Kaczmarczyk, Joseph (NCCAM)

From: Clay, Beth [Beth.Clay@mail.house.gov]
Sent: Thursday, December 13, 2001 2:48 PM
To: Beth Crane
Subject: HR 3475

H.R.3475
Sponsor: Rep Burton, Dan(introduced 12/12/2001)
Latest Major Action: 12/12/2001 Referred to House committee
Title: To amend the Internal Revenue Code of 1986 to provide that amounts paid for foods for special **dietary** use, **dietary supplements**, or medical foods shall be treated as medical expenses.

Jump to: Titles, Status, Committees, Related Bill Details, Amendments, Cosponsors, Summary

TITLE(S): (*italics indicate a title for a portion of a bill*)

- OFFICIAL TITLE AS INTRODUCED:
  To amend the Internal Revenue Code of 1986 to provide that amounts paid for foods for special **dietary** use, **dietary supplements**, or medical foods shall be treated as medical expenses.

STATUS: *(color indicates Senate actions)*
12/12/2001:

Referred to the House Committee on Ways and Means.

COMMITTEE(S):
Committee/Subcommittee: **Activity:**
House Ways and Means </cgi-bin/bdquery/R?d107:FLD005:@3(House+Ways+and+Means)|/bss/d107query.html|> Referral

RELATED BILL DETAILS:
NONE

AMENDMENT(S):
NONE

COSPONSORS(5), ALPHABETICAL [followed by Cosponsors withdrawn]: (Sort: by date </cgi-bin/bdquery/D?d107:8:./temp/~bdoKbY:@@@N|/bss/d107query.html|>)

Rep Cannon, Chris - 12/12/2001 Rep Horn, Stephen - 12/12/2001
Rep Istook, Ernest J., Jr. - 12/12/2001 Rep Pallone, Frank, Jr. - 12/12/2001
Rep Paul, Ron - 12/12/2001

Revised Outline for WHCCAMP Report (2/18/02)

- Letters of Transmittal
  - From the Secretary, DHHS to the President
  - From the Secretary, DHHS to the Congress
    - From the Secretary to the President of the Senate
    - From the Secretary to the Speaker of the House
  - From the Chair, WHCCAMP to the Secretary, Department of Health and Human Services
- List Commission Members and Affiliations
- Commission Staff
- Working Groups (Planning)
- Acknowledgements
- Table of Contents
- List of Tables and Figures
- Executive Summary
- Part I: Introduction
- Part II: Overview and Brief History of CAM
- Part III: CAM in Wellness and Prevention
- Part IV: Coordination of Research
- Part V: Education and Training of Health Care Practitioners in CAM
- Part VI: CAM Information Development and Dissemination
- Part VII: Access and Delivery of CAM
- Part VIII: Coverage and Reimbursement of CAM
- Part IX: CAM Coordinating Office
- Part X: Vision for the Future

Part XI: Appendices

A. List of Commission Meetings and Topics
B. List of Commission Meeting Invited Panelists
C. List of Open Public Session Presenters
D. List of Town Hall Meetings, Questions Addressed, and Participants
E. Executive Order 13147 and Amendment
F. Appropriation Language Providing Support for the Commission's Activities
G. WHCCAMP Charter
H. List of Organizations Responding to WHCCAMP Requests for Information
I. List of Recommendations and Suggested Implementation Actions
J. List of Recommendations and Suggested Implementation Actions By Responsible Organizations (DHHS, NIH, FDA, Private Sector, etc.)
K. Glossary and Acronyms

Part XII: Index

SG21802

Reference Format:

Cite in text using superscript numbers

Number sequentially in bibliography at the end of each chapter.

Put a line space between each reference

Journal articles

One author: Fields W.C. The use of complementary and alternative medicine. *JAMA* 2001; 512(67):1-14.

Up to four authors: Fields WC, Rooney A, Marx G, Swyers JP. Complementary and alternative medicine policy in the U.S. *Science* 2001; 23(3):79-82.

Five or more authors: (Fields WC, Rooney A. Marx G, Swyers JP, et al. How integrative is complementary medicine? *N Eng J Med* 2002;361(4):91-98.

Books and Reports

Larson DB, Swyers JP, Larson S. *The Costly Consequences of Divorce*. Rockville, MD: National Institute for Healthcare Research, 1995.

U.S. Department of Education. *National Adult Literacy Survey*. Washington, D.C.: National Center for Education Statistics,1992.

Koenig HC, Cohen H (Eds). *The Handbook of Religion and Health*. New York: Oxford University Press, 2001.

Newspaper articles

Swyers JP. FDA approves protease inhibitor ritonavir for treatment of HIV. *Washington Post*. 1996, March 3, C4.

Information obtained from web sites

National Center for Complementary and Alternative Medicine. *Frequently asked questions about CAM and NCCAM. What is Complementary and Alternative Medicine?* Available at http://nccam.nih.gov/nccam/fcp/faq/index.html.

Term format

acronyms: First time an agency or entity appears in a section, spell it out, and then use acronym (see CAM below). Spell out in recommendations (i.e., do not use acronyms in recommendations and action items).

Ayurvedic medicine: NOT ayurveda (capitalize A, but not M)

CAM: Spell out complementary alternative medicine (CAM) the first time it appears in each section, and then use acronym from then on.

chiropractic: always lowercase; never referred to as chiropractic medicine

data base: always two words).

Federal Government: always capitalize

health care: always two words

institute: If referring to a specific NIH Institute (e.g., National Cancer Institute), then capitalize, otherwise lowercase.

Internet: always capitalized

Naturopathic medicine: Capitalize Naturopathic but not medicine. Not naturopathy

Native American medicine: capitalize Native American, but not medicine

Qigong: always one word and lowercase; not qi gong

state: uppercase for proper name only (e.g., State of Minnesota); otherwise lowercase

United States: spell out unless used as a modifier (e.g., "U.S. public policy")

Workgroup: lowercase, except when referring to a specific work group (e.g., Work Group H)

Traditional Chinese Medicine: capitalize all three words.

Dummy Section

Chapter 8:
CAM in Wellness and Health Promotion

In recent years, people have recognized that a healthy lifestyle may promote wellness and prevent illness and disease, which would allow 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.

The Role of Safe and Effective CAM Practices and Products in Promoting Wellness

The most recent Federal government report on the health Status of the Nation, *Healthy People 2010*,[1] is designed to achieve two overarching goals: 1) Increase quality and years of healthy life and 2) Eliminate health disparities. These goals and objectives are the blueprint for the Nation's health promotion and disease prevention activities, and influence data collection, national health policy, and program development and implementation. *Healthy People 2010* addresses clinical, behavioral, environmental, and health system issues that impact on health, and there is a strong emphasis on health education and changing the health behaviors of individuals and communities.

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 age one and 24.[2] 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* (6). 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 (7) (8).

The Role of Schools

Schools are a particularly important part of any strategy because school provides activities and services to promote students' physical, emotional, and social development and usually require some form of health education to be taught as part of a student's total education. 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 they 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 be applicable to another.

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* The World Health Organization's definition of wellness is the most widely accepted definition and is the one used in this report.

Cover

HHS should conduct feasibility studies to determine which Type of CAM ~~from~~ practitioner

HHS shall conduct feasibility studies to determine whether ~~the~~ appropriately educated + trained CAM practitioners' ~~right play in the provision of~~ Additions to primary care teams will ~~include~~ provide ~~full~~ health services related to family medicine, IM, peds, OB/GYN that are provided by physicians + other npp PA, NP, NM's

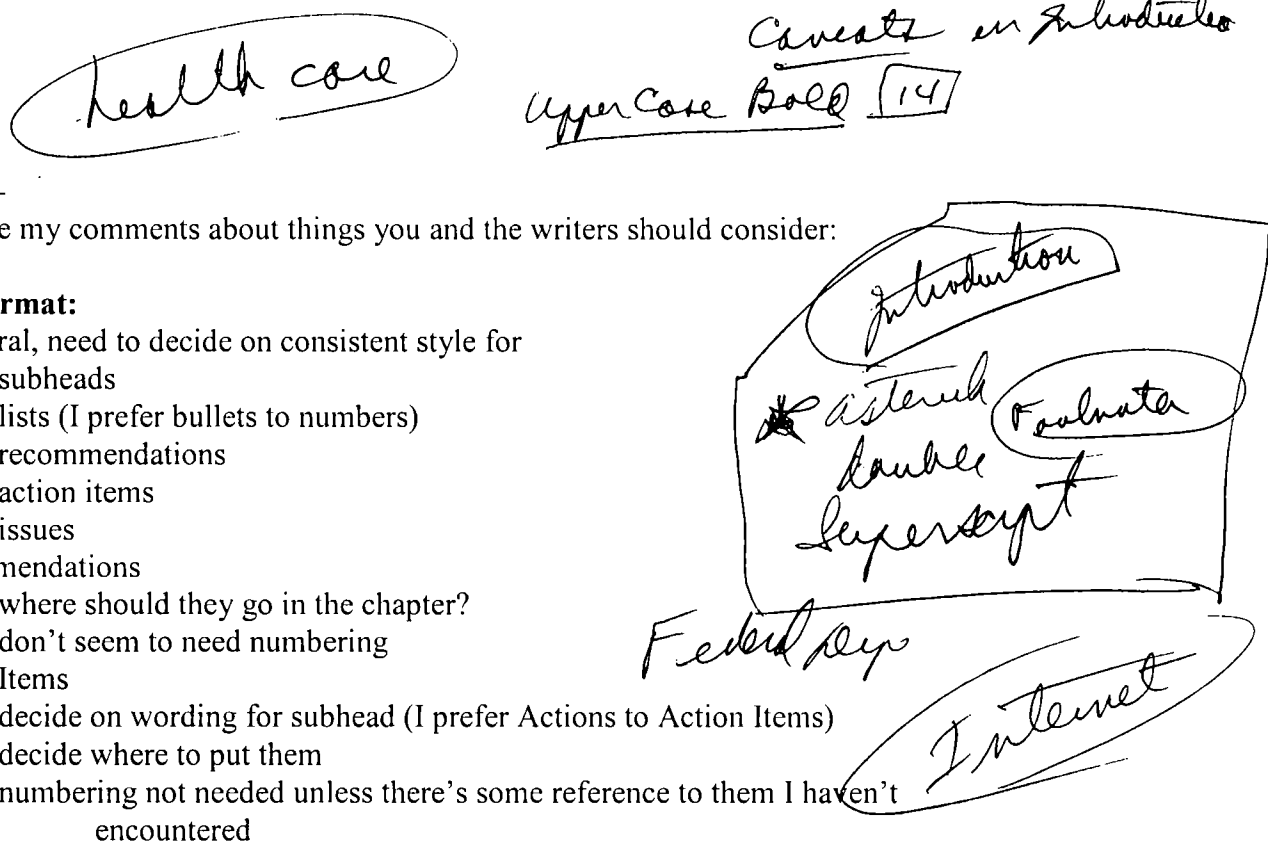
Add

HHS shall conduct feasibility study to determine whether appropriately educated + trained CAM practitioners enhance the delivery of health care provided by 1° care teams which include FP, Internists, Peds, OB/GYNs as well as PA, NP, NM's, dentists, + mental health professionals. This feasibility study ~~Studies should identify, if substantiated~~ could lead to demonstration projects to identify: 1) the type of CAM practitioner; 2) the necessary education + training for CAM practice setting and 4) the health outcomes associated with ~~their~~ the addition of these practitioners + services to comprehensive care ~~settings~~

UNHSC

① Does it exclude
② Does it include

Joe Fein
- Congress not 1° care Provider
S. 1285 — Differences
- Foot 5° - Unexpected, Uncalled for
- Chiropractic -
- Very - Poor Forgiveness
- Chiropractor Part of



Steve—
Here are my comments about things you and the writers should consider:

Text format:
In general, need to decide on consistent style for
- subheads
- lists (I prefer bullets to numbers)
- recommendations
- action items
- issues

Recommendations
- where should they go in the chapter?
- don't seem to need numbering

Action Items
- decide on wording for subhead (I prefer Actions to Action Items)
- decide where to put them
- numbering not needed unless there's some reference to them I haven't encountered

Issues
- decide whether to make them subheads or not
- if not subheads, choose consistent style
- some chapters don't have them—I think they're useful.

Don't need Introduction subhead—first few paragraphs are clearly introductory

References:
Put references (endnotes) at end of text and alphabetize. Use footnote style only for notes on text. Spell out journal titles—not all readers will be familiar with the abbreviations. Also, if an article has five or fewer authors, put their names in text with year. For reference style, I recommend the following format, which is pretty standard: authors' names, then year, article title, journal, vol, first and last pages. Don't need issue number or month if volumes are numbered consecutively, and most scientific journals are.

Definitions and usage:
Need to define the following CAM terms and use them consistently—it's particularly important to decide which ones can be used interchangeably:
- practices, approaches, therapies, interventions, treatments, services, modalities (this one really confuses me—seems to mean anything!), disciplines.

Related item: Are CAM practices and products the same as CAM services and products? CAM approaches?

Need to define and maintain consistent distinction between professional, practitioner, and provider. Start with Education and Training chapter, which implies differences. If differences have to do with credentials, need to say so and be consistent throughout. Intro says that "practitioner" applies to everyone.

Is "consumer" synonymous with "public"? I assume "patient" is used only in context of conventional medicine.

Other:

Can you lower-case some words—state, agency, center (but not Federal)? Text is inconsistent. All those capitalized nouns look antiquated, and taken in combination with the inevitable acronyms, they make an ugly page.

Try not to use CAM in heads and subheads unless necessary—overall effect is terribly repetitious. Do you want to spell it out the first time it's used in each chapter or just first time it's used in Introduction?

Avoid notion of evolution in this context—more or less highly evolved could be insulting.

menu

Dermal Hyphonas

- Sign-off Not = No agreement present language in report =

Format - will occur

Revised section - edited reordered - repurposed

Acronym (acronym by itself)

not in

- CAM in heading
- Spell out

TCM all cap
Ayurvedic medicine
Chiropractic medicine

Ken
March 2
Comments

Staff Meeting:

① Report – Palladian Partners Status

✓② Recommendations when Complete – Send Out to Work Group

ⓐ Consecutive Numbers

✓ (b) ID by Implementing Organization

Congress — Industry

Federal Agencies – General DHHS — MCO, Insurance etc

Federal + ~~Federal Agencies~~ Specific — States

NIH CMS

FDA CDC

HRSA

✓③ Review of Executive Summary – Section by Section Change

④ Folders in Work Area & Outline – Insert when Completed

✓(4A) Workgroup Members and ~~Chairs~~ Facilitator –

(5) Acknowledgments Review

✓(5B) Review of Responses to Edit Training Contact Version Statement

⑥ Timeline – March (Mail Out – Ex Summary + Access + Delivery Sections – Complete ASAP – Mail Out

March 4 – Conference Call Access + Delivery

March 5 COB all Material to Palladian for Printing

March 6 (Packard Review)

March 7 COB – to Secretary (5 copies

– To WH Cards

– To Staff

March 8 Return

Executive Summary

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established in March 2000. Executive Order 13147 establishing the Commission states that the primary task is to provide the President through the Secretary of Health and Human Services a report by March 2002, on legislative and administrative recommendations for assuring that public policy maximizes the potential benefits to Americans of CAM therapies.

