Steve Gurfit

301-435-6199

June 2001 Commission Hearing

Summary and Analysis of Themes and Recommendations on Access and Delivery

This is a revised summary and analysis of themes and recommendations on access and delivery gleaned from a variety of sources, including written and oral testimony from the December 4-5, 2000 meeting of the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) on Access to and Delivery of Complementary and Alternative Medicine (CAM), town hall meetings, other topic-specific WHCCAMP meetings, and the Access and Delivery Breakout Session at the May 14, 2001 WHCCAMP meeting.

The following access themes, which can be classified generally as "barriers," are evident:

- Conventional medicine and physician resistance to CAM
- Reimbursement, coverage, and cost issues
- Balance of consumer choice and public safety (self-care)
- Needs of special populations
- Cultural and linguistic challenges (including Traditional Healing)

Conventional medicine and practicing physicians' resistance to and lack of acceptance of CAM is cited in testimony as the basis for non-disclosure of CAM utilization and as a barrier to access to CAM services. While the current reimbursement system is influenced by an evidenced-based approach, CAM generally lacks the type and amount of western scientific evidence on safety, indications, clinical effectiveness, and cost effectiveness sought by the current reimbursement system. Moreover, data on systems of care, multiple modalities, combination therapies, various delivery systems, and diverse populations are not available. The balance of consumer choice and public safety is evident in utilization of CAM as part of self-care, particularly in women's health, and is dependent on information which can be difficult to obtain, contradictory, and of questionable accuracy. Access to CAM by special populations such as HIV/AIDS, elderly, pediatrics, and cancer patients is characterized by more numerous and significant barriers than those experienced by the general population. Cultural and linguistic barriers to access to CAM are associated with recent immigrants, native peoples, and an increasingly diverse US population especially in the context of Traditional healing.

Likewise, the following Delivery themes are apparent:

- Integration of CAM vs. CAM autonomy
- Fragmentation of CAM
- Models of service delivery
- Service delivery of CAM to uninsured and underinsured

Although there is interest in integrating CAM and conventional or western medicine to from what is frequently termed "integrative medicine," there also is strong interest in maintaining CAM as a separate autonomous system of care, because of an articulated concern about the potential for CAM to be co-opted or usurped completely by the dominant health care system. In addition, the process of integration is viewed and

performed differently by conventional health care and CAM. Conventional health care tends to incorporate selected CAM modalities in the western bioscience model, while CAM espouses integration based on a pluralism that maintains the integrity of a number of whole systems of care and healing in a collaborative environment. Currently, however, the CAM community is fragmented and does not possess unifying infrastructure or global consensus. Despite numerous attempts and failures, the best models of CAM service delivery have not been identified yet. All of the problems of CAM service delivery are magnified by the challenges of service delivery to the growing numbers of uninsured and underinsured. If CAM services and products improve health status, health disparities in uninsured and underinsured populations without CAM services and products may worsen.

The following recommendations have been grouped according to the above access and delivery themes:

Recommendations Related to Conventional Medicine and Physician Resistance to CAM:

- Direct educational resources to training all conventional health professions in clinical and cost effectiveness of CAM approaches (especially nutrition), relationship-centered care, and how to interrelate with CAM practitioners.
- Train CAM practitioners how to interrelate with conventional health care professions.

Recommendations Related to Reimbursement, Coverage and Cost Issues:

Please note that because of an evidenced-based approach to reimbursement, research recommendations were categorized under the rubric of reimbursement, coverage, and costs issues.

- Create access to CAM therapies that are considered to be safe. However, embrace reimbursement only for those therapies that have strong evidence supporting their effectiveness.
- Determine the most common guidelines for setting limits for access and apply them to CAM.
- Insert language for CAM in Federal entitlement acts, such as Medicare, Medicaid, Indian Health Service, and CHAMPUS.
- Place a major focus on wellness and recommend policies for reimbursing CAM providers for health promotion.
- Promote the incorporation of new codes into Federally funded CAM research so that cost-effective CAM treatments can be identified as a solution to escalating health care expenses, especially where these procedures could have an impact on Medicare/Medicaid recipients.
- Promote research with side-by-side comparison of conventional health care and CAM to determine which gets better results and at lower costs.

