative and Complementary Medicine

Phil B. Fontanarosa
American Medical Association

David Riley
Alternative Therapies in Health and Medicine
University of New Mexico Medical School

Christine Laine
Annals of Internal Medicine

Arnold Relman
Harvard Medical School

James Sensenig
American Association of Naturopathic Physicians

Candace Campbell
American Preventive Medical Association

Diane Davis Cole
University of Virginia Cancer Center

Katherine Jane Gorton
American Dietetic Association

Audrey DiMaria
Secretary of Art Therapy Credential Board

Judy Simpson
American Music Therapy Association

Richard Goldberg
Private practice

Nancy Kristine Haller
Feldenkrais Guild of North America

Christina Herlihy
National Certification Commission on Acupuncture and Oriental Medicine

Su Liang Ku
Florida Institute of Traditional ChineseMedicine

Sharon Stevenson
National Center for Homeopathy

Barbara Moquin
National Naval Medical Center

Matt Ward Russell
National Integrative Medicine Council

Carolyn Jones Sabatini
Pharmavite Corporation

Christina Walker
The Shenk Human Energetic Institute

July 3, 2001
Draft Report

Alan Dumoff
Private Practice

Scott Bass
Sidley Austin Brown and Wood

Dannion Brinkley
Compassion in Action

Boyd J. Landry
The Coalition for Natural Health

Steven Waldstein
North American Society of Homeopaths

Deborah Maclean Glancy

Pivate Citizen

Susan Delaney
American Association of Naturopathic Physicians

Anita Mishra-Szymanski
AOAC International

October 4-6, 2001
Progress on Final Report

Dannion Brinkley
Compassion in Action

Boyd Landry
The Coalition for Natural Health

Sung J. Liao
American College of Acupuncture

Harry F. Swope
Council for Homepathic Certification

Leonard Wisneski
Principles Group-Summit 2001

December 6-7, 2001
Draft Final Report

Boyd Landry
The Coalition for Natural Health

Candace Campbell
American Association for Health Freedom

Fabrizio Mancini
Parker College of Chiropractic

Jerry L. Hardee
Sherman College of Straight Chiropractic

Matthew Irwin

Group for Scientific Reappraisal of HIV/AIDS

Ginette Hemley
World Wildlfe Fund

Ian Anthony Cyrus
American Association of Oriental Medicine

William David Rutenberg
American Academy of Medical Acupuncture

Remy R. Coeytaux
Medical Acupuncture Research Foundation
John P. Borneman
National Center for Homeopathy

February 21-22, 2002
Review Final Report

Joyce Frye
National Center for Homepathy

Madan Khare
American Complimentary and Alternative Veterinary Medicine Association

Harry Steven Kriegal
Kriegal Marketing Group

Boyd Landry
The Coalition for Natural Health

Hiroshi Nakazawa
American Board of medical Acupuncture

Riva Touger-Decker
University of Medicine and Dentistry of New Jersey

Cassandra Meroe Wimbs
Complementary/Alternative Medicine Association

Appendix E – Organizations Providing Information on Education and Training of Health Care Professionals

Academy of General Dentistry
Academy of Guided Imagery
Accreditation Commission for Acupuncture and Oriental Medicine
Accreditation Council for Continuing Medical Education
Accreditation Council for Graduate Medical Education
Agency for Healthcare Research and Quality
American Academy of Craniofacial Pain
American Academy of Family Physicians
American Academy of Pain Management
American Academy of Pediatrics
American Academy of Physician Assistants
American Association of Colleges of Nursing
American Association of Colleges of Osteopathic Medicine
American Association of Colleges of Pharmacy
American Association of Diabetes Educators
American Association of Medical Acupuncture
American Association of Naturopathic Physicians
American Association of Oriental Medicine
American Association of Pastoral Counselors
American Board of Medical Acupuncture
American Board of Medical Specialties
American Chiropractic Association
American College of Clinical Pharmacy
American College of Health Care Administration
American College of Nurse Midwives
American College of Obstetricians and Gynecologists
American College of Osteopathic Obstetricians and Gynecologists
American College of Physicians/American Society of Internal Medicine
American Dietetics Association
American Herbalists Guild
American Holistic Dental Association
American Holistic Health Association
American Holistic Medical Association
American Holistic Nurses Association
American Institute of Homeopathy
American Massage Therapy Association
American Medical Association
American Medical Students Association
American Nurses Association
American Occupational Therapy Association
American Organization of Bodywork Therapies of Asia
American Osteopathic Association