Mission

The Executive Order states that the Commission should address:

(a) the education and training of health care practitioners in CAM;
(b) coordinated research to increase knowledge about CAM products;
(c) the provision of health care professionals with reliable and useful information about complementary and alternative medicine practices and products;
(d) guidance of appropriate access to and delivery of complementary and alternative medicine.

Guiding Principles of the Commission

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

1. A wholeness orientation in healthcare delivery. ~~Health involves all aspects~~ of ~~life—mind, body, spirit, environment—and 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 the appropriate scientific methods to help identify~~ safe ~~and effective CAM services and products and 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~~ have ~~health care appropriately responsive to them, respecting their~~ preferences and ~~preserving their dignity.~~
5. The right to choose treatment. ~~People have the right to choose freely among safe and effective care/approaches as well as among qualified practitioners who are responsive to their needs and accountable for their claims and~~ actions.
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 are essential for integrated health care. ~~Good health care requires collaborative teamwork between patients and conventional~~ and

complementary and alternative health care practitioners and researchers committed to the creation and delivery of optimal healing environments and to respect 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 for all health care professionals as well as the general public at all ages.

9. Comprehensive and timely information dissemination. Quality health care can be enhanced by promoting efforts that thoroughly and thoughtfully examine the current evidence base for CAM systems, practices, and products and make this evidence base widely, rapidly, and easily available.

10. More integral public involvement. Informed public and consumer participation must be incorporated into all research, health care prioritizations, and policy decisions, including those related to CAM, within the public and private sectors.

OVERVIEW OF CAM IN THE UNITED STATES

Complementary and alternative medicine, or CAM, is a heterogeneous group of medical, health care, and healing systems other than those intrinsic to mainstream healthcare in the United States. CAM includes the world views, theories, modalities, products and practices associated with these systems and their use to treat illness and promote health and well-being. Because the term CAM is widely used in the media and research literature, it is used throughout the remainder of this report. However, the Commission recognizes that the term "CAM" does not fully capture all of the diversity with which these systems, practices, and products are being utilized by consumers, CAM practitioners, and mainstream healthcare institutions. Various members of the Commission offered alternative terms, such as "integrative health care," "collaborative health care," "comprehensive health care," and "holistic health care," but there was no clear consensus on more appropriate terminology.

Safety Issues with CAM Use

Despite the promising evidence for the effectiveness of CAM systems, approaches, and products for managing and treating a variety of chronic conditions, most CAM therapies that are currently being used by consumers have not been adequately studied, particularly in regard to safety. Even among those CAM approaches and modalities where there is evidence of efficacy and safety, new safety concerns may arise when they are used in conjunction with conventional medications, which is the way most consumers use them.

The potential adverse interaction of CAM and conventional treatments is particularly troubling to public health officials in light of findings that a majority of people do not tell their conventional health care providers that they are using CAM. Although CAM consumers welcome a partnership with their healthcare providers, they generally believe that their most healthcare providers are closed-minded and have little knowledge about

dietary supplements. A similar lack of communication between patients and their healthcare providers was due to assumed disinterest, anticipated negative response, perceived unwillingness and inability to help, irrelevance, and the disparate healing strategies between CAM and conventional medicine. In addition to the need for significantly greater research on the efficacy and safety of CAM, there is an urgent need for all healthcare providers and patients to become more knowledgeable about what is already known about the potential benefits and harms of CAM approaches and treatments.

The Current Status and Future Prospects of CAM

~~There is every indication that~~ Some of the health care systems, modalities, and products that are commonly considered CAM currently are becoming part of mainstream health. A growing number of physicians already utilize some CAM techniques and products in their practices, consider them to be safe and effective, and make referrals to CAM practitioners. A small, but growing number of insurance companies offer coverage for CAM services. ~~Recently, CAM also has made significant inroads into mainstream medical education, with~~ more than two thirds of mainstream medical schools currently offering elective courses in CAM or including CAM topics in required courses. Nearly 15.5% of America's community hospitals offered CAM services in 2000. Still, a need remains for

~~In addition to potential structural and communication problems, other barriers include:~~

- ~~The need for~~ certification and training standards for some CAM professions;
- ~~The need for~~ consistent insurance reimbursement for safe and effective CAM practices;
- ~~The need for~~ appropriate research models; and
- ~~The need for~~ comprehensive sources of information on CAM

CAM in Wellness and Health Promotion

~~Wellness is more than the absence of disease. In recent years, there has been an increased emphasis on quality of life issues across the life span, and a recognition of the impact of healthy~~ People of all ages are seeking ways to live their lives to the fullest and enjoy a long, high quality of life, lifestyles on wellness and the prevention of illness and disease. ?

Helping people to achieve a healthy, meaningful, and long life is the fundamental purpose of any health care system. Great strides have been made in conquering disease and extending life, and our health care system reflects these remarkable scientific advances. The Commission believes that it is time for wellness and health promotion to be a national priority, and that the role of CAM in these efforts needs to be further explored.

Utilization of safe and effective CAM practices can be used to help achieve the Nation's health promotion and disease prevention goals and promote wellness throughout the life span. Nowhere are healthy behaviors and lifestyle choices more important than for our

nation's youth. Early intervention could have a significant impact on developing healthy behaviors and attitudes and prevent many of the negative behavior and lifestyle problems that begin early in life.

CAM activities and approaches may have a role in improving the health and well-being of other populations as well Despite results from several published studies, the extent of use of CAM interventions in the general population is still unknown.

The Commission recommends that safe and effective CAM practices be utilized to help achieve the Nation's health promotion and disease prevention goals and promote wellness throughout the life span. CAM practices that improve nutrition, promote exercise, and teach stress management should be integrated into the school curriculum for children from kindergarten to 12th grade.

Although a significant percentage of people who utilize CAM practices and products do so for preventive and health promotion purposes, there is little documented information on how CAM approaches can improve well-being, promote health, and reduce morbidity and mortality. A promising, yet largely unexplored area is the application of CAM wellness and prevention practices in the treatment and management of chronic disease.

Utilization of safe and effective CAM practices in the workplace should be expanded to promote wellness, health promotion, and disease prevention

The incorporation of safe and effective CAM practices in public, private, and Federal health care delivery systems and health related programs to help promote wellness, health promotion, and disease prevention.

COORDINATION OF RESEARCH

The public's interest in and use of CAM has ~~markedly~~ increased the need to examine the safety, including contraindications, efficacy, and cost effectiveness of complementary and alternative medicine (CAM) treatments, and to discover the basic mechanisms underlying these treatments. ~~The Commission fully supports increasing both~~ public and private resources for basic, clinical, and health services research in CAM ~~and believes~~ should be increased, that the paucity of private investment in research on herbal and other CAM products popular with the public needs to be addressed.

The Commission agrees that basic, clinical, and health services research are all essential to achieving the integration of CAM into the healthcare system. 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. Information learned from research also serves as a basis for regulating the quality and use of CAM products and devices, and improves access to safe and effective CAM practices and products and health insurance coverage for them. The Commission believes that, in addition to the safety and efficacy of CAM practices and products, CAM-related questions requiring

study include why people use CAM, how lifestyle and self care affect health and disease, how practitioner-patient interactions affect treatment outcomes.

Research is also needed to pursue answers to questions posed by CAM that are outside of the conventional medical paradigm. The Commission believes strongly in the value of building a science base in CAM as the foundation for the acceptance and integration of safe and effective CAM therapies. CAM practitioners have noted that in conventional medical practice, professional judgments are made at times without conclusive evidence of effectiveness. These judgments are based not only on the practitioner's training and experience, but also on an accepted and expanding body of knowledge found in the peer-reviewed research literature. Such judgments in the practice of CAM, however, often are not viewed in a similar light because of the lack of a sufficient evidence base on which to form them. As the research literature in CAM expands, the professional judgments of trained and experienced CAM practitioners that are predicated on an underlying body of evidence-based knowledge will be accepted with greater assurance.

Current CAM Research Activities

The Commission commends NCCAM for its excellent leadership and contributions to CAM research and research methodology, research training, and infrastructure development, and fully supports increasing the Center's crucial activities in these areas, including its information dissemination responsibilities. The Commission also recognizes the important work of the NIH Office of Dietary Supplements (ODS) and other NIH Institutes and Centers such as NCI's OCCAM and the National Library of Medicine (NLM). In addition, the Commission commends current collaborations and encourages further collaborations between NCCAM and other Federal agencies with research and health responsibilities, such as the Agency for Health Care Research and Quality (AHRQ) and the Food and Drug Administration (FDA). The Commission believes that all Federal agencies need to be more proactive in evaluating aspects of CAM, if relevant to their missions.

The Commission considers the funding of research on the safety and efficacy of frequently purchased or promising dietary supplements and other natural products that may not be patentable to be of paramount importance. This includes research to determine if the products are suitable and safe to use with other CAM and non-CAM products and the development of analytical methods for producing better quality products. Meeting these needs requires both substantial research support from the public sector and increased incentives to stimulate more private sector support for this research.

The Commissioners agree that to be methodologically sound, CAM studies must have a clear question (hypothesis); a sound study design; a qualified and appropriately constituted research team; objective, verifiable data; carefully defined outcome measures; and balanced conclusions that meet acceptable standards of evidence.

Expanding Areas of Scientific Inquiry

The Commission recognizes the potential of CAM research to contribute to emerging areas of scientific study beyond isolated treatments for conditions or diseases. The CAM research spectrum is broad. It includes areas that are almost indistinguishable from conventional medicine except for application, such as exercise/diet/lifestyle therapies, herbal/nutritional supplements, behavioral/mind-body methods; pain management; the effects of culture on health and treatment; and the ability of the body to heal. It also includes areas that may receive less attention but 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. In addition, it includes areas that challenge biological/scientific concepts and assumptions, such as homeopathy, bioenergy (vital force; e.g., Qi, prana), bioelectromagnetic therapy, and therapeutic prayer.

Moving Non-Approved Treatments to Clinical Investigation

The Commission recognizes the need to increase the opportunities for physicians and other health care professionals who believe they have promising data on non-approved CAM treatments to move successfully to clinical investigation of the treatment while meeting their ethical, professional, and human subject protection. All Federal agencies should develop programs to evaluate practice-based observational data as the basis for potential research support, and communicate the availability of such initiatives in a proactive manner to CAM and conventionally-trained practitioners. The IRBs that review CAM research studies are encouraged to include CAM expertise in the review. The Commission recommends that state professional regulatory bodies should consider including language in their guidelines stating that licensed or other authorized practitioners will not be sanctioned solely because they are engaged in CAM research if they are (1) engaged in CAM research that is approved by an appropriately constituted IRB, (2) are following human subject protection requirements, and (3) are meeting the same licensing or other authorizing standards of practice to which all similarly licensed or authorized practitioners are held.

The Commission recommends the same high standards of quality, rigor, and ethics 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 coverage and reimbursement for CAM products and devices.

Public Use and Input

The growing influence of the public on the health care system and considerable public interest in why people are turning to CAM points to the need learn more about why people use CAM and to ensure public participation in shaping the direction of CAM research. Federal government requirements and opportunities for public participation in shaping the direction of health care research and related activities currently exist.

The Federal government should support research to determine 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.

Research Training and Infrastructure

The Commission fully appreciates the crucial role that a strong research infrastructure plays in training skilled researchers to study CAM questions, producing grant applications in CAM that successfully compete for support, and conducting rigorous CAM research. Sustained, adequate funding is essential to building and maintaining long-term research capacity for training clinical investigators and health services researchers in CAM, and scientists who are interested in studying the underlying mechanisms of CAM products, practices, systems and concepts. The same rigorous training is required for both CAM and conventional medical researchers and must be available to both. Conventional researchers need a knowledge of CAM concepts and approaches and both CAM and conventional investigators must have rigorous training in the fundamental elements of quality clinical, basic, or health services research. The Commission believes that all Federal agencies with health care missions and training programs should support the training of researchers to address CAM-related questions relevant to their mission.

CAM Research Results: Systematic Reviews and Evaluations

The Commission agrees that publication of CAM research results in recognized, rigorously peer-reviewed research journals is needed to provide reliable information about CAM to researchers, practitioners, and ultimately the public. To ensure a fair and accurate review, both CAM and conventional medical expertise should be represented on journal review boards when reviewing CAM research submissions.

The Commission supports strengthening the process for producing concise systematic reviews of the research literature written for and available to such audiences as scientists, practitioners, community health centers, policy makers.

Education and Training of Health Care Practitioners in CAM

The Commission believes that the education of CAM and conventional health professions should include information on both CAM and conventional health care. Incorporation of CAM in conventional health professions education will enable conventional providers to discuss CAM with their patients and clients, provide guidance on CAM use, collaborate with CAM practitioners, and make referrals to CAM practitioners. Inclusion of conventional health care in CAM practitioner education will allow CAM practitioners to communicate and collaborate with conventional providers and make referrals to conventional providers. This will require CAM faculty, curricula, and program development at both CAM and conventional institutions. The Commission is aware of the interest of CAM students to participate in loan and scholarship programs and the importance of that participation. In light of increased and innovative CAM educational

activity, the Commission recognizes the value of and barriers to national CAM education and training guidelines. The Commission also appreciates the need to evaluate whether or not residencies and postgraduate training should be established for appropriately educated and trained CAM practitioners. To enhance and protect the public's health and safety, the Commission recognizes the role of relevant CAM continuing education particularly for all practitioners who provide CAM practices and products.

The Commission recommends that the education, training and credentialing of CAM and conventional practitioners be improved to ensure public safety, and to increase the availability of qualified CAM practitioners and knowledgeable conventional practitioners.

The challenges related to developing core curricula of knowledge about CAM for conventional health professional schools, postgraduate training programs, and continuing education programs are identical to those for CAM students and include : (and to improve communication and collaboration between CAM and conventional students, practitioners, researchers, educators, institutions, and organizations include:)

- Professional, organizational, and institutional resistance;
- Lack of funding;
- Need to provide adequate incentives to adopt these curricula;
- Numerous logistical design, development, and implementation issues;
- Need to achieve consensus of curricula;
- Availability of adequately trained faculty and faculty development; and
- Limited ability to make any addition to very full curricula.

Conventional health professional schools, postgraduate training programs, and continuing education programs should develop core curricula of knowledge about CAM in conjunction with CAM experts and CAM institutions, so that conventional health professionals can discuss and provide guidance to their patients and clients for the appropriate use of CAM.

All 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.

All CAM education and training programs should develop curricula that reflect the fundamental elements of biomedical science and conventional practice in order to ensure safe and beneficial care of patients who use their modalities.

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 is needed. In addition, there is a need to establish collaboration between funding sources and organizations to better identify programs, faculty, resources, and opportunities to improve CAM education and training increased Federal,

State, and private sector support should be made available to expand CAM faculty, curricula, and program development at accredited CAM and conventional institutions.

Eligibility of CAM students to participate in existing loan and scholarship programs should be expanded. However, the challenges of expanding the eligibility of CAM students to participate in existing loan and scholarship programs include the:

- Preference for conventional health care providers to fill the largely unmet need;
- Requirement for legislative 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.

National Cam Educational and Training Guidelines

DHHS and other Federal Departments and Agencies should convene conferences to 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 that subsequently should be made available to the States and professions for their consideration.

The challenges of establishing national CAM educational and training guidelines include:

- Licensure and perceived encroachment on States' rights;
- Degree of complexity owing to numerous disciplines or professions involved with a given modality;
- Lack of educational standardization within professions;
- Absence of a clearly delineated scope of practice for each profession;
- Funding requirements; and
- Wide-spread resistance.