Recommendations Related to Balance of Consumer Choice and Public Safety:

- Allow use of any medical treatment that has been in use in another country without evidence of harm.
- Encourage the FDA to require nutritional supplement and herbal remedy manufacturers to label their products with warning against possible adverse effects or toxicity, and recommendations for proper usage.
- Institute a system, such as that proposed by the World Health Organization, to establish guidelines for the assessment of herbal products to ensure proper identity and quality of both raw materials and finished products.
- Involve well-trained herbalists in the scientific study of safety and efficacy of herbs.

Recommendation Related to Needs of Special Populations:

- Develop demonstration projects that will allow hospice programs to provide care without a reimbursement, criteria, or prognostic cap.

Recommendations Related to Cultural and Linguistic Challenges (Including Traditional Healing):

- Require the FDA to recognize a "traditional medicines" category that would take into account the historical and traditional uses of herbs and permit manufacturers to put this information on the label.
- Develop "peer" education programs to disseminate credible information on CAM to minority and ethnic communities.

Recommendations Related to Integration of CAM vs. CAM Autonomy:

- Break down barriers to collaboration of conventional health care with CAM practitioners.
- Develop a 20-year plan to integrate conventional medicine into patient-centered, whole-person health care.
- Do not fully integrate CAM therapies into mainstream medicine.

Recommendations Related to Models of Service Delivery

- Provide access for all populations to nutritional programs such as the Dean Ornish program.
- Use nurses as a resource to integrate CAM into conventional medicine and serve as a bridge to help educate doctors.
- Develop a system of integrative medicine in which a cadre of CAM and conventional health care practitioners, each with his/her own scope of practice and tools, coordinate care, cross-refer, and co-manage patients.
- Fund and coordinate systematic reviews of specific CAM methods organized by clinical conditions.
- Increase research by CAM practitioners and experienced clinical researchers on clinical implementation of specific CAM treatments for specific conditions.

Recommendations Related to CAM Service Delivery to Uninsured and Underinsured:

- Link school loan forgiveness programs for CAM practitioners to service to underserved populations.
- Facilitate inclusion of underserved populations in CAM clinical research and require provision of standard conventional care instead of placebo.
- Include a service component to uninsured, underinsured, and underserved populations in Federally-supported CAM training and research grants.
- Include CAM in all Federal programs to reduce health disparities.
- Fund Community and Migrant Health Centers to use their unique abilities to deliver CAM and educate uninsured and underinsure populations about CAM in culturally competent ways.
- Conduct surveys of CAM utilization in underserved populations, since CAM data on these ethnically, racially, and culturally diverse populations are lacking and patterns of CAM use, sources of CAM products and practices, and adverse experience profiles may vary significantly from published data.

CAM Communications and Reports Issue # 5

White House Commission on Complementary and Alternative Medicine Policy Meetings

Understanding Coverage and Reimbursement, May 14 - 15, 2001
Research Challenges, May 15 – 16, 2001

Reimbursement and research were the central focus of this final fact-finding hearing of the White House Commission on Complementary and Alternative Medicine Policy. Testimony opened with presentations from the Health Care Financing Administration (HCFA), the U.S. Office of Personnel Management, the National Conference of State Legislatures, the American Association of Health Plans, Blue Cross and Blue Shield Association of America, Aetna/U.S. Healthcare, and several foundations and health care policy groups. The key issues related to reimbursement of CAM products and services were delineated as follows:

Cost and Premium Setting Issues
The only way to entice health benefit plans (insurance and managed care plans) to offer CAM services is to fully document their cost effectiveness and the resultant cost offsets in increased worker productivity and reduced conventional medical services. While a "cost neutral" policy is always a concern for health care decision-makers, it will be even more pronounced in the coming year as substantial increases in core insurance premiums are predicted.

In addition, a central tenet of insurance premium setting is that most people, usually estimated at 80%, will not use the services for which coverage is offered (or in the case of some managed care plans, directly provided). With an estimated 40% of consumers using CAM, the complexity of estimating premiums is heightened beyond the capacity of most insurance actuary groups.

Policy Issues
Added to the central barrier of cost are reimbursement problems related to the social policy question of what is a collective responsibility and what is an individual responsibility in health care; generalized individual and institutional resistance to change; possible conflicts of interest among benefit policy-makers who also practice conventional medicine; the related issue of lack of CAM expertise on public and private insurance policy boards; and specific regulatory barriers to classes of practitioners.