American Pharmaceutical Association
American Physical Therapy Association
American Polarity Therapy Association
American Psychological Association
American Public Health Association
American Qigong Association
American Society for the Alexander Technique
American Society of Health-System Pharmacists
Association of American Indian Physicians
Association of American Medical Colleges
Association of Applied Psychophysiology and Biofeedback
Association of Physician Assistant Programs
Association of Professional Chaplains
Association of Professors of Gynecology and Obstetrics
Association of Schools of Public Health
Barbara Brennan School of Healing
Bureau of Health Professionals, HRSA
Complementary Medicine Program/University of Maryland
Council of Colleges of Acupuncture and Oriental Medicine
Council of Osteopathic Student Government Presidents
Duke Center for Integrative Medicine
Federation of State Medical Boards of the United States, Inc
Federation of Straight Chiropractors and Organizations
Feldenkrais Guild of North America
Hellerwork International
Hospice and Palliative Nurses Association
Institute of Medicine, National Academy of Sciences
International Chiropractic Association
Joint Commission on Accreditation of Healthcare Organizations
Josiah Macy Jr. Foundation
Kawaikapuokalani K. Hewitt
National Association for Holistic Aromatherapy
National Association of Social Workers
National Black Nurses Association
National Board of Medical Examiners
National Board of Osteopathic Medical Examiners
National Center for Homeopathy
National Certification Commission for Acupuncture and Oriental Medicine
National Commission on Certification of Physician Assistants
National Committee for Quality Assurance
National Dental Assistants Association
National Health Service Corps (HRSA, BPHC)
National Qigong Association
Nurse Healers-Professional Associates International
Office of Dine [Navajo] Culture, Language, and Community Services
Papa Ola Lokahi

Pew Charitable Trusts
Program in Integrative Medicine/University of Arizona
Reflexology Association of America
Society for Public Health Education
Student Osteopathic Medical Association
The Continuum Center for Health and Healing/Beth Israel Medical Center/
The Oncology Nursing Society
The Rolf Institute of Structural Integration
Upledger Institute
World Chiropractic Alliance
Yoga Alliance

Appendix F – White House Commission on Complementary and Alternative Medicine Policy Workgroup Members

COMMISSION WORKGROUPS AND MEMBERS

Workgroup: Coordination of Research
Wayne B. Jonas, M.D., Co-Facilitator
Dean Ornish, M.D., Co-Facilitator
George M. Bernier, Jr., M.D.
Effie Poy Yew Chow, Ph.D., R.N.
William R. Fair, M.D.
Veronica Gutierrez, D.C.
Tieraona Low Dog, M.D., A.H.G.
Geraldine B. Pollen, M.A., Staff Liaison

Workgroup: Education and Training of Health Care Practitioners
George M. Bernier, Jr., M.D., Co-Facilitator
Joseph E. Pizzorno, Jr., N.D., Co-Facilitator
David Bresler, Ph.D., L.Ac., OME
Joseph J. Fins, M.D., F.A.C.P.
Buford L. Rolin
Donald W. Warren, D.D.S.
Joseph M. Kaczmarczyk, D.O., M..P.H., Staff Liaison

Workgroup: CAM Information Development and Dissemination
David Bresler, Ph.D., L.Ac., OME, Co-Facilitator
Tieraona Low Dog, M.D., A.H.G. Co-Facilitator
Thomas Chappell
George T. DeVries, III
Julia R. Scott
Xiaoming Tian, M.D., L.Ac.
Corinne Axelrod, M.P.H., L.Ac., Dipl.Ac, Staff Liaison

Workgroup: Access and Delivery
Joseph J. Fins, M.D., F.A.C.P., Co-Facilitator
Linnea Signe Larson, LCSW, LMFT, Co-Facilitator
George M. Bernier, Jr., M.D.
George T. DeVries, III
Conchita M. Paz, M.D.
Joseph E. Pizzorno, Jr., N.D.