Demonstration Projects of Postgraduate Training and Residencies

CAM education and training should continue beyond the entry, professional school, or qualifying degree level. Currently, the chiropractic profession appears to have the most extensive type of fulltime postgraduate CAM education and training in the form of residencies in radiology, orthopedics, family practice, and clinical sciences.

Before establishing new or expanding current CAM postgraduate education and training programs, the appropriate CAM practitioners for postgraduate education and training should be identified and the feasibility, type, duration, and impact of postgraduate CAM education and training for these CAM practitioners should be ascertained.

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

- Determining which CAM practitioners should participate in CAM postgraduate education and training demonstration projects;

- Developing and applying selection criteria and processes;
- Funding;
- Professional and institutional resistance; and
- Limited availability of a sufficient number of training sites, patients, and faculty.

Demonstration projects of residencies and postgraduate training for appropriately educated and trained CAM practitioners should be conducted to determine the feasibility of such residencies and postgraduate training and their impact on clinical competency, quality of health care, and collaboration.

All practitioners who provide CAM products and services should consider completing relevant CAM continuing education programs to enhance and protect the public's health and safety.

Availability of information on the training and education of CAM providers delivering CAM health services to enhance consumer knowledge and choice.

Training, licensing requirements, certification, scope of practice, regulations, and even definitions for CAM practitioners can vary considerably. This is further complicated because licensing requirements and scope of practice vary from state to state, and certification can be granted by different organizations, ranging from an organization approved by the Department of Education to someone merely printing certificates. Navigating through this complex maze of titles and certificates is a challenge for consumers, most of whom are unfamiliar with the nuances of each of these professions. Information on a practitioner's level and training should be readily available to help consumers to make informed choices in their selection and use of a practitioner. Also, to help ensure public safety, information on State regulations, requirements, and disciplinary actions should be readily available to consumers.

CAM Information Development and Dissemination

Over the past several decades, new technologies have been developed that enable people all over the world to rapidly gain access to information. This is true for information in general, and is especially relevant to health information, including complementary and alternative medicine (CAM). To assure public safety in the continually evolving area of CAM, accurate information must be available so that people can make informed choices about their use. This information far too often is nonexistent, inaccurate, or difficult to find. Many people quickly become overwhelmed by the vast array of the often-conflicting information that is available.

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 on health and healing, different patterns of use of health care services and products, and different ways of accessing information. This also applies to people of different age groups, people with varying literacy levels, and people with specific health conditions.

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

The proliferation of internet use has enabled people to access vast amounts of health care information that would not have previously been available to them. Along with the advantages of being able to quickly find information on virtually any topic, there are concerns about quality, particularly in regards to CAM information. This is particularly true in the case of CAM where a significant amount of evidence-based material is not yet available.

Availability of Reliable, Useful and Early Accessible Information

Consumers, health professionals, and the media often look to the Federal government for reliable and authoritative information on a wide range of health topics. Information on CAM from the Federal government is inconsistently available and often difficult to locate. Significant gaps in CAM information on diseases, health conditions, practitioners, and products exits. where appropriate, CAM information should be added and new materials developed.

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 quickly get objective and comprehensive information on CAM. People without home or work access to the Internet often will use publicly available resources, such as public libraries, to research information. The National Library of Medicine has begun working directly with public libraries through the American Library Association to train local librarians to use the Internet to find health information. This effort should be expanded to include more training and focus on CAM, and include other resources for CAM information.

Quality and accountability of CAM information on the Internet.

The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers, with an estimated 60 million U.S. adults having used the Internet to obtain health-related information last year. However, the quality, accuracy, accessibility, and timeliness of the information vary greatly.

Public-private partnerships that include industry groups, consumers, and governments have been successful in developing guidelines and establishing standards for many products and services The government can play an important role in bringing key people together to develop voluntary, non-binding guidelines that will assist the industry in setting minimum standards for quality, accuracy, accessibility, and timeliness of CAM-related information on the internet.

There will always be a need for consumers to evaluate and validate information they receive from the Internet. Public education in using the Internet as a source of health information can help guide an individual's knowledge and decision-making on their

health. Funding should be provided to DHHS and the Department of Education to conduct a joint public education campaign that teaches the public how to evaluate health care information, including CAM information, on the Internet and other vehicles that disseminate public information.

Public access to CAM products that meet or exceed minimum standards of quality and consistency.

One of the fastest growing areas in CAM has been the use of dietary supplements. This makes complete and accurate labeling and package insert information on ingredients, and potential benefits and risks even more important for consumers. The current system does not adequately make this information easily available to consumers. As a result, public interest related to safety and effectiveness of dietary supplements has also increased. While some dietary supplements are used for nutritional purposes, some are believed to be beneficial for disease prevention and treatment. Problems with composition, purity, adulteration, and contamination have been reported and raise concern about safety. Laboratory testing of dietary supplements has shown that some manufacturers need to improve the quality of their products. Studies have shown that some dietary supplements do not contain the ingredients or the amount of the ingredients declared on the label.

These examples highlight the need to assure the safety of dietary supplement products and the ability of the regulatory agencies to respond quickly when a problem is identified that claims are substantiated by adequate scientific evidence. The Commission views the absence of a requirement to provide safety data as a weakness of the current regulatory system because it provides little guidance on scientifically valid information and data on safety and effectiveness to consumers.

The formal publication and implementation of Good Manufacturing Practices (GMPs) are still pending. The proposal concerning for Dietary Supplements should be published expeditiously, followed by a timely review of comments and completion of a final rule.

Finished products imported from some countries may not meet the standards set forth by the GMPs or the standards of responsible manufacturers. These may still 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 intentionally adulterated products from entering the US marketplace.

Since passage of DSHEA in 1994, many new dietary supplement products have been introduced in the United States, yet validated analytical methods have not been developed for many of these supplements, particularly botanicals. Efforts of Government, industry, and scientific organizations have begun developing validated analytical methods for botanical and dietary supplements so that consensus can be reached regarding the chemical and physical standards for composition and quality need to be enhanced and accelerated. The Commission is aware that Congress included language in the FY 2002 HHS Appropriation Bill and recommends that this progress be continued.

Public access to accurate information on the quality and safety of CAM products.

The Federal Trade Commission (FTC) is responsible for assuring that advertising is truthful, not misleading, and substantiated so that consumers can make informed decisions about the products being marketed. Since the passage of DSHEA, the FTC has placed an increased emphasis on monitoring the advertising of dietary supplements.

To assist the dietary supplement industry in conforming to the standards of the FTC has produced a guide that provides detailed explanations and descriptions of acceptable statements. Current FTC efforts , should be significantly expanded to decrease the amount of false or deceptive advertising, solicit public comments on CAM advertising, and expand the utilization of CAM experts in the process of examining these advertisements.

The regulation of dietary supplements and other products such as foods, prescription drugs, over-the counter drugs, and special dietary foods is determined by the intended use of the product. Product labels must conform to the laws and regulations that govern its intended use. Thus, a vitamin, mineral, or a botanical that claims to diagnose, prevent, mitigate, treat, or cure a disorder must be FDA approved as a drug for such information to be included in the label claim.

Claims related to a nutrient/disease relationship for the purpose of disease risk reduction, 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 (NLEA) and can be used for dietary supplements as well as conventional foods. The NLEA allows health claims to be made only after an 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 does allow a product to claim a health benefit if the manufacturer provides evidence of an "authoritative statement" from a Federal Agency or a scientific organization, such as the National Academy of Sciences. In addition, manufacturers of dietary supplements may make label claims related to structure and function of the body. However, label claims about treating, preventing, curing, or mitigating diseases are not allowed as these are reserved for drug claims. Not having to undergo drug approval has greatly enhanced the availability of dietary supplement products, yet has limited the availability of information to consumers on potential benefits and risks and appropriate use. It may also act as a deterrent to investment in research on potential disease benefits, risks, and appropriate conditions of use. There is a need for incentives for manufacturers to develop the required data and to petition the FDA for a health or drug claim.

The general public has an expectation 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 advertising and labeling of dietary supplements. Since many dietary supplements are purchased without the knowledge or advice of a physician, pharmacist, nurse, or other 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.

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 assure appropriate oversight and ensure public safety.

The Commission recognizes the technical and complex legal and regulatory nature of this issue and encourages ongoing participation and consultation with the public. The Commission recommends that the public have access to accurate information on the quality and safety of CAM products. To reach this goal, Congress and DHHS should solicit further public input on the labeling of dietary supplements, followed by timely proposed rulemaking and/or appropriate oversight and legislative reform by Congress so that truthful, not misleading, and scientifically valid information on the benefits and appropriate use of dietary supplements is made easily available to consumers on the product label as well as at the point of sale. An independent review board should be established to develop objective methods for the evaluation and review of safety of dietary supplements.

Collection and dissemination of information on adverse events of dietary supplements.

The majority of dietary supplements are likely to be safe for human consumption, yet, as with any biologically active substance, adverse events can and do occur. Therefore, post-marketing monitoring of adverse events is a critical step to a better understanding of the effects and interactions of dietary supplements and the ability to respond quickly when problems do occur.

The FDA monitors adverse events through a voluntary Adverse Events Reporting (AER) system for the early identification of emerging problems with a specific product, or for identifying general trends in dietary supplement related morbidity and mortality. The Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it "an inadequate safety valve."[1] This report identifies the limitations of the current system in detecting serious adverse events related to dietary supplements and provides recommendations to improve the system. The Commission agrees that the collection and dissemination of information on adverse events of dietary supplements be improved. Congress should require dietary supplement manufacturers and suppliers to register with the FDA and the FDA should encourage voluntary registration until such a requirement is in effect so that manufacturers and suppliers can be promptly notified if a serous adverse event is identified.

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

Recent Congressional support of improving the FDA'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 FDA. Additional resources and support should be provided to the FDA to a) simplify the Adverse Event Reporting System for dietary supplements to facilitate easier usage; b) streamline the database for timely review and follow-up of received reports, and c) increase outreach activities to health professionals (including poison control centers, emergency room physicians, CAM practitioners, mid-level marketers) and consumers to improve both manufacturer and public awareness and participation in voluntary event reporting.

Access and Delivery of CAM

Increase in the use of CAM has created a pressing demand for improved access to qualified CAM practitioners, safe and effective treatments and approaches, and better coordination and integration of health care services.

Factors that affect demand for CAM include the prevalence of chronic illnesses and impact on disability; the availability of health-related information, the impact of income on health; consumer involvement in personal health care; and consumer interest in CAM. The last factor reflects the public's broader concern with reexamining and revitalizing the way health care is currently delivered and received.

These are two broad categories: practice issues and delivery issues. Practice issues are concerned with the evolution of practitioners toward cohesive professional standards, regulatory oversight of practitioners and professionals to safeguard the public, and public policies to encourage the growth of qualified practitioners and professionals as part of the health care workforce. The delivery issues, include evaluating services that are already available and services that are needed.

There is an urgent need for clarity about who should be doing what in the health care system. Those who practice comprehensive approaches to health care must demonstrate their ability to deliver safe and effective services and products; adherence to adequate and appropriate educational and ethical standards and other generally accepted and understood characteristics of professional status. Many CAM professional organizations are moving toward professional status by adopting national standards for examination, certification, and accreditation. Such credentials promote public confidence in the safety and efficacy of CAM.

It can be difficult to determine who is qualified to practice, because of the variability of certifications from CAM professional organizations, especially those without national standards for CAM systems or modalities. That task is compounded for organizations that operate across state lines, which must contend with occupational certification and licensure regimes that diverge widely from state to state.

Access to qualified and competent practitioners, and to safe, effective, affordable CAM services and beneficial CAM products should be improved for all Americans.

State Regulation of CAM Practitioners to ensure public accountability

States grant legal authority to all practitioners to protect the public and to ensure access to safe and effective practices. Consumers should be able to choose from qualified conventional and CAM practitioners. From the perspective of many CAM providers, regulation (licensure, in particular) presents a tension between their desire to increase standardization of CAM education, training, and practices across states and their desire to keep CAM practice flexible, nonstandardized, and linked to subjective, interpersonal, and intuitive aspects of care. Although increased licensure of CAM may help facilitate research, ease referrals, enhance access, and increase consumer protection, many practitioners fear it may also decrease individualization of services, time spent per patient, and the range of patients' treatment options. However, the public has a right to expect care from a competent practitioner who can help them navigate through the multiple choices and decisions they must make about the care available to them. Thus, any regulations of CAM practitioners must consider public safety. The Commission recognizes the distinct roles and authorities of Federal and state governments in regulating CAM practitioners. Appropriate regulation of CAM practitioners requires uniform and understandable language that clearly describes regulations and their functions for consumers, provider organizations, businesses, and the professions. Regulatory functions should be streamlined, and states should increase the accountability of regulatory systems to the public.

States look to national professional groups as well as the Federal government to set standards of education and training for licensure and to create accrediting bodies for educational institutions in the health professions."

The Federation of State Medical Boards draft guidelines recognize and preserve wide latitude in physicians' exercise of their professional judgment and do not preclude the use of methods that are "reasonably likely to benefit patients without undue risk." States are encouraged to establish and apply standards equally to conventional and to CAM practices and products. Establishing such guidelines and standards is critical to improving access to qualified CAM practitioners. The regulatory bodies of health professions, such as dentists and physical therapists, should establish similar guidelines and standards to allow practitioners in these professions use safe and effective CAM approaches in their professional practices.

Accreditation of facilities offering CAM

Consumers have a right to expect that the facilities in which care is delivered are safe and accountable. Most health care facilities and organizations are accredited by private accrediting organizations. These organizations require that the staff of such facilities be licensed, meet relevant training and experience standards, and demonstrate current competence.

The Commission urges accrediting organizations to include CAM practitioners or other CAM experts in their advisory structure. These organizations also could participate in educating the public and conventional medical professionals about CAM. They could convene forums to develop consensus on appropriate access to and delivery of CAM in clinical settings; educate conventional health care providers; and inform the public about standards regarding safe, effective, and appropriate delivery of CAM, and what those standards mean to them.

The Federal government, in collaboration with states, should assist CAM practitioners in developing consensus on the definition of their profession or practice and standards of practice, including education and training. Their conclusions should be considered by states and regulatory bodies in determining the appropriate status of these practitioners, including registration, licensure, or exemption.

The Department of Health and Human Services' advisory committee should work closely with state legislatures, regulatory boards, and CAM practitioners to develop guidelines for the regulation and oversight of licensed and registered practitioners who utilize CAM services and products. Nationally recognized accrediting bodies of health care organizations and facilities should establish ongoing access to CAM expertise to ensure that accreditation standards reflect emerging developments in CAM. Nationally recognized accrediting bodies of health care organizations and facilities should also clarify how accreditation requirements apply to CAM and should promote appropriate collaboration with CAM practitioners in order to foster understanding and awareness of CAM. Innovative centers and practitioner groups that treat illness and promote health in a manner that is centered on the patient and community are emerging in response to growing patient and practitioner interest in combining conventional health care and CAM. The trend toward patient-centered care and self-care is beginning to be reflected in employee assistance programs, hospice centers, and community health centers and hospitals. Integrative health care would include: (1) comprehensive–assessing and responding to the needs of a patient's body, mind, and spirit; (2) collaborative–recognizing the limitations of any one practitioner, technique, specialty, or discipline and providing care through a multidisciplinary team; and (3) individualized—tailoring treatment to each patient.