Structural and Political Issues
A central concern of several presenters was the lack of appropriate procedure coding for CAM procedures. The larger problem is a procedure code's inability to capture the nature of CAM practitioner-patient interactions. The more focused problem is the lack of an agreed-upon mechanism for developing codes to reflect even the mechanics of CAM

services. Without this basic structural component of reimbursement, implementation of CAM coverage policy is certain to be difficult.

The political problems associated with CAM reimbursement are many. In the public sector, perhaps the biggest problem is the complexity of the health care system, with many interest groups and proposed solutions. As CAM practices and services cut across the entire health care system, they are affected by all of the complex social and financial aspects of the system. For private reimbursement policy makers, the political concerns relate to liability for promotion of unproven therapies and a desire to, as stated by Alan Korn of Blue Cross Blue Shield Association of America, "maintain open, consistent, and defensible business practices."

Twelve states' efforts to develop "health freedom laws", allowing much greater access to CAM providers, could significantly expand demand for CAM services and reimbursement. Clearly, federal perspectives on tax and social program policy, now in development, will also impact the potential for CAM services reimbursement.

From the testimony the Commission received on reimbursement, it was evident that CAM is a key issue for many public and private health insurance providers, consumers, and employers. As reported by the Washington Business Group on Health representative, 70% of consumers want health insurance coverage for CAM and 78% want more research on CAM. Equally clear from the level of interest in CAM expressed by their representatives, reimbursement and financing of CAM are central issues for the insurance and managed care plans, as well as for state and federal health care policy-makers.

Given this interest and the related complex issues, the Commissioners proposed the following recommendations:

1) Require National Institutes Health and/or the Agency for Agency for Healthcare Research and Quality to develop a website focused on the scientific evidence for CAM. This website should be promoted to insurers and other health care financing policy groups.

2) Develop publicly financed demonstration projects that evaluate different strategies for reimbursement for CAM products and services.

3) Instruct the Health Care Financing Administration to evaluate CAM for clinical outcomes and its impact on use of other medical services.

4) Offer tax credits to businesses that provide services to employees that reduce health risks and increase wellness.

5) Encourage large employers, perhaps through grants, to collect utilization and outcome data on CAM and to undertake demonstration projects equivalent to those done by the public sector (see recommendations # 2 and 3 above).

6) Support inclusion of CAM experts on reimbursement policy advisory boards.

7) Require broad-based public education on CAM services and practices.

Following the presentations and recommendations on reimbursement, the working groups on CAM access and delivery produced the following recommendation (which had been held over from the prior Commission meeting):

1) Teach collaboration and relationship skills to all medical practitioners.

2) Develop a public information campaign on CAM for health care providers and the general public.

3) Create a federal office to oversee regulations for CAM products.

4) Increase funding for research on safety and effectiveness of CAM products and services.

5) Provide educational loan forgiveness programs for providers who deliver CAM in areas of special need.

6) Encourage state medical boards to do more to protect and work with CAM practitioners.

7) Create self-care and wellness programs for preschool through grade 12 children.

8) Consider a Congressional mandate to include CAM reimbursement in Medicare and Medicaid reimbursement.

The May meeting continued with presentations from several foundations active in CAM research including the Medtronic Foundation, the Robert Wood Johnson Foundation, the Susan G. Komen Breast Cancer Foundation, and the Samueli Institute for Information Biology. These were followed by speakers representing the Agency for Healthcare Research and Quality (AHRQ), the National Library of Medicine, CAM programs at several conventional and CAM academic medical centers, the Cochrane Collaboration, the National Council Against Healthcare Fraud, the New England Journal of Medicine, the Journal of the American Medical Association, Annals of Internal Medicine, Alternative Therapies in Health and Medicine, the Journal of Alternative and Complementary Medicine, and the National Center for Complementary and Alternative Medicine at the National Institutes of Health (NCCAM). A similar group presented at the prior research meeting, held October 5-6, 2000. As with the prior meeting, several key concepts were described, as follows:

- The current state of CAM research requires creation of basic infrastructure support, both public and private, and for institutions and individual researchers.