Buford L. Rolin
Julia R. Scott
Michele M. Chang, C.M.T., M.P.H., Staff Liaison

Workgroup: Coverage and Reimbursement
George T. DeVries, III, Facilitator
Joseph J. Fins, M.D., F.A.C.P.
Linnea Signe Larson, LCSW, LMFT
Dean Ornish, M.D.
Conchita M. Paz, M.D.
Xiaoming Tian, M.D., L.Ac.
Maureen Miller, RN, M.P.H. , Staff Liaison

Workgroup: CAM in Wellness and Health Promotion
Dean Ornish, M.D., Facilitator
Effie Poy Yew Chow, Ph.D., R.N.
William R. Fair, M.D.
Wayne B. Jonas, M.D.
Charlotte R. Kerr, R.S.M.
Joseph E. Pizzorno, Jr., N.D.
Julia R. Scott
Corinne Axelrod, M.P.H., L.Ac., Dipl.Ac, Staff Liaison

Workgroup: Coordinating Federal CAM Efforts
Donald W. Warren, D.D.S., Facilitator
Effie Poy Yew Chow, Ph.D., R.N.
Veronica Gutierrez, D.C.
Wayne B. Jonas, M.D.
Joseph M. Kaczmarczyk, D.O., M.P.H., Staff Liaison

Workgroup: Guiding Principles, Definition and Overview of CAM in the United States
Thomas Chappell, Co-Facilitator
Wayne B. Jonas, M.D., Co-Facilitator
Effie Poy Yew Chow, Ph.D., R.N.
Veronica Gutierrez, D.C.
Wayne B. Jonas, M.D.
Charlotte R. Kerr, R.S.M.
Conchita M. Paz, M.D.
Joseph E. Pizzorno, Jr., N.D.
James P. Swyers, M.A., Staff Liaison

Appendix G – Statement from Commissioners

LETTER FROM JOSEPH FINS, M.D. AND TIERAONA LOW DOG, M.D.

March 10, 2002

The Honorable Tommy G. Thompson
Secretary, Health and Human Services
Washington, DC 20201

Dear Mr. Secretary:

We would like to thank the American public for allowing us to serve on the White House Commission on Complementary and Alternative Medicine Policy. The Commission struggled with many complex issues and the final report reflects the enormous effort and hard work of the Commissioners and staff. We support many of the Commission's recommendations and appreciate the efforts to accommodate a diversity of views and achieve a consensus. Nonetheless, we feel it necessary to write this additional statement to provide clarification as these recommendations are considered for implementation. These are views we have stated consistently throughout the Commission's twenty months of deliberations.

The Executive Order 13147 directed that The White House Commission on Complementary and Alternative Medicine (CAM) Policy "shall provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine."

While many of the Commission's recommendations will help maximize the benefits of proven safe and effective approaches, practices and products, they do not appropriately acknowledge the limitations of unproven and unvalidated "CAM" interventions or adequately address the minimization of risk.

In this statement we will seek to be specific in our critique about these risk/benefit questions. In this effort we hope to give voice to the healthy skepticism that exists in many sectors of American public life with regard to complementary and alternative medicine, a perspective that may not have been adequately represented in the constitution of the Commission or in the testimony that we heard.

1. Acknowledging the Limitations of Unproven CAM Interventions While the

Report acknowledges that much of what is considered "CAM" has not been

shown to be safe and effective, a presumption exists that complementary and alternative medicine will be found to be beneficial. This advocacy tone persists in the Report despite great efforts to achieve editorial balance. Despite qualifying statements added to the Introduction of the Report -- which we endorse -- the body of the document continues to give voice to a perspective that suggests that most "CAM" interventions will be proven to be safe and effective through scientific research. Last minute revisions to the Introduction do not mitigate more global statements that permeate the Report. There continues to be language suggesting that "CAM" will lead us into a new paradigm of health care that will provide answers for those with chronic disease, as well as our aging and under-served populations. We will discuss these concerns in the context of research priorities, access and the underserved, the provision of primary care services and medical education.

1.1 Research Priorities

We strongly endorse the need for more research; however, we recognize that research dollars are finite. The Commission's lack of a prioritization strategy for research initiatives, given the many areas that "CAM" encompasses, makes a general endorsement of research of limited value. Promising areas of research should be investigated because they potentially have something to offer to the health of the American people or because they advance our scientific understanding of illness and healing. Asking for more research money to investigate an approach, practice or product simply because it is "CAM" is an ideological, not evidence-based approach to science. Recommendations for research on "frontier areas of science" without a strategy for building this research on scientific foundations may result in spending precious health care research dollars on areas that are unlikely to yield any beneficial data such as "iridology", "psychic healing" et. al. While dogmatic disbelief of everything that is not currently explainable is foolish, and indeed unscientific, it seems equally foolish to ask the taxpayer to bear the enormous expense of sorting out those areas that are plausible from those that are improbable.