Delivery Issues Affecting Access to CAM

While CAM practitioners most often furnish services as solo practitioners or members of small groups, increasingly hospitals, managed care organizations, health insurers, and large self-insured employers are developing models to make CAM therapies available to members, subscribers, and employees. These models bring CAM to the practice of conventional medicine through referral, consultation, co-management, and adjunct (supportive) therapies. The spectrum of existing models, all relatively new.

While CAM practitioners are most often found in private sector settings, hospitals, managed care organizations, health insurers and large, self-insured corporations are developing models whereby CAM therapies are made available to members/subscribers/

employees. These models bring CAM to the practice of conventional medicine through referral, consultation, co-management, and adjunct (supportive) therapies. The spectrum of existing models, all relatively new, is broad and includes:

The Department of Health and Human Services and other appropriate Federal agencies should use health care workforce data; data from national surveys on CAM, and regional public health reports on CAM activities to identify current and future health care needs that qualified CAM practitioners may help address.

The Secretary of Health and Human Services should identify common uses and practices of indigenous healing in the United States and recommend ways of improving collaboration between indigenous healing traditions and the current health care system. This should be done in a manner that protects the cultural heritage of indigenous healing traditions, educates health care practitioners, includes members of indigenous groups, and maximizes access to qualified practitioners, safe and beneficial services, and effective products.

The emergence of CAM approaches as a consumer movement suggests an acknowledgment of an integrated, self-healing life system with the role of internal self-regulation, personal attitudes and beliefs, and the healing nature of relationships as paramount. Consumers are doing their own research, and serving as individual research models, trying alternatives to conventional treatments, and pressing for more options. Nutrition, exercise and lifestyle changes that include increasingly more CAM products and practices may play a significant role in preventing and treating disease, and improving quality of life. In most instances, consumers can rely on health care providers to guide them to safe and effective paths to recovery and health. In all cases, health care providers should be well-trained, highly qualified practitioners.

To improve access to CAM, the Commission recommends that access to qualified and competent practitioners, affordable, safe and effective CAM services, and beneficial CAM products be better facilitated for all Americans. The Commission also recommends that practitioners who provide CAM services and/or products be regulated by states using a more standardized and understandable framework that includes exemption categories, registration, and licensure, and that ensures accountability to the public.

Action Items:

The Secretary of DHHS should convene a national policy advisory committee to: a) address issues related to the regulation of CAM professionals and practitioners; b) provide guidance to States as they develop regulatory and oversight standards applicable to CAM practitioners; and c) provide a forum for dialogue on other issues related to maximizing access to qualified practitioners, safe and effective CAM services, and beneficial CAM products.

DHHS and other appropriate Federal agencies should utilize health care workforce data and data from national surveys on CAM and regional public health reports on CAM

activities to identify current and future health care needs that qualified CAM practitioners may help to address.

The Federal Government should convene conferences on effective approaches to the integration of safe and beneficial CAM into allopathic settings, using successful models of integrated care, such as hospice settings, community health clinics, and the private and non-profit sector, and make this information available to practitioners and the public.

The Secretary of DHHS should produce a report on indigenous healing traditions in the United States that identifies common use and practices, and provides recommendations to improve collaboration between such practices and current health care systems in a manner that protects the cultural heritage of such traditions, appropriately educates health care practitioners, involves members from these traditions, and maximizes access to qualified practitioners, safe and beneficial services, and effective products.

Coverage and Reimbursement for CAM

The coverage and reimbursement policies of organizations that pay for, provide or insure health care services have played a crucial role in shaping the health care system in this country. Coverage policy for CAM will play a similar role in influencing the public's access to complementary and alternative medicine, but also the future structure of the nation's health care system as conventional medicine and CAM intertwine and, in some cases, converge into a unified system.

The model for health care coverage in this country is one of third party sponsorship. This model can be generally described as one where employers, other private sponsors, and government agencies act as purchasers in buying coverage, sometimes directly from providers but often from insurance and managed care companies which, in turn, pay health care providers. Under this model, the purchaser bears most of the expense, usually in the form of a health plan premium, and the individual consumer is sheltered from the true cost of health care. This is not true for CAM where most fees for services and products currently are paid out-of-pocket by the consumer. As a result, many consumers are not able, or may be simply unwilling, to use these products and therapies because they are not covered under a health plan.

Over the last several years, some health plans have begun to cover selected CAM services, although the prevalence of this coverage is relatively low compared to coverage of conventional therapies. Chiropractic has become a commonly covered benefit, but the incidence of other CAM coverage (such as acupuncture and massage therapy) is much less. Where there is health plan coverage, it usually has limitations such as the number of visits, type of practitioner, and/or clinical applications that will be approved or reimbursed for the service. Employers are starting to ask their health insurance and managed care companies to cover CAM benefit in response to employee requests. Other reasons employers are adding this coverage are to attract and retain employees, in response to state mandates, and the potential benefits of CAM. At present, CAM is being offered as part of a health plan in several ways, including:

- As a supplement or a "rider" to the basic benefit package, usually with controls on use such as copayments, visit limits or annual limits, or required use of a credentialed network;
- As a discount program where individuals pay out-of-pocket but receive discounts off CAM products and fees when using a credentialed CAM network;
- As a core benefit for specified benefits and with coverage controls;
- 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.

Overcoming Barriers to Coverage of Safe and Effective CAM

Health care interventions known to be safe and beneficial should be reviewed and given consideration for coverage under health benefit programs, regardless of whether the intervention is considered conventional medicine or CAM. Such consideration has not often occurred 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 and, in doing so, CAM should be held to the same standards as conventional medicine.

The fundamental barriers to coverage and reimbursement identified by the Commission including are: 1) the need for a fair and impartial consideration of safe, effective CAM interventions, 2) the need for more clinical research documenting medical effectiveness (or ineffectiveness), 3) the need for health services research including cost-benefit studies and effective models for integration with conventional medicine, 4) the availability of practitioners legally authorized to practice within a state, 5) the availability of appropriate criteria for deciding when to pay for CAM services, and 6) the availability of evidence and other information that will enable employers, insurers and managed care companies to develop coverage policies for CAM. Efforts to address these barriers should begin now, and continue into the future as the report's recommendations and action steps take effect.

These barriers to coverage and reimbursement may be viewed under two broad, fundamental issue areas that will require the response of purchasers, insurers, managed care organizations, federal agencies, states, and others to the public's increasing use of CAM interventions.

Testing the benefits and cost-effectiveness of CAM services and products, and communicating the findings

Purchasers, insurers, and managed care organizations have strong incentives to tightly manage their health care expenditures, and to target health coverage at interventions that are proven to be medically effective. They explain their limited coverage of CAM

because there is not enough evidence of its benefits, and they do not know enough about its costs and cost-effectiveness. The growing evidence of cost-effectiveness documented in professional literature, such as that seen for heart disease, cancer, diabetes, surgical stays, premature births, and wellness programs, often goes ignored or unseen, are not replicated or are not addressed. An agenda as well as funding is needed for health services research on a broad array of questions regarding the benefits and cost-effectiveness of CAM and health promotion programs.

At an operational level, health plans, policy makers, and health researchers do not have the common claims forms and coded data necessary to perform cost, utilization, actuarial, and other types of analyses for many CAM service and products. Currently available coding systems complicate this situation further. For example, the Common Procedural Terminology (CPT) coding system used for conventional medical services has a limited number of codes for a small number of CAM services. The highly descriptive ABCcodes system specifically developed for CAM, as currently designed, does not allow CAM and conventional medical data to be efficiently merged.

Related to these issues is the lack of knowledge and understanding of CAM. Timely, reliable information about CAM practices and products is needed to make prudent coverage decisions, overcome any unfavorable predispositions to CAM, and maximize the availability of safe, cost-effective health care to the public. Given the size and breath of the health care industry, this will be a challenge.

Equitable and impartial consideration of safe, effective CAM interventions

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 when provided by a qualified practitioner. The Commission supports methods, standards, and process that are not prejudiced toward one philosophy of health care or the other, but that give equitable consideration to safe and efficacious interventions for both conventional health care and CAM. For this to occur for CAM, health insurers, managed care organizations, and government agencies will need to make some accommodation for CAM's different philosophical approach to health care, and should not unilaterally overlay the conventional model onto CAM. In addition, these entities will need to develop expertise in the area of CAM, and include CAM experts on workgroups and advisory bodies.

Another area for facilitating the equitable consideration of safe and effective CAM therapies is within the coverage determination processes of health insurers, managed care organizations, and government agencies. In particular, their threshold questions whether a service is investigational and is medically necessary either do not address CAM or need modification to recognize the philosophical approach on which the effectiveness of CAM therapies may rest. For example, most CAM practitioners, when seeing patients and applying their interventions, do not have a disease as their focus or rationale for use, but look instead at the whole person, root causes, and the interaction of organ systems. At

this time, few criteria are available to guide practitioners in deciding the investigational and the medical or, more appropriately, the clinical necessity of CAM interventions. Efforts are needed to correct this situation, such as conferences to assess the state-of-the-science of a particular CAM treatment and to develop clinical criteria to guide the use of CAM interventions.

As with conventional medicine, coverage of and reimbursement for CAM services are linked to the CAM practitioner's ability to furnish services legally in the state where the health plan operates. Thus, insurers, managed care organizations, even government agencies that are interested in covering safe, cost-effective CAM interventions may not be able to do so if the practitioners of the services are not properly licensed (or otherwise legally authorized) by the state. These state laws help ensure that the public is cared for by qualified practitioners whose services 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. Thus, states need to assess and address their need to act on licensure, certification, registration, exemption, or other form of legal recognition for CAM practitioners.

Lastly, the federal tax code can be used to foster coverage and reimbursement for CAM interventions also. The code allows employers and other health plan sponsors to deduct the cost of providing accident and health insurance, and is heavily weighted toward conventional medical care and physician direction of services. This approach should be modified to allow purchasers, health insurers, and managed care companies to develop health benefit packages that include safe and beneficial CAM interventions that fully qualify for favorable tax treatment under the law and regulations.

To assist in providing equitable and impartial consideration of safe, effective CAM interventions, Lawmakers, health plans and employers currently are ill-equipped to make decisions regarding CAM at a time when public pressure is increasing to make CAM more accessible. The Commission recognizes that costs and cost-effectiveness of health care interventions are important factors in considering changes to coverage policy, and supports efforts to provide decision-makers with information in this regard. Better information is especially needed for CAM interventions used more widely by consumers or where research indicates clinical effectiveness.

The Commission believes that more information is needed on the cost-effectiveness of specific CAM interventions for various conditions, and for different models of CAM practice, the clinical and financial impact of integration with conventional medicine, and the relative costs of CAM treatments versus the costs of conventional medical treatments. Information also is needed as to whether CAM interventions reduce utilization of conventional medical services and pharmaceuticals for groups such as those with heart disease, cancer, chronic pain, or with other chronic illnesses as well as the terminally ill. In addition, more information is needed about the short and long-term cost-benefits of wellness programs and self-care, as well as the impact of CAM practices on the short- and long-term health status on men, women, and children. Likewise, employers and other

Steve—
Here are my comments about things you and the writers should consider:

Text format:
In general, need to decide on consistent style for
- subheads
- lists (I prefer bullets to numbers)
- recommendations
- action items
- issues

Recommendations
- where should they go in the chapter?
- don't seem to need numbering

Action Items
- decide on wording for subhead (I prefer Actions to Action Items)
- decide where to put them
- numbering not needed unless there's some reference to them I haven't encountered

Issues
- decide whether to make them subheads or not
- if not subheads, choose consistent style
- some chapters don't have them—I think they're useful.

Don't need Introduction subhead—first few paragraphs are clearly introductory

References:
Put references (endnotes) at end of text and alphabetize. Use footnote style only for notes on text. Spell out journal titles—not all readers will be familiar with the abbreviations. Also, if an article has five or fewer authors, put their names in text with year. For reference style, I recommend the following format, which is pretty standard: authors' names, then year, article title, journal, vol, first and last pages. Don't need issue number or month if volumes are numbered consecutively, and most scientific journals are.

Definitions and usage:
Need to define the following CAM terms and use them consistently—it's particularly important to decide which ones can be used interchangeably:
- practices, approaches, therapies, interventions, treatments, services, modalities (this one really confuses me—seems to mean anything!), disciplines.

Related item: Are CAM practices and products the same as CAM services and products? CAM approaches?

Need to define and maintain consistent distinction between professional, practitioner, and provider. Start with Education and Training chapter, which implies differences. If differences have to do with credentials, need to say so and be consistent throughout. Intro says that "practitioner" applies to everyone.

Is "consumer" synonymous with "public"? I assume "patient" is used only in context of conventional medicine.

Other:

Can you lower-case some words—state, agency, center (but not Federal)? Text is inconsistent. All those capitalized nouns look antiquated, and taken in combination with the inevitable acronyms, they make an ugly page.

Try not to use CAM in heads and subheads unless necessary—overall effect is terribly repetitious. Do you want to spell it out the first time it's used in each chapter or just first time it's used in Introduction?

Avoid notion of evolution in this context—more or less highly evolved could be insulting.

Groft, Stephen (NCCAM)

To: Commissioners E-mail
: WHCCAMP Staff
Subject: Coordinating Federal CAM Efforts

Attached is the "Coordinating Federal CAM Efforts" prepared by Dr. Joseph Kaczmarczyk following the meeting last week. If you have any concerns or suggested revisions, please send them to me. Joe and I will discuss and revise accordingly. if you have any trouble opening the attachment, please send me a note and I will send a full text document.

Thank you.

Steve Groft

CAMCentralFinal.22
702JMK.rtf

Groft, Stephen (NCCAM)

Cc: WHCCAMP Staff
Subject: Update and Revised Information Development and Dissemination Section of the Report

Follow Up Flag: Follow up
Flag Status: Flagged

Information Development and Dissemination Section

Attached as a Rich Text File is the Final Draft of the Information Development and Dissemination Section of the Report. Please review and send any comments or suggested changes to me as soon as possible. If necessary, Corinne Axelrod and I will discuss proposed changes with you. We will continue to send out each section as it is prepared by the staff coordinator.

Discussion of Access and Delivery Section

Dr. Max Heirich is preparing a revised version of this section. We hope to have a document for your review by either late Thursday night or Friday morning. Max has been incorporating the December text, the revised Recommendations and Actions from last week, and the expanded information discussed at the meeting. **Please send me the times when you are available on Monday(preferable) or Tuesday (before noon EST if possible) to participate in a telephone conference to discuss this section**. If you have comments on the revised section and are willing to share them with the Commission prior to the teleconference, it would help to focus the discussion on potential problem areas or areas of disagreement.

Response Deadlines for Report

Please note we plan to have all documents go into a copying stage by Tuesday night March 5 to prepare the Final Report to be delivered to the Secretary on March 7. We will send you a copy of the Final report via FedEx overnight delivery at the same time it is delivered to the Secretary. After the transmittal letters are signed by the Secretary we will complete the Publishing and Printing of the document for distribution by the Government Printing Office. The document will also be placed on our website that will be maintained by NCCAM.

If you have any questions on these issues, please give me a call on 301-435-6199

Steve Groft

InformationDevelop DissemFinal....