- The nature of CAM necessitates that researchers seek collaboration with CAM providers and/or educators, and that funding administrators and established researchers have both didactic and experiential exposure to CAM practices.

- A major issue for most research institutions in relating to CAM is attitudinal, and can include both excess enthusiasm and significant hostility.

While the October 2000 WHCCAMP research meeting focused on descriptive reports from institutions that had developed CAM clinical and/or research initiatives, the May meeting specifically highlighted areas of concern and requirements for further development of CAM research. The major questions and issues discussed were:

- What is the required level of evidence to consider a CAM practice acceptable? This issue was voiced by Commissioner Member, Dr. Joseph Pizzorno when he asked, "At what point can you decide that the case is made (for a CAM practice or system)?" While this question was not answered at the meeting, it was clearly seen as a central issue in CAM research, one that is expected to affect recommendations for policy actions.

- Are available research methodologies adequate to clearly investigate CAM practices? The consensus among presenters at the May meeting was that the answer is yes, because researchers are gaining more understanding of CAM concepts and because research methodologies are becoming more sensitive and sophisticated.

- For many CAM practices, perhaps best exemplified by Homeopathy, there is a need for serious investigation of mechanism of action. Related to this is the issue expressed by Richard Hammerschlag of the Oregon College of Oriental Medicine, when he said, "CAM reveals ways the body works that biomedicine has not yet explored." These two aspects of CAM point to the need to invest in basic science research in the field of CAM.

- Perhaps the most important discussions at the May research meeting focused on herbal medicine. For the first time, there was sustained expression of concern regarding safety issues related to herbs. Specific topics included lack of adverse event reporting, product labeling inaccuracies, potential for problem herb-drug interactions, and deficiencies in FDA oversight. There were calls for repeal of DSHEA, with others suggesting that the law should stand but with amendments.

In terms of recent developments in CAM research, the most significant were those described by the NCCAM and AHRQ. NCCAM program officers reviewed the substantial investment being made in research training, for both institutions and individuals. The AHRQ's CAM representative described the basic survey reports and outcome studies the agency has supported, as well as recently released and planned

evidence reports. These publications are frequently used by medical specialty societies as the basis for practice guidelines on use of medical modalities and products, and thus may influence large numbers of conventional practitioners' perspectives on CAM.

At the conclusion of testimony, the Commissioners developed the following recommendations to address the research challenges:

1) In the short term, conventionally trained researchers should be sent to CAM schools to provide courses in research methodology.

2) NCCAM should be directed to develop research methodology curriculum support (technical and financial) for faculty of CAM colleges.

3) For projects that focus on evaluation of research literature in CAM, collaboration with CAM practitioners should be encouraged.

4) Peer-reviewed journals should enlist CAM practitioners or experts for their review boards.

5) NCCAM should consider publishing a journal (electronically or in print) similar to the Office of Dietary Supplement at NIH's "Year's Best" research.

6) All federal health care agencies should put CAM research information on their websites.

7) The NCCAM website should list contact names for foundations with interests in CAM.

8) A federal group should be developed to coordinate public-private research.

9) Foundations should pool their resources to fund one or more large CAM projects.

10) Resources should be devoted to informing the public about research findings.

The testimony received during the public comment period at the end of the three-day meeting largely focused on support for the Commission's recommendations. It included presentations from CAM practitioners, dietary supplement manufacturers, and several CAM specialty societies, associations and colleges.

Notes:

1) The June issue of *CAM Communications and Reports* will cover education and training issues not specifically mentioned in prior reports. The July issue will review the Interim Report.

2) As in prior reports, the listed recommendations are suggestions made by Commissioners during the hearing or working sessions on specific areas of concern. A complete list of proposed recommendations will be included in the Interim Report.

For more information on the Commission, contact the White House Commission on Complementary and Alternative Medicine Policy, 6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817-7707, 301-435-7592, fax 301-480-1691, email whccamp@od.nih.gov website: www.whccamp.hhs.gov.

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Total Pages including cover: ____

Comments:

Jim,
Great meeting! Thank you. Here is the first unedited draft. I have additional changes to make in view of todays meetings. Please send changes back to me & I will make in the document.