With sound research priorities in mind, we feel it is important to point out that many of the recommendations made in the research and access sections of the Report are already being undertaken by NCCAM, a Center within the National Institutes of Health. NCCAM has established fifteen specialty research centers that cover "CAM" approaches for many areas of major public health need. These centers are focused on studying the underlying mechanisms of "CAM" modalities, cancer treatments, "CAM" for end-of-life care, botanicals, the use of "CAM" therapies to reduce health disparities and integrative medicine.[i] Given the concentration of expertise and existing infrastructure at NCCAM, recommendations for a wide sweeping "CAM" research agenda to be implemented across a large number of federal agencies does not appear to be a cost-effective or logical way to make progress.

1.2 Access and the Underserved

When the Commission sought to be inclusive by expanding access to "CAM" products, providers and modalities to underserved populations through demonstration projects or other programs it did not adequately appreciate that these recommendations were being made for populations which have limited or no access to conventional medical care. In this context, the provision of "CAM" becomes neither a complementary nor integrative intervention, but rather a less validated alternative to conventional care. The Commission heard testimony that many underserved populations utilize folkloric or "CAM" interventions because they cannot afford access to conventional care.[ii] It is worth considering whether these individuals would prefer a drug benefit over access to unproven supplements or if they would seek out "CAM" providers if they had the resources to receive care from primary care practitioners. Given the state of the science, most "CAM" interventions can only be said to add to and not replace conventional interventions. A consideration of "CAM" entitlements or an expansion of insurance benefit packages is one thing in the context of preexisting access to conventional medical care. It is ethically quite another in the absence of such coverage.

While there is room for diversity in the health care system, we should not be a party to creating a separate but unequal care system. It is our strong belief that we should provide basic health care to every American before expanding benefits to include treatments or approaches that have not been shown through rigorous research to treat or prevent disease. We must never foster a second-tier of medical care for those who are economically disadvantaged.

1.3 Primary Care Practitioners

The Commission debated at great length whether or not we would recommend that "CAM" practitioners be included in loan-forgiveness and scholarship programs, especially as it relates to their possible inclusion in the National Health Service Corps. The Report carefully delineates the eligibility requirements for inclusion in this program and why Title VII of the Public Health Services Act does not recognize "CAM" practitioners as primary care providers eligible for inclusion in this program. While we endorse demonstration projects that seek to identify what, if any, value "CAM" providers add to established primary care teams, we want to go on record noting that we do not believe that CAM providers are fungible with the primary care providers enumerated in Title VII. This concern does not mean that some CAM practitioners do not have the potential to add to the public health or meaningfully affect the lives of patients. It is simply that they are not positioned for equivalency with conventional primary care providers. Efforts to equate their degree of training, or the scientific basis of their practice, with that of the designated primary care specialties puts the public at risk of receiving unvalidated and non-evidence based primary care.

1.4 Education and Training of Conventional Practitioners

Conventionally trained health care practitioners must be able to dialogue with their patients about a wide variety of topics including sexuality, domestic violence, substance abuse, spirituality, death and dying, pain, emotional health and non-conventional therapies. We strongly support the need for health care providers to be able to critically assess the evidence for approaches, practices and products that their patients may be using, however, most medical schools (approximately 72%) already teach courses on what is considered "CAM". If the critique is that conventional medical curricula are lacking in areas such as nutrition, self-care instruction or preventive medicine, the appropriate response is to improve the teaching of this subject matter. Furthermore, as medical educators we believe that recommendations for curricular reform will be better received if they are not cast in language that implies a mandate. Whatever is included in the medical curriculum must remain true to scientific integrity, avoid ideological indoctrination and guard against teaching unproven treatments to the next generation of health care providers.

2. The Minimization of Risk

To fully meet the spirit of the Executive Order, the Report would need to do more than identify the benefits to be maximized. It would also need to avoid the assumption of avoidable risk, especially when the benefits are uncertain and the risks are clear. We will now comment on how the Report's lack of definitional clarity limits appropriate risk management, address public preferences regarding regulation and consider the special concerns of vulnerable populations.

2.1 Lack of Definitional Clarity

Addressing the risks or benefits associated with "CAM" interventions is difficult because the recommendations suffer from a lack of specificity. Generic recommendations neither serve the public interest nor protect the public health because they fail to distinguish between approaches, practices and products for which there is some scientific evidence and those that either stretch the realm of logic or are demonstrably unsafe. The Report's inability to discriminate amongst "CAM" practices, products and practitioners leaves its recommendations open to interpretation. This limits their applicability as public policy.