2/24/02

WHCCAMP REPORT

BASIC STYLE SHEET AND LIST OF ACRONYMS

Format Style:

Font:

- Times New Roman throughout the report
- Main chapter heading: ~~18~~ point 16 point
- Everything else: 12 point

Headings:

- Remove "introduction" heading from each chapter. The Introduction of the report will be the only introduction section in the report.
- Uppercase bold for each chapter main heading (e.g., **ACCESS AND DELIVERY**)
- First level heading: bold (**CAM and Cancer**)
- Second level heading: bold underline (**Why Cancer Patients Use CAM**)
- Third level heading: underline (Economic Reasons)
- Fourth level heading: italic (*Yearly Expenditures*)

Footnote Format:

- Denote in text using asterisks (*, **, ***). No more than three per page.

Recommendation Format:

- Take out "commission recommends" from recommendations
- Take out "item" from action items

Reference Format:

Cite in text using superscript numbers

Number sequentially in bibliography at the end of each chapter.

Journal articles

One author: Fields W.C. The use of complementary and alternative medicine. *JAMA* 2001; 512(67):1-14.

Up to four authors: Fields WC, Rooney A, Marx G, Swyers JP. Complementary and alternative medicine policy in the U.S. *Science* 2001; 23(3):79-82.

Five or more authors: (Fields WC, Rooney A. Marx G, Swyers JP, et al. How integrative is complementary medicine? *N Eng J Med* 2002;361(4):91-98.

Books and Reports

Larson DB, Swyers JP, Larson S. *The Costly Consequences of Divorce*. Rockville, MD: National Institute for Healthcare Research, 1995.

U.S. Department of Education. *National Adult Literacy Survey*. Washington, D.C.: National Center for Education Statistics,1992.

Koenig HC, Cohen H (Eds). *The Handbook of Religion and Health*. New York: Oxford University Press, 2001.

Newspaper articles

Swyers JP. FDA approves protease inhibitor ritonavir for treatment of HIV. *Washington Post*. 1996, March 3, C4.

Information obtained from web sites

National Center for Complementary and Alternative Medicine. *Frequently asked questions about CAM and NCCAM. What is Complementary and Alternative Medicine?* Available at http://nccam.nih.gov/nccam/fcp/faq/index.html.

Term format

acronyms: First time an agency or entity appears in a section, spell it out, and then use acronym (see CAM below). Spell out in recommendations (i.e., do not use acronyms in recommendations and action items).

Ayurvedic medicine: NOT ayurveda (capitalize A, but not M)

CAM: Spell out complementary alternative medicine (CAM) the first time it appears in each section, and then use acronym from then on.

chiropractic: always lowercase; never referred to as chiropractic medicine

data base: always two words).

Federal Government: always capitalize

health care: always two words

institute: If referring to a specific NIH Institute (e.g., National Cancer Institute), then capitalize, otherwise lowercase.

Internet: always capitalized

Naturopathic medicine: Capitalize Naturopathic but not medicine. Not naturopathy

Native American medicine: capitalize Native American, but not medicine

Qigong: always one word and lowercase; not qi gong

state: uppercase for proper name only (e.g., State of Minnesota); otherwise lowercase

United States: spell out unless used as a modifier (e.g., "U.S. public policy")

Workgroup: lowercase, except when referring to a specific work group (e.g., Work Group H)

Traditional Chinese Medicine: capitalize all three words.

List of Acronyms: (to be included in an Appendix)

AAMC:American Association of Medical Colleges

AANP: American Association of Naturopathic Physicians

ADD: Attention Deficit Disorder

AER: Adverse Events Reporting System

AHPA: American Herbal Products Association

AHRQ: Agency for Healthcare Research and Quality

AMA: American Medical Association

1/25/02

1,000 Copier Hardbound / Little Press — u

2,500 Web Press — 20x50

Karen Owens — 200

Models — 1,400

1,600

2,000

200 pages

- Absence of Research
- absence Communicable x Coordinated
- Prevent + Delivery
- Problems of Education + Training
- Coverage + Reimbursement

Groft, Stephen (NCCAM)

From: Fisher, Ken (NCCAM)
Sent: Tuesday, February 12, 2002 3:37 PM
To: Groft, Stephen (NCCAM)
Subject: Passing thoughts

Reading the edits that Blair did was difficult in certain chapters because I couldn't determine what she did (research, wellness, access, coverage) without reading the previous drafts simultaneously. As you noted the Tracker used on the introduction, education mad the scanning easier. I think the best use of my time will be reading carefully the version that goes to the WHC next week.

I noticed in Information that Corinne deleted a number of website addresses and phone numbers. I think there needs to be an appendix where "Sources of Additional Information" are identified. his would save the reader the bother of looking them all up etc.

Similarly, an important issue is the need for inclusion of "cross-references". For example, Issue # 2 in Wellness needs to be cross-referenced to Research and visa-versa. Similarly, Issue # 3 and #4 of Wellness should be cross-referenced with Coverage

Finally, In regard to Linnea's Feb 4th Email, in the section where all the Recommendations (and Action Items?) are together, or, in the Introduction (?) the report needs to say something like: "The WHC recognized early in its deliberations that while its Charge focused on recommendations to the Federal GUMIT, the development of a sound scientific basis for CAM modalities and practices as well as integration of CAM with conventional medical practice will require concerted efforts of both the Federal government and numerous components of the private sector. The public at large has already made know its collective opinion that these two aspects of CAM are desirable goals for the nation. The Federal Government by itself can not attain these; hence, the WHC has included a number of Recommendations and Action Items that identify opportunities for the private sector."

kdf

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White House Commission on Complementary
and Alternative Medicine Policy
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301-480-1691 (fax)
mailto:fisher@mail.nigh

BHPr: Bureau of Health Professions

BPHC: Bureau of Primary Health Care

BHP: Bureau of Health Professions

CDCP: Centers for Disease Control and Prevention

CME: Continuing Medical Education

CMS (formerly the Health Care Financing Administration): Centers for Medicare and Medicaid Services

CNME: ????

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

FCC: Federal Communications Commission

FDA: Food and Drug Administration

FSMB: Federation of State Medical Boards

FTC: Federal Trade Commission

HMO: Health Maintenance Organization

HP 2010: Healthy People 2010

HRSA: Health Resources & Services Administration

IOM: Institute of Medicine

LAc: Licenced Acupuncturist

MEPS:

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

NHANES:

NHIS:
NHSC: National Health Services Corp.

NIEHS:

NIH: National Institutes of Health

NIST: National Institutes of Standards and Technology

NLEA: Nutrition Labeling and Education Act

NLM: National Library of Medicine

NSF: National Science Foundation

OD: Office of the Director, NIH

ODS: Office of Dietary Supplements

OIG: Office of the Inspector General

OMB: Office of Management and Budget

OMH: Office of Minority Health

OP???

OSTP: Office of Science and Technology Policy

OWH: Office of Women's Health

PHS: Public Health Service

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: Veterans Administration

WHCCAMP: White House Commission on Complementary and Alternative Medicine Policy

WHO: World Health Organization

(Note to Commissioners: *This glossary is for terms that appear in the report or for terms that help explain the meaning of other terms in the glossary. It is not intended to be a comprehensive glossary of all terms used in the CAM or health care fields. Some of the terms listed below may be eliminated and others added, depending on the final revisions of the text*)

Glossary:

acupuncture: Acupuncture is the stimulation of special points on the body, usually by the insertion of fine needles. In its original form, acupuncture was based on the principles of Traditional Chinese Medicine. According to these, the workings of the human body are controlled by a vital force or energy called "Qi" (pronounced "chee"), which circulates between the organs along channels called meridians. There are 12 main meridians, which run superficially and longitudinally, and these correspond to 12 major functions or "organs" of the body. Both traditional and Western acupuncturists identify acupuncture points by their location on the meridians, for example, gall bladder 30 or large intestine 4.

benefits: valued health outcomes or improvements in quality of life or social conditions having some known relationship to health promotion or health-care intervention.

acute illness: an illness that has a rapid onset, severe symptoms, but a short course.

allopathy: a system of treating disease by inducing a pathologic reaction that is antagonistic to the disease being treated. It is a term that was first coined by homeopaths to differentiate it from homeopathy, which is based on the principle that "like cures like" (see homeopathy).

Ayurvedic medicine: Ayurveda is India's traditional system of medicine. Ayurvedic medicine (meaning "science of life") is a comprehensive system of medicine that places equal emphasis on body, mind, and spirit, and strives to restore the innate harmony of the individual. Some of the primary Ayurvedic treatments include diet, exercise, meditation, herbs, massage, exposure to sunlight, and controlled breathing.

biological therapies: biological therapies include, for example, the use of laetrile and shark cartilage to treat cancer and bee pollen to treat autoimmune and inflammatory diseases.

body work:

botanical medicine: Another term for herbal medicine.

chiropractic: chiropractic focuses on the relationship between structure (primarily the spine) and function, and how that relationship affects the preservation and restoration of health, using manipulative therapy as an integral treatment tool. Such procedures specifically include the adjustment and manipulation of the articulations and adjacent tissues of the human body, particularly of the spinal column.

chronic illness: Illnesses that are prolonged, do not resolve spontaneously, and are rarely cured completely.

cost benefit: A measure of the cost of an intervention relative to the benefits it yields, usually expressed as a ratio of dollars saved or gained for every dollar spent on a program.

cost-effectiveness: A measure of the cost of an intervention relative to its impact, usually expressed in dollars per unit of effect.

diagnosis: The art of distinguishing one disease from another; the use of scientific and skillful methods to establish the cause and nature of a person's illness.

double blind: A term pertaining to a clinical trial or other experiment in which neither the subject nor the person administering the treatment knows which subjects are receiving actual treatment and which subjects are receiving a placebo.

dysfunction: A term used in medicine to describe abnormal, impaired, or incomplete functioning of an organ or part.

effectiveness: The extent to which the intended effect or benefits that could be achieved under optimal conditions are achieved in practice.

efficacy: The extent to which an intervention can be shown to be beneficial under optimal conditions.

energy therapies: Energy therapies focuses either on energy fields originating within the body (biofields) or those from other sources (electromagnetic fields). Biofield therapies are intended to affect the energy fields, whose existence is not yet experimentally proven, that surround and penetrate the human body. Some forms of energy therapy manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields. Examples include Qi gong, Reiki and Therapeutic Touch.

epidemiology: The study of the distribution and causes of health problems in populations.

evaluation: The comparison of an object of interest with a standard of acceptability.

guided imagery: Guided imagery is a self-help technique in which an individual follows suggestions from a recording, doctor, or therapist, to focus their thoughts and create imagery that helps them relax and learn to manage specific physical symptoms or other issues.

healing:

health: The state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

health determinants: The forces predisposing, enabling, and reinforcing lifestyles, or shaping environmental conditions of living, in ways that affect the health of populations.

health education: Any planned combination of learning experiences designed to predispose, enable, and reinforce voluntary behavior conducive to health in individuals, groups, or communities.

health enhancement: A dimension of health promotion pertaining to its goals of reaching higher levels of wellness beyond the mere absence of disease or infirmity.

health promotion: The process of enabling people to increase control over, and to improve, their health.

herbal therapies: Herbal therapies include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations. Traditional use of herbal medicines refers to the long historical use of these medicines. Their use is well established and widely acknowledged to be safe and effective, and may be accepted by national authorities.

Homeopathic medicine: Homeopathic medicine is an non-mainstream Western system that is based on the principle that "like cures like," i.e., that the same substance that in large doses produces the symptoms of an illness, in very minute doses cures it. Homeopathic physicians believe that the more dilute the remedy, the greater its potency. Therefore, they use small doses of specially prepared plant extracts and minerals to stimulate the body's defense mechanisms and healing processes in order to treat illness.

holistic medicine: Holistic medicine is a system of health care that seeks to foster a cooperative relationship among all those involved, leading towards optimal attainment of the physical, mental emotional, social and spiritual aspects of health. It emphasizes the need to look at the whole person, including analysis of physical, nutritional, environmental, emotional, social, spiritual and lifestyle values. It encompasses all stated modalities of diagnosis and treatment including drugs and surgery if no safe alternative exists. Holistic medicine focuses on education and responsibility for personal efforts to achieve balance and well being.

lifestyle: The culturally, socially, economically, and environmentally conditioned complex of actions characteristic of an individual, group, or community as a pattern of habituated behavior over time that is health related but not necessarily health directed.

massage: Massage therapists manipulate the soft tissues of the body to normalize those tissues.

meditation: meditation is a self-directed practice for relaxing the body and calming the mind. The meditator makes a concentrated effort to focus on a single thought or sound to block out external stimuli. Most meditative practices come from Eastern religious practices but they can be found in all cultures of the world. Types of meditation include Transcendental meditation, mindfulness meditation, meditative prayer, etc.

meridians:

mind-body interventions: Mind-body interventions employ a variety of techniques designed to facilitate the mind's capacity to affect bodily function and symptoms. Only a subset of mind-body interventions are considered CAM. Many that have a well-documented theoretical basis, for example, patient education and cognitive-behavioral approaches are now considered "mainstream." On the other hand, meditation, certain uses of hypnosis, dance, music, and art therapy, and prayer and mental healing are categorized as complementary and alternative.

morbidity: The existence or rate of disease or illness in a population.

mortality: The event or rate of death in a population.

Native American medicine:

Naturopathic medicine: Naturopathic medicine views disease as a manifestation of alterations in the processes by which the body naturally heals itself and emphasizes health restoration rather than disease treatment. Naturopathic physicians employ an array of healing practices, including diet and clinical nutrition; homeopathy; acupuncture; herbal medicine; hydrotherapy (the use of water in a range of temperatures and methods of applications); spinal and soft-tissue manipulation; physical therapies involving electric currents, ultrasound and light therapy; therapeutic counseling; and pharmacology.

nutrition: Nutrition is a fundamental pillar of human life, health and development across the entire life-span. From the earliest stages of fetal development, at birth, through infancy, childhood, adolescence, and on into adulthood and old age, proper food and good nutrition are essential for survival, physical growth, mental development, performance and productivity, health and well-being.

Outcome evaluation: Assessment of the effects of a program on its ultimate objectives, including changes in health and social benefits or quality of life

paradigm:

placebo: An inert substance that is given to a control group of patients in a blinded trial. A placebo is used to distinguish between actual benefits of an intervention or medication and the benefit an individual expects to receive from an intervention or therapeutic treatment.

planning: The process of defining needs, establishing priorities, diagnosing causes of problems, assessing resources and barriers, and allocating resources to achieve objectives.

policy: The set of objectives and rules guiding the activities of an organization or an administration, and providing authority for the allocation of resources.

program: A set of planned activities over time designed to achieve specified objectives.

Qi (chi): Pronounced "chee," it is the energy that many Eastern philosophies believe connects and animates everything in the universe; it includes both individual qi (personal life force) and universal qi.