Steve

(If there is any problem with this facsimile, please call Doris Kingsbury at 301-435-7592)

White House Commission on Complementary and Alternative Medicine Policy

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Introduction

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order 13147 on March 7, 2000, to develop a set of legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public. The Commission has been charged to submit a report to the President and Congress by March 2002.

The President's Executive Order outlined four broad topic areas for consideration by the Commission:

1. Coordinated research to increase knowledge about CAM practices and products;
2. The provision to health care professionals of reliable and useful information about CAM that can be made readily accessible and understandable to the general public;
3. Guidance for appropriate access to and delivery of CAM; and
4. The education and training of health care practitioners in CAM.

Commission Membership

Twenty Commissioners have been appointed by the President, representing a diverse range of expertise in medical, scientific, and CAM fields. The Commissioners include the Chair, James S. Gordon, M.D., and members including George M. Bernier, Jr., M.D.; David E. Bresler, Ph.D.; Thomas M. Chappell; Effie Poy Yew Chow, Ph.D.; George T. DeVries, III; William R. Fair, M.D.; Joseph J. Fins, M.D.; Veronica Gutierrez, D.C.; Wayne B. Jonas, M.D.; Charlotte R. Kerr, R.S.M.; Linnea S. Larson, LCSW; Tieraona Low Dog, M.D., A.H.G.; Dean Ornish, M.D.; Joseph E. Pizzorno, Jr., N.D.; Conchita M. Paz, M.D.; Buford L. Rolin; Julia Scott; Xiaoming Tian, M.D.; and Donald W. Warren, D.D.S.

Full Commission Meetings

The Commission focused on one or more of the four major topic areas during each of its meetings. The October 5-6, 2000 meeting focused on Coordinated CAM Research. The December 4-5, 2000 meeting focused on Access and Delivery of CAM Services and Products. The Commission's meeting of February 22-23, 2001 reviewed the subject of Education, Training and Credentialing for CAM Practices. The Commission's meeting on March 26-27, 2001 focused on Wellness, Self-Care and the Development and Dissemination of CAM Information to the Public. The meeting on May 14-16 reviewed Coverage and Reimbursement of CAM Services and

continued the discussion of the Coordination of CAM Research. All meetings have been open public sessions held in Washington, D.C.

Town Hall Meetings

To maximize the opportunity to receive public input, the Commission held a series of Town Hall Meetings throughout the country over several months. The meetings were held in San Francisco, Seattle, New York City, and Minneapolis. Additionally, the public was invited to present comments during Commission meetings held in Washington, D.C. Written comments may be sent electronically, by fax, or by mail. More information about the Commission is available on its website. (http://whccamp.hhs.gov)

The Commission is expected to issue the Final Report prior to March 7, 2002. Individuals and organizations are encourage to provide comments on the issues before the Commission for consideration by the members and staff.

The Commission maintains an active website at http://whccamp.hhs.gov. Comments, recommendations, and suggestions can be sent to the Executive Director though the website. A schedule of meetings, the Federal Register announcements of the meetings, agendas, and transcripts from the meetings are readily available at the internet site. Periodic visits to the website is the best mechanism to view the status of activities of the Commission.

Issues Before The Commission

The Commission was asked to develop a set of legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public. Each of the issues discussed in the Interim Progress Report are ~~tangentially or~~ directly related to this requirement.

Coordination of Complementary and Alternative Medicine Research and Related Regulatory Activities

Coordination of Research

Because the public in large numbers continues using complementary and alternative medicine (CAM), research on CAM products and practices is an important public health and safety issue. To address the need for dependable information on CAM products and procedures, research that meets high standards of design and execution is required. For many CAM products and practices there is little reliable information about safety and efficacy. Anecdotal reports, observations by individual practitioners, and small studies are important first steps in pursuing the development of the critical mass of objective, high quality data that will guide the public in their decisions to use CAM products and practices based on the evidence of safety and efficacy provided by methodologically sound research studies.