The Report's lack of definitional clarity undermines the legitimacy of safe and effective non-conventional approaches by failing to distinguish them from treatments that are improbable or fraudulent. For instance, there is strong evidence that relaxation therapies help reduce chronic pain in patients with a variety of medical conditions.[iii] Glucosamine sulfate has been found superior to placebo for the treatment of osteoarthritis.[iv] However, chelation therapy has not been shown to be beneficial for the treatment of ischemic heart disease,[v] though is still promoted as a treatment. Alternative diets, coffee enemas, ozone therapy,

and shark cartilage offer little for cancer patients, however, acupuncture, aromatherapy, and meditation may be useful for nausea/vomiting, mild relaxation, and pain/anxiety, respectively.[vi]

The Report's inclusion of all "CAM" practices, without appropriate nuance, fails to adequately appreciate the heterogeneity of these practices. This omission undermines those areas within CAM that have already demonstrated safety and efficacy and may be ready for integration into the healthcare system.

Wellness and Health Promotion

"Promoting wellness", "health promotion" and "prevention practices" are phrases that recur throughout the Report and are cited as being the focus of many "CAM" approaches. It is unclear what these terms actually mean, as no clear examples are provided in the document. If it means that one can enhance his or her sense of well being through a healthy diet, regular exercise and other lifestyle modifications, there is little debate. There is a large body of evidence for the beneficial role of nutrition, exercise and stress management in the scientific literature. The Commissioners debated the inclusion of these lifestyle approaches under "CAM" and the final Report acknowledges that these approaches are found in both "CAM" and conventional medicine, but claims that there is a "greater emphasis" placed upon them in "CAM." One has only to visit the local book store to find the numerous "fad" diet books that fall under "CAM" nutrition; high fat - high protein diets, eat according to your blood type diets and fruitarian diets, to name a few. There is no single "CAM" nutritional approach. In addition, if one were to accept that there actually is a greater "emphasis" on sound, scientific nutrition and exercise amongst "CAM" practitioners, there is no documented evidence that they are any more successful than conventional practitioners in motivating their patients to make lifestyle changes.

The Report fails to point out that "CAM" "health promotion" and "prevention practices" also include preventing disease by "balancing qi", "eliminating parasites and toxins," "cleansing the liver" and/or by "cleansing the blood" via a multitude of supplements and questionable practices. Our uncritical acceptance of "CAM" wellness and health promotion can be interpreted as an endorsement of these claims. It is absolutely unclear what role, if any, "CAM" practices play in preventing disease and to what extent patients are burdened with useless treatments and products in their pursuit of "wellness".

The Contributions of Public Health and Medicine to Wellness

Registered dietitians, clinical nutritionists, conventionally trained scientists, physicians and public health professionals have done the bulk of the research in the area of nutrition. It is important not to overlook the contributions of the pioneering Framingham study that documented the epidemiology of obesity, smoking and heart disease, which led to heart healthy diets, smoking cessation,

and a greater emphasis on exercise. Through rigorous science we now have a much better understanding of the role foods, nutrients and exercise play in health and disease. The notion that only "CAM" supports healthy nutrition is neither accurate nor fair.

Furthermore, the suggestion that conventional medicine is primarily focused on disease, while "CAM" is primarily focused on health promotion and prevention was a point of contention on the Commission. This perspective fails to adequately acknowledge public health initiatives that have been an integral part of medicine for decades, efforts that have dramatically improved the health of the Nation.

Cooptation of Spirituality

The most troubling of these conflations is the inclusion of spirituality under the rubric of "CAM." There is no question that many Americans find comfort in prayer, religion and/or spiritual practices and that more attention should be paid to the role of spirituality in health care. Nonetheless, it is disconcerting that the Report often categorizes spirituality as a "CAM" modality. The Report cites papers that assert that when a patient is diagnosed with cancer and turns to prayer for comfort - he or she is considered to be using "CAM." When spirituality is so designated, "CAM" prevalence grows dramatically. The truth is that spirituality transcends any arbitrary designation of conventional and non-conventional medicine and cannot be claimed by any particular group. Furthermore, the conflation of spirituality and/or religion with CAM could lead to an abridgement of the free exercise of religion by subjugating its practice to a regulated modality.

In sum, generic pronouncements about "CAM" neither serve the public interest nor protect the public health. It is essential to separate the effective from the ineffective, the safe from the unsafe and to contextualize these practices against conventional modalities before any of them can be recommended for incorporation into the Nation's healthcare system. While recognizing that research will eventually answer many of these questions, the Commission's inability to distinguish and critically evaluate broad categories of practitioners and modalities in a meaningful way, limits the applicability of many worthy recommendations.