Qigong: Qigong is a component of traditional oriental medicine that combines movement, meditation, and regulation of breathing to enhance the flow of vital energy (qi) in the body, to improve blood circulation, and to enhance immune function.

quality of life: The perception of individuals or groups that their needs are being satisfied and that they are not being denied opportunities to achieve happiness and fulfillment.

regulation: The act of enforcing policies, rules, or laws.

risk factors: Characteristics of individuals that increase the probability that they will experience a disease or specific cause of death as measured by population relative risk ratios. Risk factors may include genetic, behavioral, and environmental exposures and sociocultural living conditions.

settings: Organizations or institutions where health promotion is carried out.

spirituality: Spirituality involves the cognitive and affective aspects of belief in a divine being and/or sacred or ultimate truth. One may experience spirituality through a number of routes or "structures" including religion, which could be described as the search for the sacred or divine through institutionally prescribed ways of viewing the world and living one's life. People may experience spirituality differently depending on whether one is a monotheist (belief in one God as in Christianity, Islam, and Judaism), a polytheist (a belief in a variety of divine beings or spirits as in Eastern traditions, such as Hinduism, and Native American traditions) or nontheistic (a belief not in a divine being but in the sacredness of life and/or nature as in "New Age," "emerging," or "humanistic" traditions).

spiritual healing: A process whereby an individual or group of individuals endeavors to bring about the healing of another person by using conscience intent or prayer, without the intervention of any known physical means.

stakeholders: People who have an investment or a stake in the outcome of a program and therefore have reasons to be interested in the evaluation of the program.

surveys: Methods of collecting information for a group or population to estimate the norms and distribution of characteristics from a sample, using direct observation, questionnaires, or interviews.

tai chi: Tai Chi is an ancient Oriental practice that consists of a sequence of movements, many of which are originally derived from the martial arts. Although the way they are performed in Tai Chi is slowly, softly and gracefully with smooth and even transitions between them. One of the avowed aims of Tai Chi is to foster the circulation of this chi (see qi) within the body, the belief being that by doing so the health and vitality of the person are enhanced.

Therapeutic Touch: Therapeutic Touch is derived from the ancient technique of "laying-on of hands" and is based on the premise that it is the healing force of the therapist that affects the patient's recovery and that healing is promoted when the body's energies are in balance. By passing their hands over the patient, these healers identify energy imbalances.

therapy: Treatment of a disease or pathologic condition. SEE: *treatment*

traditional medicine: Traditional medicine includes a diversity of health practices, approaches, knowledge, and beliefs incorporating plant, animal, and/or mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness. The terms "complementary medicine" and "alternative medicine" are used inter-changeably with traditional medicine in some countries.

Traditional Chinese Medicine: Traditional Chinese Medicine, also known as Traditional Oriental Medicine, emphasizes the proper balance or disturbances of qi (pronounced chi), or vital energy, in health and disease, respectively. Traditional Chinese medicine consists of a group of techniques and methods, including acupuncture, herbal medicine, oriental massage, and qi gong (a form of energy therapy described more fully below).

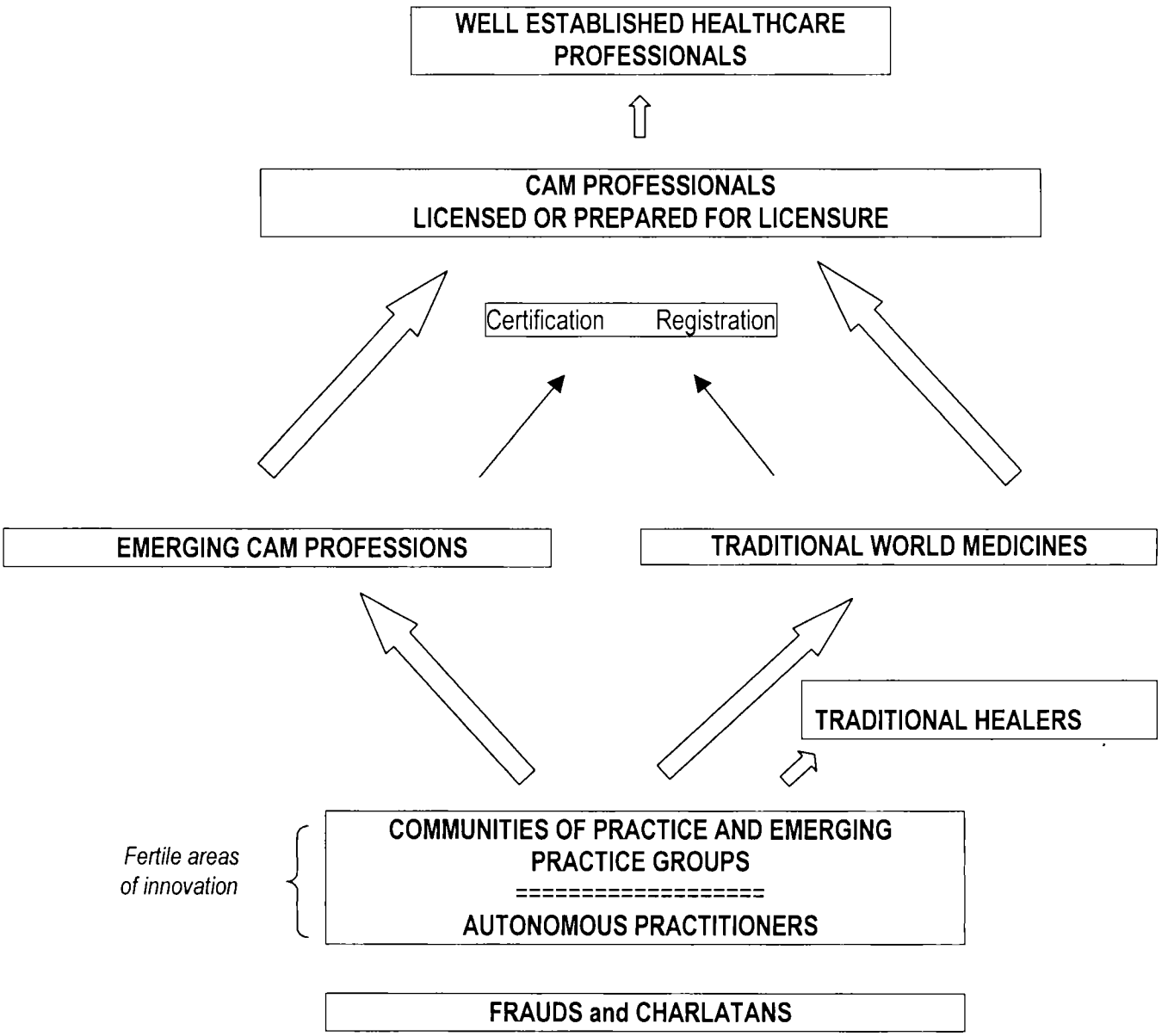
treatment: Any specific procedure used for the cure, management, or amelioration of a disease or pathological condition. Treatment can be active (i.e., directed specifically toward the cure of disease), causal/specific (i.e., directed toward the cause of the disease), expectant (i.e., directed at the relief of symptoms as they arise but not directed at a specific cause), palliative (i.e., designed for the relief of symptoms rather than curing a disease), preventive (i.e., directed to prevention of disease), supportive (i.e, employed to supplement specific therapy), and/or symptomatic (i.e., directed toward constitutional symptoms, such as shock and pain).

vitalism:

wellness: A dimension of health beyond the absence of disease or infirmity, including social, emotional, and spiritual aspects of health.

EMERGENCE OF CAM PROFESSIONAL GROUPS in the UNITED STATES

"A Credentialing Taxonomy"



Groft, Stephen (NCCAM)

From: Veronicapgdc@aol.com
Sent: Monday, January 28, 2002 4:20 PM
To: Groft, Stephen (NCCAM)
Subject: My list

Professional contacts

Congress of Chiropractic State Associations (50)
Federation of Chiropractic Licensing Boards (50)
National Board of Chiropractic Examiners
Association of Chiropractic Colleges (17 in U.S.)
5 National Associations (WCA, ICA, ACA, FSCO, CLA)
Research Journal-JVSR
Guidelines Council-CCP
Publications (The Chiropractic Journal, ICA Review, Clinical Chiropractic, etc)

State Legislators (Washington)
Gov. Gary Locke
Mike Kriedler, Insurance Commissioner
House and Senate Appropriations & Health Related Committee Chair (via our lobbyist)
Bob Drewel, Snohomish County Executive

Federal Legislators
Sen. Patty Murray
Congressman Rick Larsen
Senators Harkin, Lott, Hatch (2 sons-in-law are chiropractors), Congressmen Manzullo, Burton by way of our lobbyist in D.C. Probably more, but I know the above are chiropractic and alternative health supporters.

The Coalition
For Natural Health

BOYD J. LANDRY
Executive Director

1-800-586-4CNH (4264) • Fax 1-800-598-4CNH (4264)
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boydlandry@naturalhealth.org

100% RECYCLED PAPER

Traditional naturopaths

PHOTOCOPY
PRESERVATION

Kaczmarczyk, Joseph (NCCAM)

From: Groft, Stephen (NCCAM)
Sent: Wednesday, February 20, 2002 5:08 PM
To: Kaczmarczyk, Joseph (NCCAM)
Subject: FW: Revised Chapter by Chapter critique

WHCCAMP Report
chapter by chap...

-----Original Message-----
From: Max Heirich [mailto:mheirich@umich.edu]
Sent: Wednesday, February 20, 2002 7:33 AM
To: jsgordon@mindspring.com; sg18b@nih.gov
Subject: Revised Chapter by Chapter critique

This morning I awakened realizing that there needed to be an explanatory paragraph about chapters four and six before I shared my chapter by chapter critiques with the Commissioners. Please replace the attachment that I sent last night, for duplication and distribution, with the one that is attached here. Thanks.

A memorandum to Jim Gordon (and members of the White House Commission on Complementary and Alternative Medicine Policy):

Jim, I'm glad you found my earlier critique of the draft report helpful. You asked me to comment more specifically chapter by chapter. I have only a short time available this evening, but shall at least give it a try.

As noted earlier, the report has so many recommendations that one loses track of them. I think the Commission should prioritize the ones they most want to emphasize. Perhaps each of us should mark recommendations and action steps that seem the most critical to keep in the report. This memorandum will not attempt that. Instead it will share my overall reactions, chapter by chapter…

As you will see, I will be suggesting a different strategy for presenting the content of chapters four and six. My recommendations re: the kind of policy stance most likely to bring wide agreement with these chapters grows out of my own experience beginning in 1993. For four years I chaired a National Task Force of seventeen organizations that were attempting to write certification, training and performance guidelines for workplace health promotion. We faced similar issues to those confronting CAM policy advisers now, and my own first drafts were in many ways similar to the stance I see in WHC chapter drafts four and six. I learned the hard way that this approach can lose important support, and can splinter earlier effective coalitions. We regrouped, chose a slightly different strategy, and were eventually able to get national endorsement from a portion of the original coalition, after we had adopted an approach closer to the one I propose here. That experience colors my response to these chapters and the advice about that that I offer.

I hope these chapter-by-chapter summaries, taken from the notes I wrote in the margins as I read the draft, are useful. Best wishes to all, and congratulations on the progress made thus far. I think this can shape into a document that can have some real impact.

Now for the notes:

A missing ingredient that is much needed: An Executive Summary of no more than three to five pages.

Introduction and Chapter Two: The writing works fairly well, but the whole document will have more impact if it gets set in the context of larger public policy issues for which CAM developments could be relevant. (As discussed in my earlier note.) This could come either in the Introduction or in Chapter Two at the end. (Discussions in each later chapter then could point to their relevance for the policy issues identified early on in the Report.)

Chapter Three: This is a strong chapter. As I sketched out its argument and recommendation in my notes I wrote five comments in the margins: "Recommendation 1, that federal agencies should receive increased funding for clinical, basic and health service CAM research, ignores what tax cuts have done to federal budgets. If this recommendation is taken seriously, it is likely to mean less funding for other activities. Given political pressures to protect current budget allocations, how can we make this more than a platitude? Should we specify how this might be done, in the present budgeting context, or simply leave it as a generalized wish?"

"Recommendation 3, action step 3.1: HOW should the Federal government stimulate private investment in research on CAM modalities and approaches designed to improve self-care and wellness behaviors? An excellent idea, but too vague."

Under Research Training and Infra-structure, just before Recommendation #8, I noted that "NCCAM seems to be planning to discontinue funding of CAM research centers and to be returning to simple funding of individual research or education grants. This will have implications for how CAM researchers collaborate and interact, and for the range of CAM-related activities they can undertake. Does the WHC want to address this, or not? Most of #8 assumes that the Centers will continue."

"Is it also important to strengthen the ability to study CAM when used outside conventional medical clinical settings for research?"

** "Does 9.1 recommend the right agencies? In my earlier testimony I had recommended giving NIH and AHRQ joint responsibility for conducting and updating systematic reviews of peer-reviewed research literature on safety, efficacy, and costs of CAM practices and products. Washington insiders took me aside and suggested that the National Library of Medicine might be better positioned to do this and might be freer from political pressures to shape reviews. They suggested that AHQR has received such heavy criticism that it is very cautious about what it does. Is this good advice?"

Chapter Four: Education and Training of CAM and Conventional Practitioners I had more trouble with this chapter, because I thought some of the recommended action steps did not recognize the range of useful CAM training programs that now exist. Some work well as they are, and might be hampered by trying to force them into the "alternative medical school" model that works well for chiropractery and naturopathy. Specifically,

1.6: Should CAM training programs be made more uniform? What will be gained? What will be lost?

1.7: Are we trying to convert all CAM practice to a variation on the medical model? For what kinds of training programs are common backgrounds in science, physiology, etc., as understood in western medicine needed? Might such training be superfluous, or hamper the kind of training being given in some modalities?

1.8: A good suggestion. Why not try it first with Chiropractic colleges and Colleges of Naturopathy?

1.9: An interesting idea. Voluntary or mandatory? And what content?

Chapter Five: CAM Information Development and Dissemination: An important topic. Some of the content of this chapter repeats what is elsewhere. We should decide what belongs where….

The first recommendation is too vague, and action step 1.2 seems too global. How would we accomplish that goal?

Chapter Six: Access to and Delivery of CAM: This chapter struck me as being the most problematic chapter in the report. It advocates a particular solution to problems of access and delivery, rather than laying out the problems that are under discussion, the range of solutions that are in contention, currently, and suggesting advantages and disadvantages of the various ways in which these issues currently are addressed. It totally ignores policy positions such as that adopted by the State of Minnesota, or the kinds of issues being looked at in California. If the chapter followed an alternate strategic approach, which I would recommend, it could acknowledge the variety of legitimate concerns that need to be addressed, the implications various solutions will have for the future, and pose a series of questions that need to be addressed when deciding these issues. I think it is important for this to be done. If the chapter does not take this kind of "balanced approach" it will generate contention and distrust, and the Commission might get charged with attempting to railroad solutions that benefit one CAM interest group at the expense of others. Some groups within CAM will see the present chapter as offering a version of the "AMA strategy" that was used in the early 20th century, when many of the traditions now seeking a legitimate role in health care were forced to the sidelines through political means. I think it is important to avoid that kind of labeling of the Commission's work.

More specific comments on chapter six:
Recommendation #1 will take the Commission into a highly political and politicized arena. I think it is unrealistic to assume that all states will follow a uniform set of recommendations, or that those who do accept such recommendations will apply them uniformly.

Instead, why not emphasize that regulatory reform is needed, and perhaps discuss how different types of regulatory reform will affect present CAM practice and its relation to conventional medicine?

I have not read the Federation of State Medical Boards' model guidelines to regular "unconventional medical practice", but I wondered whether State Medical Boards' concerns provide an appropriate model for us… E.g., One of the unresolved struggles within CAM concerns the extent to which MDs will dominate decision-making and practice for CAM uses. Without further explanation, this proposal sounds like it might be "asking foxes to guard the henhouse". Perhaps that's unfair. If p 8 spelled out what their model guidelines look like, readers could judge for themselves. The first paragraph of p 9 might be all right.