Commission uncertain of further action
consistency, quality

It is govt's responsibility to assure safety of all products, need to work ⊂ state + private sector to develop a position of shared responsibility

Not Known
- new legislation is needed
- Implementation of current legislation

Health care service delivery ~~continues~~ undergo major changes. Public policy needs to fully assess the impact of constant ~~innovation~~ in the integrative ~~Group includes~~ Good health environment (1)

Overarching Theme of wellness, Prevention, Health Promotion + Society
Disease Prevention, Safety of Public

↑ Research including health services, basic, clinical ~~applic~~ ch
Cost effectiveness
Herbal Products assessment of quality, identity, ~~and~~ content
safety ~~of both~~ of both raw materials + finished products
(Academic Centers, Govt Programs + Institutes & Centers R+D)

Information on CAM practices + products need to be developed for most interventions for all health care providers and the public ~~including~~ to address all the diverse populations (multi-ethnic) of the United States

Better Educational System for all Health Care Providers

~~CAM use by the general public~~
by the General public

The Use of CAM and practices + Products by the ↑ continues to grow. For most ~~practices~~ CAM modalities little information exists to substantiate or refute the claims of safety and effectiveness. The extensive use of these interventions by the general population requires considerable attention on the part of the private and public sector to assure maximum benefits and safety precautions are made known to all to guarantee the public health + safety

Information

To address the need for reliable and forthright information on CAM products and procedures, research meeting the highest standards of design ~~and~~ and execution is required. For many CAM ~~practices~~ +

Education et al

need overarching

for 2 to

identify issues

(highlighted)

Doc 12
6/12

6 June 2001 DRAFT Recommendations on Education, Training, Credentialing, and Licensure

Licensed Conventional Health Care Professionals:

- Develop a generic national curriculum for health professionals on CAM therapies and the skills necessary to assess CAM use by patients and their families with an emphasis on therapeutic relationship and interpersonal skill development.
- Develop a train-the-trainer initiative to provide health professions faculty with the skills to teach future health care professionals about CAM therapies.
- Create an easily accessible, evidence-based data resource on CAM therapies designed for health professions educators [and clinicians].

Conventional Health Care Professionals:

Undergraduate Education:

- Convene education leadership conferences to develop standards of CAM education and position Titles VII and VIII of the PHS Act as vehicles for faculty development and curriculum development initiatives.
- Expose students to CAM early and have CAM practitioners/professionals introduce the philosophy and underlying concepts of CAM.
- Provide joint training opportunities for conventional and CAM students.
- Include CAM on national board examinations

Graduate Education:

- While CAM education should be foundational at the undergraduate level, CAM education at the graduate level should provide opportunities for developing more sophisticated CAM skills in an interdisciplinary environment.
- Provide joint (i.e., both conventional and CAM) graduate education training opportunities.

Continuing Education (CE):

- Develop CE for conventional health care professionals to provide a basic understanding of CAM and its ability to complement conventional treatment.
- Include CAM in health professions continuing education but consider financial barriers to CE.
- Require all health care professionals to receive some form of education in herbal therapies
- Involve CAM practitioners and educators in creating sources of complete information on herbs and drug interactions.
- Require course materials on herbal remedies to include the history of botanical medicines and extent of regulation of herbal products.

CAM

Undergraduate Education:

- Provide comparable access to funding and resource opportunities available to conventional health professions.

- Allow CAM students to participate in scholarship and loan repayment/forgiveness programs.
- Provide joint training opportunities for CAM and conventional students.

Graduate Education:

- Provide comparable access to funding and resource opportunities available to conventional health professions.
- Require minimum levels of post-graduate education (such as residencies) for all non-allopathic and non-osteopathic physicians, leading to state certification or licensure.
- Provide joint (i.e., both CAM and conventional) graduate education training opportunities.

Continuing Education (CE):

- Develop and provide appropriate CE for CAM practitioners.

Credentialing and Licensure (and more): The following guidelines may be useful to States as they develop