2.2 Public Preferences and the Regulation of Supplements

The access section of the Report is predicated upon the premise that, "The public has expressed interest in maintaining easy access to CAM practitioners." Notwithstanding the selection bias of those who presented public testimony to the Commission, the data does not support that this is the view of a majority of Americans. In fact, if we consider the regulation of dietary supplements as a well-studied case in point, the literature indicates that the use of dietary supplements

has decreased and that the majority of Americans support increased regulation of supplements, including requiring the Food and Drug Administration to review the safety of new dietary supplements prior to their sale.[vii] This support for increased regulation and safer products is likely a consequence of publicity surrounding St. John's Wort and drug-interactions, the potential liver toxicity of Kava,[viii] the presence of the anti-coagulant warfarin in PC-SPES, an herbal product used for prostate cancer[ix] and the presence of heavy metals in a number of Asian herbal preparations.[x] We strongly support a number of recommendations made in the Report regarding the quality, safety and advertising of dietary supplements and the full implementation of the Dietary Supplement Health and Education Act (DSHEA). However, it remains to be seen if the full implementation of DSHEA will provide the public with the right combination of access and safety that national surveys indicate it desires. For this reason, we strongly endorse the recommendation that Congress re-evaluate DSHEA following full implementation.

2.3 Vulnerable Populations

Patients will often resort to "CAM" practices, modalities and practitioners upon the diagnosis of a debilitating, chronic or terminal condition. Recent Senate hearings have documented the special vulnerability of the elderly on fixed-incomes to these phenomena.[xi] The Report's contention that medicine lacks adequate treatment for pain and symptom management could contribute to the mistaken notion that conventional medicine has nothing to offer patients who chronically ill or in the process of dying. It is important that the public be aware of the fine work done in hospices around the country and the emergence of palliative care as an important evidence-based clinical discipline able to ameliorate patient and family distress.

3. Closing Statement

We hope that the American public is well served by the Commission's work. The Commission made enormous progress during its deliberations and we support many of its recommendations. We believe that some of aspects of "CAM," when appropriately defined, have the potential to benefit the health of the American public. However, the Commission's inability to appropriately acknowledge the limitations of unproven and unvalidated "CAM" interventions or adequately address the minimization of risk necessitates this statement.
We remain optimistic that the work of the Commission and the many people who presented testimony before it will make a contribution to the public's understanding of this complex issue. We hope that the diversity of views on this topic does not engender divisiveness. Where medical care is concerned, the common good calls for ideology and advocacy to yield to scientifically sound evidence of safety and efficacy. We are confident that this can be accomplished

with respect and compassion for all Americans.

We appreciate the honor of serving with our fellow Commissioners and thank you for your consideration.
Respectfully Submitted,

_____	_____
Tieraona Low Dog, M.D.	Joseph J. Fins, M.D., F.A.C.P.

---

i. http://nccam.nih.gov/
ii. Huerta E. Testimony before the WHCCAMP. March 26, 2001
iii. Integration of behavioral and relaxation approaches into the treatment of chronic pain and insomnia. NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia. JAMA 1996 Jul 24-31;276(4):313-8.
iv. Towheed TE, Anastassiades TP, Shea B, Houpt J, Welch V, Hochberg MC Glucosamine therapy for treating osteoarthritis (Cochrane review): In: Cochrane Library. Issue 2. In: Oxford: Update Software, 2001.
v. Knudtson ML, Wyse DG, Galbraith PD, et al. The Program to Assess Alternative Treatment Strategies to Achieve Cardiac Health (PATCH) Investigators. Chelation therapy for ischemic heart disease: a randomized controlled trial. JAMA 2002 Jan 23-30;287(4):481-6
vi. Ernst E. A primer of complementary and alternative medicine commonly used by cancer patients. MJA 2001; 174: 88-92
vii. Blendon RJ, DesRoches CM, Benson JM, Brodie M, Altman DE. Americans' views on the use and regulation of dietary supplements. Arch Intern Med 2001 Mar 26; 161(6):805-10.
viii. http://www.fda.gov/medwatch/SAFETY/2001/kava.htm
ix. http://www.fda.gov/medwatch/SAFETY/2002/safety02.htm#spes
x. Ernst E. Toxic heavy metals and undeclared drugs in Asian herbal medicines. Trends Pharmacol Sci 2002 Mar 1;23(3):136-9
xi. Baratz RS. Testimony before the Senate Committee on Aging. September 10, 2001. http://aging.senate.gov/hr73rb.htm