Recommendation #2 and its action steps, if adopted, could set in motion a set of dynamics that would change the historic character of much of CAM. Thus this recommendation and the way it is discussed in this draft could set off a hue and cry within the CAM constituency that could dissipate support for the Commission and its work. The chapter and its recommendations, as currently drafted, runs the risk of generating hostile reactions that could dominate discussion of the entire report.

(I am not suggesting that the Commission needs to avoid all controversy. Rather, the FIRST White House Commission of CAM Policy needs to set a tone for future discussion of contentious issues.)

I think the subject matter of this chapter would be better addressed by spelling out the issues that need to be considered when adopting policy in this area: e.g., protection of the public, maintaining free competition in the provision of CAM services, protection and preservation of CAM styles and traditions of working, freedom to choose health workers in whom one has confidence, etc. (I haven't thought out these parameters very well, but they at least get one started.) Then one can discuss the different solutions that are being advocated, and their advantages and disadvantages for each of the concerns you have identified. One might propose careful observation of the experiments currently underway re: regulation in different states, and propose a series of questions to ask about their effects over time. The answers to these questions, then could guide policy groups in the future who try to address these issues….

Chapter Seven: Coverage and Reimbursement is a strong chapter, overall. I suggest that the Commission should decide whether it is advocating "cost-benefit" studies or "cost effectiveness" studies. These have rather different implications for what one analyzes and how one draws conclusions. (I suspect you want to recommend "cost-benefit" analysis, which normally utilizes a much less complex set of variables and shorter time spans.)

On p 5, lines 14-23 strike me as making a somewhat naïve argument, that might be dismissed by health policy experts. "interventions known to be safe and beneficial should be reviewed and given consideration for coverage under health benefit programs (whether conventional medicine or CAM). I agree with the principle, but this recommendation ignores how benefits payments actually work. If something is an accepted procedure for reimbursement, it gets reimbursed regardless of what else also is being done. Thus adding CAM procedures to the approved list does nothing to discourage continuation of other, more expensive and possibly less effective treatments. Every time you add something to the approved benefits list you increase the cost for care-- This means that in order for such a recommendation to be taken seriously, and implemented, we will need to suggest a way to do this that leads to use of the cheapest and most effective strategies for dealing with a health problem, rather than a proliferation of health care costs.

"Equitable and impartial consideration of safe, effective CAM interventions—Coverage policies and processes need to indicate how to do this without escalating total health care spending.

What do we mean by "medically necessary" on pp 17-18?

Under discussion of the Tax Code, what about suggesting "performance-based" tax credits for CAM and prevention programs that lower health risks, during the time period before lowered disease care costs will compensate for the additional costs incurred in using these strategies? (action step 2.6 also)

Recommendation #2 might need an additional clause, such as this: "and develop reimbursement strategies that will encourage use of those services that are most effective for the least cost"

Chapter Eight: CAM in Wellness and Health Promotion has some excellent proposals, but the "voice" of the chapter needs work in order for it read persuasively.

Recommendation #1 probably needs rewording. We seem to advocate use of CAM and then ask for research to see if it works…. The last paragraph on p 8 seems to hand over responsibility for CAM promotion to groups unlikely to make this a high priority (e.g. Institute of Medicine and Public Health Association).

Recommendation # 2 and action steps 2.1 and 2.2 strike me as excellent.

The sidebar for workplace health promotion is excellent

Recommendation #3, action step 3.2 needs rewording. And here might be a place to advocate performance-based tax incentives….

P 13 "Federal programs should serve as a model…" How? And how relate this to cost-benefit concerns?
Recommendation 4, action step 4-1 strikes me as too vague. It lists several agencies that should incorporate safe and effective CAM practices into their services, but does not suggest what or how.

4.3 struck me as particularly promising.

I also really liked 4.5, but wanted a bit more specificity about how this might be done.

Chapter Nine: Coordinating Federal CAM Efforts has some intriguing suggestions.

I would recommend changing some of the language used to describe the Advisory Council: "would bring together the various stake holders in CAM to develop an agenda that reflects public opinion" This language can be read as meaning that people with vested interests and money in the CAM community will shape public opinion. Some word other than "stake holders" might serve better.

I think the recommendation sets too limited tasks for this office: The office should do more than "coordinate and facilitate the integration of safe and effective complementary and alternative health care practices into the nation's health care system". It should also help preserve the independence of alternative medicine, etc., etc.

This chapter will be appealing IF chapters four and six have more balanced discussion of the issues they address, and IF chapter seven can address inclusion of reimbursement in a context that does not threaten major escalation of health care costs. If those problems are not addressed, various public interests are likely to resist creating a federal agency that could play a role they would consider as detrimental to the public's interest, or that might become a vehicle for interest-group domination of decision making.

This chapter provides a potentially attractive solution to how to move forward. This should not be the final ending note, however. There needs to be some kind of summary statement that provides a powerful emotional appeal for proceeding with the agenda laid out in this report.

Part XI: Appendices

A. List of Commission Meetings and Topics
B. List of Commission Meeting Invited Panelists
C. List of Open Public Session Presenters
D. List of Town Hall Meetings, Questions Addressed, and Participants
E. Executive Order 13147 and Amendment
F. Appropriation Language Providing Support for the Commission's Activities
G. WHCCAMP Charter
H. List of Organizations Responding to WHCCAMP Requests for Information
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J. List of Recommendations and Suggested Implementation Actions By Responsible Organizations (DHHS, NIH, FDA, Private Sector, etc.)
K. Glossary and Acronyms

Part XII: Index

SG21802

Disposition Significant Issue

- Accept the Report

-

Follow Up - Telephone Final Review of Some Questions

~~Final Town~~ Commission - Issues "Can You Live

What can't you live with & how should it be stated

Groft, Stephen (NCCAM)

From: Kaczmarczyk, Joseph (NCCAM)
Sent: Wednesday, February 27, 2002 6:22 PM
To: Groft, Stephen (NCCAM); 'jjfins@mail.med.cornell.edu'
Subject: RE: Action1.6

Importance: High

27 Feb 02

Steve and Joe,

Here is what I had in my notes...

"DHHS 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 which include FP, internists, Peds, Ob/GYNs, as well as PAs, NPs, CNMs, dentists, and mental health professionals. This feasibility study could lead to demonstration projects to identify: 1) the type of practitioners, 2) necessary education and training, 3) practice setting, and 4) health care outcomes associated with [JJ's penmanship was illegible] with the addition of these practitioners and services to comprehensive care." the necessary training education

I modified it to say...
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) necessary education and training, 3) practice setting, and 4) health outcomes attributable to the addition of these practitioners and services to comprehensive care.

Joe

-----Original Message-----
From: Groft, Stephen (NCCAM)
Sent: Wednesday, February 27, 2002 5:54 PM
To: Kaczmarczyk, Joseph (NCCAM)
Subject:

Joe,

Do you have a copy of the recommendation that Joe Fins put together on friday. he called and wanted to discuss tomorrow afternoon at 1

If you have it, could you e-mail it to Joe Fins.

How did the 3Joes get into this one?

Thanks.
Steve

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PROFESSIONAL ISSUES

VA says "no" to chiropractors as primary care physicians

But the Dept. of Veterans Affairs legislation does create an advisory committee that could recommend expansions to chiropractic scope of practice.

By Jay Greene, *AMNews* staff. March 4, 2002.

Language allowing chiropractors to be designated as primary care physicians in the VA was not included in a bill signed recently by President Bush.

The legislation, however, authorizes the Dept. of Veterans Affairs to create a chiropractic advisory committee to recommend policies on referrals, direct access, scope of practice and service definitions of chiropractic care. The advisory committee, which includes chiropractors and physicians, has authority through 2004.

Officials for the American Academy of Family Physicians, one of the physician groups that opposed the chiropractic provisions, said they were pleased that the primary care designation was taken out of the bill because they don't believe chiropractors are primary care physicians. In the VA, primary care physicians typically treat patients with hypertension, heart disease, diabetes, pulmonary diseases, depression and other diseases.

"We believe there is a role for chiropractors in the VA system. We just don't believe they are trained to serve as primary care providers at this time," said Warren Jones, MD, AAFP president and former medical director at the Defense Dept. "If you have chiropractic needs, we think veterans should have access to a chiropractor."

While Dr. Jones has some reservations about the VA chiropractic advisory committee, he said similar committees on chiropractic care that he has dealt with in the past at the Dept. of Defense had worked well.

"I am confident the committee will look at the skills chiropractors possess and the needs of veterans and come up with appropriate

decisions," said Dr. Jones, a clinical professor of family medicine at the University of Mississippi Medical Center in Jackson. "Chiropractors are not trained to make differential diagnosis like a primary care physician. Physicians will refer to chiropractors for low back pain if warranted."

The bill also requires the VA to "designate at least one site [for chiropractic services] in each geographic service area." Current VA policy allows chiropractors under professional service contracts to treat veterans for "chiropractic spinal manipulative therapy for musculoskeletal problems of the spine."

Although supportive of making chiropractic care available to veterans, Dr. Jones said he was concerned that mandating services in every region could lead to inappropriate use of resources. "If a physician wants to refer to a chiropractor, we hope that is made available to veterans," he said. "I have referred patients with low back pain to chiropractors, but only after I ruled out other more serious conditions."

Officials for the American Chiropractic Assn. said mandating services in every region is important because they say the VA has been slow to make available chiropractic care in certain areas. VA officials say demand is low in some regions.

Another provision in the bill requires the VA to "carry out the program through personal service contracts and by appointment of licensed chiropractors in department medical centers and clinics." The VA currently contracts with chiropractors and is working on job pay scales to hire chiropractors in high demand areas, officials said. A congressional committee estimates that it would cost $800,000 the first year to hire chiropractors.

The VA bill -- "Disabled Veterans Service Dog and Health Care Improvement Act of 2001" -- also features requiring service dogs to be provided to disabled veterans, additional specialized treatment for veterans and the creation of a nursing commission to address the issues associated with an aging veteran population.

Back to top.

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Groft, Stephen (NCCAM)

From: Dr. Joe Pizzorno [drpizzorno@salugenecists.com]
Sent: Wednesday, February 27, 2002 9:34 AM
To: Stephen Groft

Steve,

A couple of things:
1) I notice the growth in CAM institution enrollment data I provided was not included. I think this an important balance to the growth in CAM programs at conventional institutions.
2) We did not address the issue of order.
3) I've not received a request for available times for the conference call. My schedule (as I am sure is true of other Commissioners) is quite full, and getting worse.

Joe

Groft, Stephen (NCCAM)

To: drpizzorno@salugenecists.com
Subject: RE: Follow up

Joe,

There are so many things we can and should talk about as

-----Original Message-----
From: Dr. Joe Pizzorno [mailto:drpizzorno@salugenecists.com]
Sent: Monday, February 25, 2002 10:50 AM
To: Groft, Stephen (NCCAM)
Subject: RE: Follow up

Steve,

Congratulations again on saving the Commission and leading us to develop a successful process. I am so impressed with your organizational and interpersonal skills. The report we created and recommendations we are sending to Congress will facilitate the advancement of the U.S. healthcare system. I hope you take a lot of pride for your accomplishments.

I left Friday with one major concern: the lack of a Commission decision on the compromise Joe Fins and I worked out. Joe told me that our agreement was the high point of the Commission process for him and a harbinger of the ability of CAM and conventional to work together. I feel very strongly that Joe should experience this success that is so important to him. Obviously, I wanted much more supportive language for CAM inclusion in rural and underserved loan forgiveness programs, but am intent on following through on the compromise in the spirit of facilitating the collaboration the CAM and conventional systems need to achieve. I request it be the first topic we discuss at the conference call.

Re the conference call: It seems to me that all we have to discuss is loan forgiveness recommendation language. Considering the streamlined process we used for the text of the other sections, the text of Access and Delivery could be easily handled just through written feedback from the Commissioners. I am concerned that, unless strictly curtailed, the conference call could serve as a forum to reopen discussion of any recommendation or text already agreed to. Considering the grueling hours last week working laboriously through the recommendations, I believe any discussion of decisions already made should be strictly off limits.

Attached is a CAM taxonomy diagram Pam Snider and I created after discussion with Tieraona. Assuming it looks reasonable to you, I suggest forwarding to Max and Maureen. I think it helps differentiate the various CAM practitioner communities.

Finally, a reminder to utilize the designation Dr. for my bio. I notice it had not been changed in the last bio printing.

Joe

Marriott's
DESERT SPRINGS VILLAS
A Marriott Vacation Club Resort

Facsimile transmittal – Cover Sheet

To: Steve Graff Fax: 301-480-1691

From: Susanne Gutierrez Date: 2-26-02

Re: Yesterday's phone conversation Pages: 5, including cover pg.

1091 Pinehurst Lane, Palm Desert, CA 92260 Phone (760)779-1200 Fax (760)779-1203

The last minute broadside by Joe Jing on Friday, before adjournment, was unexpected, unskilled for, and unforgivable as relates to the NHSC.

From the first meeting my position has been that chiropractors deserve an opportunity to serve & prove that they have a unique and desirable approach to healthcare. Chiropractic has proven to be safe & effective & chiropractors are valuable healthcare team members.

It's not possible to accept that individuals living in areas designated as MUA's are less deserving of free choice in healthcare than others.

I will not support, but will emphatically oppose, any effort to expand Title III loan forgiveness unless chiropractors are included on the health care team as part of the Primary Recommendations.

At this point, a feasibility study is an unacceptable compromise. A demonstration project is a compromise position.

If at the end of a demonstration project, chiropractic does not prove to be a service of choice, is not proven to be safe & effective or have any value, then and only then do chiropractors NOT deserve to participate.

Until that time all of the Commission's Guiding Principles support the opportunity for chiropractors to serve.

Veronica Betancourt

Senate Bill 1281

Includes Chiropractors in VHSC
However, the bill as written states that:
"(1) Chiropractic doctors are skilled at providing a wide range of ~~primary~~ HEALTH ~~care~~ services
(2) Chiropractic doctors are often the only providers available to provide ~~health care~~ in many rural communities

This bill has been opposed by a faction of Chiropractors who believe Chiropractors are trained to fulfill the requirements of the Public Service Act, where the definition of primary health care services means:
"health services regarding family medicine, internal medicine, pediatrics, Ob-gyn, dentistry or mental health."

In this context ~~I agree~~ Chiropractors do not qualify. However, the legislation does reaffirm my earlier contention that there is a legislative intent to include Chiropractic.

Sen. Kennedy also introduced S.1533, which initially included Chiropractic. However, the funding section was stripped. I have not seen the legislation, but if the content was the same as S.1281, I would totally concur!

Again, since my first meeting, I have stated that Chiropractic is not Chiropractic medicine, and Chiropractors are not Chiropractic Physicians. This terminology only serves to confuse the public perception of what we do and why.

The role that Chiropractors can play as primary care providers (see the VA bill) and health care team members is defined by the Association of Chiropractic Colleges/ ACC Paradigm. I submitted this document months ago & Dr. Fabrizio Mancini (Parker College of Chiropractic President) presented it as the model again in December 2001.

This document was signed by all Chiropractic college presidents & endorsed by all the national & International associations (ACA, ICA, WCA, FSCO), the NBCE, the FCLB, and the Congress of Chiropractic State Associations (COSA).