- Articulate the following five principles to help guide states in developing regulations: (1) many providers want licensure to gain legitimacy and avoid criminal liability under medical license laws; (2) licensure is largely a matter of state law--states rely on the professional organizations to set standards and structures; (3) licensure has a potential dark side, in terms of diminishing the heart and soul of CAM practice; (4) several licensed CAM professions may share legal authority to practice a given modality; and (5) adopt one of several different models for licensing CAM providers based on the state's interest: (a) mandatory licensure, (b) title licensure, (c) registration, (d) exemption, (the Minnesota model), or (e) some variation or combination of the first four. Several options are available
- Promote state licensure or certification of CAM practitioners to regulate and provide a common standard of practice.
- Do not promote licensure, certification, or regulation of CAM practitioners.
- Develop consistent educational standards for CAM practitioners and accountability within the licensing and credentialing process.
- Develop national standards for CAM health care that are comprehensive, evidence-based, updated regularly, and accessible to everyone.
- Fund confidential, non-discoverable CAM quality improvement and peer review to enhance the quality of care.
- Develop incentives and an easy-to-use method(s) of reporting adverse reactions, interactions, and /or events associated with CAM products and practices and communicating this information to conventional and CAM providers as well as consumers.
- Require adequate record keeping of all providers of CAM products and practices so that outcomes can be complied and evaluated.
- Encourage full disclosure by all practitioners of their qualifications to provide CAM products and practices.

~~301-926-6806~~ KF

MM

> 1000 recommendations

I Comments from Members
- Format of Meeting
- Missing Items for Discussion to Obtain Information

II Status of Recommendations

III Format of July 2-3 meeting

7:45 - 9:45

2hr Breakout Session - Review of Recommendations
- What do we want to get -
  - Specific Recommendations
  - Areas of Concurrence

- ~~[illegible]~~ Secondrce - no more speakers
- Surgeon-Spirit Healing
- Office at Secty level

Intend Representative Question
Major areas of Recommendations
Other areas of Concern - add to Discussion
[illegible]

Lay People Turn to CAM

George [illegible]
after Interim Report

What recommendations are needed to address issues in Ex. Order

Need to retain rules
Small Group vs Whole Group -
concern

ASHTO
NGA < RGA / DGA

- Activate concerns Bldg
- Commission
- Early Discussion assume - Responsibility for section.

Orientation & Participation - of Members - More discussion

Jim Summary at each session
conclusion

move the country forward
[illegible]

Number (1)

Steve:

Some thots on the attached summaries + the July 2nd - 3rd meeting.

1) The agenda as now structured gives WHC five 2 hour time blocks. This is not consistent with scope of topic & level of WHC concurrence.

Shorten time period: Research (see also below) Information Dissemination

Lengthen time period: Access, Delivery, Reimbursement, Education etc

2) I'm not certain that Research + Regulation go together, I suggest adding a discussion on Regulation but keep it brief

3) Ditto, Education, Training (a, b) / Licensing + Credentialing (c, d). Topics a + b go together; topics c + d go together, but on different. Perhaps a 2.5-3.0 hour period, devoted in half (a+b), then (c+d).

305-365-5635

due to the limited interest of the traditional pharmaceutical industry into the investigation of CAM practices and products, a ~~strong~~ prominent role for Federal involvement ~~of the~~ is required ~~demanded~~ to develop the basic and clinical research infrastructure required to conduct the rigorous scientific research and the training of research investigators to evaluate CAM interventions. ~~These~~ Mechanisms and procedures for ~~their evaluations need to~~ infrastructure and evaluations should be similar to those employed in ~~developing~~ establishing and maintaining the current biomedical research community

Accurate reliable information on safety and effectiveness
health care providers and the public to make and good
adequate decisions about ~~those~~ initiating,
continuing, or discontinuing ~~treatments~~.
Anecdotal observations by ~~CAM~~ health care ~~conventional~~ practitioners,
and small studies are important first steps in
pursuing the development of the critical mass of objective,
high quality data on the S+E of CAM practices and
products to enable the public to make reasoned
decisions on the use or non-use of these CAM modalities
& this information should be readily available to the
public on all practices and products intended
for use by the public

Research

As with traditional biomedical research projects, randomized controlled
clinical trials are the preferred method of research
inquiry when possible. It is recognized that CAM
interventions ~~frequently~~ may present methodological
~~&~~ complexities due to the the number or type of intervention
under investigation. All studies should contain some
basic elements - a research hypothesis that can be tested,
a good study design and experienced research team, verifiable data,
and objective conclusions. Findings should be
reproducible by other research investigators or teams.
Individualized therapy and practitioner effect on outcome
should be examined within the ~~each~~ study design

White House Commission on Complementary and Alternative Medicine Policy

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4. The education and training of health care practitioners in CAM.