In summary: Chiropractors locate & correct subluxations & remove interference to the nerve system's ability to maximize expression & function. Chiropractors work with the body's innate ability to heal itself. We facilitate the body's ability to heal from the inside-out. We are holistic in our approach

This is a unique & clearly different approach to health promotion - disease prevention.

The allopathic model offers drugs & surgery to relieve pain and diagnose & treat symptoms. The mechanistic approach.

With this re-iteration of what Chiropractic is & what Chiropractors do, I trust the Commission will ~~~~ recommend Chiropractors to be included within the VHSC within their scope of training & the paradigm defined throughout the profession.

Veronica Gallegos DC

More information?

Veronica through 3/2 @ 760-779-1200, Room 9672

Jay 760-779-1203

Jim Alcantara: 202-659-2979

Groft, Stephen (NCCAM)

From: Boyd J. Landry [boydlandry@naturalhealth.org]
Sent: Wednesday, February 27, 2002 12:08 PM
To: Groft, Stephen (NCCAM)
Subject: RE: CA SB 577

Thanks for the "traditional naturopath"

http://info.sen.ca.gov/pub/bill/sen/sb_0551-0600/sb_577_bill_20010419_amended_sen.html

BILL NUMBER: SB 577 AMENDED
BILL TEXT

AMENDED IN SENATE APRIL 19, 2001

INTRODUCED BY Senator Burton

FEBRUARY 22, 2001

An act to add Section 2053.5 to the Business and Professions Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

SB 577, as amended, Burton. Health: complementary medicine and alternative health care practitioners

Existing law regulates the practice of medicine in the state, and in that regard prohibits persons who are not licensed as physicians and surgeons from engaging in certain activities constituting the practice of medicine.

This bill would require the State Department of Health Services to conduct a study and report to the Legislature regarding the types of complementary medicine available in the state, the regulation of complementary medicine and complementary medicine practitioners, an evaluation of options for oversight of the complementary medicine industry, and ways to promote consumer access.

This bill, notwithstanding any other provision of law, would provide that a person who discloses to a client that he or she is not a licensed physician shall not be in violation of certain provisions of the Medical Practice Act unless that person engages in specified diagnosis, treatment, and other activities with respect to another person.

This bill would also make various findings of the Legislature concerning the utilization of complementary and alternative health care services.

Vote: majority. Appropriation: no. Fiscal committee: yes no. State-mandated local program: no.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. (a) The State Department of Health Services

SECTION 1. The Legislature hereby finds and declares all of the following:

(a) Based upon a comprehensive report by the National Institute of

Medicine and other studies, including a study published by the New England Journal of Medicine, it is evident that millions of Californians, perhaps more than five million, are presently receiving a substantial volume of health care services from complementary and alternative health care practitioners. Those studies further indicate that individuals utilizing complementary and alternative health care services cut across a wide variety of age, ethnic, socioeconomic, and other demographic categories.

(b) Notwithstanding the widespread utilization of complementary and alternative medical services by Californians, the provision of many of these services may be in technical violation of the Medical Practice Act (Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code). Complementary and alternative health care practitioners could therefore be subject to fines, penalties, and the restriction of their practice under the Medical Practice Act even though there was no demonstration that their practices are harmful to the public.

(c) The Legislature intends, by enactment of this act, to facilitate access by Californian residents to complementary and alternative health care practitioners who are not providing services that require medical training and credentials. The Legislature further finds that these nonmedical complementary and alternative services do not pose a risk to the health and safety of California residents, and that restricting access to those services due to technical violations of the Medical Practice Act is not warranted.

SEC. 2. Section 2053.5 is added to the Business and Professions Code, to read:

2053.5. Notwithstanding any other provision of law, a person who discloses to a client that he or she is not a licensed physician shall not be in violation of Section 2051, 2052, or 2053 unless that person does any of the following:

(a) Conducts surgery or any other procedure on another person that punctures the skin or harmfully invades the body.

(b) Administers or prescribes x-ray radiation to another person.

(c) Prescribes or administers legend drugs or controlled substances to another person.

(d) Recommends the discontinuance of legend drugs or controlled substances prescribed by an appropriately licensed practitioner.

(e) Willfully diagnoses and treats a physical or mental condition of any person under circumstances or conditions that cause or create great bodily harm, serious physical or mental illness, or death.

(f) Holds out, states, indicates, advertises, or implies to a client or prospective client that he or she is a physician, a surgeon, or a physician and surgeon. shall conduct a study based on existing literature, information, and data on the scope of complementary medicine in California. The study shall include:

(1) A report on the types of complementary medicine therapies available in the state.

(2) A report on existing regulation of complementary medicine and complementary medicine practitioners.

(3) An evaluation of options for oversight of the complementary medicine industry in order to protect providers and consumers.

(4) A report recommending ways to promote consumer access to a broad range of healing and health care information.

(b) The study shall be submitted to the Legislature no later than October 1, 2002.

Boyd J. Landry
PMB 100-408
1220 L St. NW
Washington, DC 20005
202-586-4264
202-598-4264 (fax)
202-216-9488 (DC Residents)
boydlandry@naturalhealth.org
http://www.naturalhealth.org

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> -----Original Message-----
> From: Groft, Stephen (NCCAM) [mailto:grofts@od31em1.od.nih.gov]
> Sent: Wednesday, February 27, 2002 10:45 AM
> To: 'boydlandry@naturalhealth.org'
> Subject: RE: CA SB 577
>
>
> Boyd,
>
> Thank you. i was unable to open as such. Could you copy and
> send as a full
> text in the E-mail.
>
> Take it easy.
>
> Steve
>
> -----Original Message-----
> From: Boyd J. Landry [mailto:boydlandry@naturalhealth.org]
> Sent: Wednesday, February 27, 2002 11:46 AM
> To: Groft, Stephen (NCCAM)
> Subject: CA SB 577
>

http://info.sen.ca.gov/pub/bill/sen/sb_0551-0600/sb_577_bill_20010419_amended_sen.pdf

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CAM in Wellness and Health Promotion

(Note: The term "evaluation" is used broadly and includes research and demonstration programs as appropriate. This will be explained in the text)

Recommendation 1: CAM practices and products that have been shown to be safe and effective should be evaluated to determine their potential to promote wellness and help achieve the Nation's health promotion and disease prevention goals.

Actions :

1.1 The Healthy People Consortium should evaluate the role of CAM practices and products in addressing the 10 leading health indicators and develop strategies to encourage the use of those CAM practices and products found to have benefit in addressing these indicators.

1.2 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. Information from these data should be incorporated into the *Healthy People 2020* goals and objectives where appropriate.

1.3 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 healthy 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.

1.4 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. Those found to be applicable should be include in school curriculums as appropriate.

1.5 The Health Resources and Services Administration, the Centers for Disease Control and Prevention, the United States Department of Agriculture, 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 potential benefit should be included in the guidelines.

1.6 Federal agencies, in partnership with the business community, should develop incentives for schools to make available healthier school lunches and snacks, 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

1.7 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 subsequently include them in Federal worksite wellness and health promotion programs and Federal health coverage plans as appropriate.

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PROFESSIONAL ISSUES

VA says "no" to chiropractors as primary care physicians

But the Dept. of Veterans Affairs legislation does create an advisory committee that could recommend expansions to chiropractic scope of practice.

By Jay Greene, *AMNews* staff. March 4, 2002.

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"I am confident the committee will look at the skills chiropractors possess and the needs of veterans and come up with appropriate

decisions," said Dr. Jones, a clinical professor of family medicine at the University of Mississippi Medical Center in Jackson. "Chiropractors are not trained to make differential diagnosis like a primary care physician. Physicians will refer to chiropractors for low back pain if warranted."

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Although supportive of making chiropractic care available to veterans, Dr. Jones said he was concerned that mandating services in every region could lead to inappropriate use of resources. "If a physician wants to refer to a chiropractor, we hope that is made available to veterans," he said. "I have referred patients with low back pain to chiropractors, but only after I ruled out other more serious conditions."

Officials for the American Chiropractic Assn. said mandating services in every region is important because they say the VA has been slow to make available chiropractic care in certain areas. VA officials say demand is low in some regions.

Another provision in the bill requires the VA to "carry out the program through personal service contracts and by appointment of licensed chiropractors in department medical centers and clinics." The VA currently contracts with chiropractors and is working on job pay scales to hire chiropractors in high demand areas, officials said. A congressional committee estimates that it would cost $800,000 the first year to hire chiropractors.

The VA bill -- "Disabled Veterans Service Dog and Health Care Improvement Act of 2001" -- also features requiring service dogs to be provided to disabled veterans, additional specialized treatment for veterans and the creation of a nursing commission to address the issues associated with an aging veteran population.

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Groft, Stephen (NCCAM)

From: Judy Simpson [Simpson@musictherapy.org]
Sent: Friday, February 15, 2002 2:32 PM
To: Groft, Stephen (NCCAM)
Subject: Music Therapy

Dear Director Groft,

We met briefly during earlier meetings of the WHCCAMP and I was recently informed you needed additional information regarding music therapy. I referred some of your questions to the Certification Board for Music Therapists (cbmt.com) as the questions related to issues around credentials. Perhaps they have already sent the information you requested.

The question that relates to our association regarded the number of schools which offer a music therapy degree. There are 70 schools with undergraduate programs (which is entry level for our profession) and 25 of those schools also offer graduate music therapy programs.

If you need additional information, please feel free to contact me directly and I would be happy to assist.

Sincerely,
Judy Simpson

Judy Simpson, MT-BC
Government and Public Relations Associate

American Music Therapy Association
8455 Colesville Road, Suite 1000
Silver Spring, MD 20910
tel: 301-589-3300
fax: 301-589-5175
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3500 350,000 ← 350-0

Research

Art Therapy & Music Therapy

Judy Simpson

Meyerhoff

White House

B

M.S

Board Certification

Board

Stephen Cassaday

Schools – Service – (Fund Gov, Gov)

HRSA School Health

– Violence Towards Women

– Abuse to Children – Prevention & aftercare

– Elderly

– Mental Health

NIMH NIA NCI NCCAM NCCAM

CHID ⟷ Check

Educating membership

– Public/Relations

Federal Issues

State Issues

Groft, Stephen (NCCAM)

To: Veronicapgdc@aol.com

Cc: WHCCAMP Staff

Subject: RE: Background Information for February 21-22 Meeting

Veronica,

Thank you for the suggestions. I will pass these on to ther staff to review and we can discuss at the meeting. I believe the terms medical necessity and perhaps medical criteria are in the law and we are not able to change the law as written. C ongress could do it with addittional legislation.

Steve

-----Original Message-----
From: Veronicapgdc@aol.com [mailto:Veronicapgdc@aol.com]
Sent: Thursday, February 14, 2002 11:35 PM
To: Groft, Stephen (NCCAM); tierney334@yahoo.com; cmapaz@totacc.com; Bresler@aol.com; DeanOrnish@aol.com; drwarren@artelco.com; EastWestQi@aol.com; gbernier@utmb.edu; georged@ashn.com; jsgordon@mindspring.com; drpizzorno@salugenecists.com; jjfins@mail.med.cornell.edu; Jrsct6@cs.com; linnealarson@mac.com; Tom@toms-of-maine.com; Lowdogmd@aol.com; wjonas@usuhs.mil; DrFair@haelth.com; MingTian@aol.com
Subject: Re: Background Information for February 21-22 Meeting

Thank you so much for the opportunity to review online the material we will be receiving tomorrow.

I've just completed reading the Recommendations and Actions and would like to mention some items that give me some concern about their wording.

Coordination of Research
Recommendation 3: Please consider: "Federal.....and self care, and (delete on); (insert) identify such therapeutic approaches that congruently integrate CAM and conventional medicine.

This allows for the previously discussed option to integrate or not.

Recommendation 7.6: final sentence: "..and what they find satisfying or unsatisfying about them."

I've always found that terminology odd. I would suggest, "...and how they are perceived to impact quality of life issues."

Education and Training
Recommendation 1, Action step 11.1.

It still reads to me as if the "conventional" health professionals will play the role of gatekeepers. Please end the sentence as it reads with "...so that conventional health professionals can discuss CAM with their patients and clients." Delete: "and guide them in the appropriate use of CAM."

A well informed consumer (and that is one of our goals) does not necessarily need guidance. Having a pediatrician throw his hands up in the air this week when one of our patients told him she was taking her ten year old son off milk and bringing him into a chiropractic office was inappropriate "guidance". The patient has made the decision to immediately find another pediatrician.

Action step 1.2 - I would like to see some examples given for "fundamental elements of biomedical science and conventional practice in order to ensure safe and beneficial care of patients."

Are we talking about consent for care disclosure forms? Malpractice coverage?

Action step 1.7 - The recommendation sounds rather overwhelming to me, as written. I would suggest adding "where needed" to the end of the first sentence, so that is doesn't sound like all professions need to return to the drawing board.

Coverage and Reimbursement

Recommendation 2: makes reference to "qualified" practitioners. Will there be a definition somewhere in the document of "qualified"? This becomes a very subjective term otherwise.

Action Step 2.8 - I've addressed this terminology in the public meeting of December. Let's change the term "medical" to "clinical". Medical criteria and medical necessity for complementary and alternative health care approaches often don't exist.

Thank you, again, for the opportunity to comment. The document is rapidly approaching wonderful!

Veronica

Groft, Stephen (NCCAM)

From: Linnea Larson [linnealarson@mac.com]
Sent: Monday, February 04, 2002 12:58 PM
To: jsgordon@mindsrping.com; Groft, Stephen (NCCAM); Tom@tomsofmaine.com; tierney334@yahoo.com; cmapaz@totacc.com; Bresler@aol.com; DeanOrnish@aol.com; drwarren@artelco.com; eastwestqi@aol.com; gbernier@utmb.edu; georged@ashn.com; drpizzorno@salugenecists.com; jjfins@med.cornell.edu; jrsct6@cs.com; lowdogmd@aol.com; wbjonas@aol.com; veronicapgdc@aol.com; mingtian@aol.com; Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Miller, Maureen (NCCAM); Kaczmarczyk, Joseph (NCCAM); Fisher, Ken (NCCAM); jpswyers@starpower.net; Pollen, Geraldine (NCCAM); tom@neweconomy.org; linnealarson@mac.com
Subject: Comment on the nature of report recommendations

Hello Good People,

I have continued to review the drafts since the January 25 deadline for submission of our comments. I hope, although the deadline is passed, that this can be used on this phase of our work.

The report contains many recommendation statements and action items that encourage "private and nonprofit organizations" to do one thing or another. Such recommendations fall outside the scope of our charge set forth in Executive Order 13147 as follows..."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." Since the actions of "private and nonprofit organizations" do not constitute public policies our call for such actions is outside the scope of our charge.

This is not to say that the actions of "private and nonprofit organizations" are unaffected by or unrelated to the implementation of public policies. Clearly, the public goal of ensuring an adequate supply of allopathic physicians, for example, is fulfilled in part, through the actions of private institutions. And, there are many other examples. But, it is our charge to identify ways that public policies can effectuate similar benefits related to CAM.

So if we want our recommendations to affect the actions of "private and nonprofit organizations" we should call on the President to do this. The President, especially with the support of the Congress, has vast resources to direct toward such ends. These characteristically are applied as positive or negative incentives (i.e., payments for desired actions and penalties for undesired actions).

Appeals to private initiative, while well intentioned, will not bring about the improvements in our healthcare system we all seek. A report developed within the scope of our charge will be most effective.

I would appreciate any comments anyone has to give me on this matter.

Thank you,

Linnea