Commission Membership

Twenty Commissioners have been appointed by the President, representing a diverse range of expertise in medical, scientific, and CAM fields. The Commissioners include the Chair, James S. Gordon, M.D., and members including George M. Bernier, Jr., M.D.; David E. Bresler, Ph.D.; Thomas M. Chappell; Effie Poy Yew Chow, Ph.D.; George T. DeVries, III; William R. Fair, M.D.; Joseph J. Fins, M.D.; Veronica Gutierrez, D.C.; Wayne B. Jonas, M.D.; Charlotte R. Kerr, R.S.M.; Linnea S. Larson, LCSW; Tieraona Low Dog, M.D., A.H.G.; Dean Ornish, M.D.; Joseph E. Pizzorno, Jr., N.D.; Conchita M. Paz, M.D.; Buford L. Rolin; Julia Scott; Xiaoming Tian, M.D.; and Donald W. Warren, D.D.S.

Full Commission Meetings

The Commission focused on one or more of the four major topic areas during each of its meetings. The October 5-6, 2000 meeting focused on Coordinated CAM Research. The December 4-5, 2000 meeting focused on Access and Delivery of CAM Services and Products. The Commission's meeting of February 22-23, 2001 reviewed the subject of Education, Training and Credentialing for CAM Practices. The Commission's meeting on March 26-27, 2001 focused on Wellness, Self-Care and the Development and Dissemination of CAM Information to the Public. The meeting on May 14-16 reviewed Coverage and Reimbursement of CAM Services and

continued the discussion of the Coordination of CAM Research. All meetings have been open public sessions held in Washington, D.C.

Town Hall Meetings

To maximize the opportunity to receive public input, the Commission held a series of Town Hall Meetings throughout the country over several months. The meetings were held in San Francisco, Seattle, New York City, and Minneapolis. Additionally, the public was invited to present comments during Commission meetings held in Washington, D.C. Written comments may be sent electronically, by fax, or by mail. More information about the Commission is available on its website. (http://whccamp.hhs.gov)

The Commission is expected to issue the Final Report prior to March 7, 2002. Individuals and organizations are encourage to provide comments on the issues before the Commission for consideration by the members and staff.

The Commission maintains an active website at http://whccamp.hhs.gov. Comments, recommendations, and suggestions can be sent to the Executive Director though the website. A schedule of meetings, the Federal Register announcements of the meetings, agendas, and transcripts from the meetings are readily available at the internet site. Periodic visits to the website is the best mechanism to view the status of activities of the Commission.

Issues Before The Commission

The Commission was asked to develop a set of legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public. Each of the issues discussed in the Interim Progress Report are tangentially or directly related to this requirement.

Coordinated Research on Complementary and Alternative Medicine and Regulatory Activities

Because the public in large numbers continues using complementary and alternative medicine (CAM), research on CAM products and practices is an important public health and safety issue. To address the need for dependable information on CAM products and procedures, research that meets high standards of design and execution is required. For many CAM products and practices there is little reliable information about safety and efficacy. Anecdotal reports, observations by individual practitioners, and small studies are important first steps in pursuing the development of the critical mass of objective, high quality data that will guide the public in their decisions to use CAM products and practices based on the evidence of safety and efficacy provided by methodologically sound research studies.

Good scientific evidence about CAM modalities requires creativity in research methodology and flexibility in study design of research projects. To develop this evidence an adequate pool of

well-trained researchers familiar with CAM is needed and adequate support for CAM research is required from Federal agencies with research and regulatory related responsibilities and the private sector. Increased involvement of CAM practitioners and CAM educational programs with conventional academic health centers should aid in bringing about the integration of CAM into research programs through collaborative research projects, research training programs, and education programs for all research investigators. One of the goals of these collaborations should be the production of research results that will meet the rigorous publication requirements of all published and on-line journals. The public and all health care providers need to have access to positive, negative, or inconclusive results of the published literature resulting from all biomedical research projects.

Training, Education, Credentialing, and Licensing

6 June 2001 DRAFT Recommendations on Education, Training, Credentialing, and Licensure

Licensed Conventional Health Care Professionals:

- Develop a generic national curriculum for health professionals on CAM therapies and the skills necessary to assess CAM use by patients and their families with an emphasis on therapeutic relationship and interpersonal skill development.
- Develop a train-the-trainer initiative to provide health professions faculty with the skills to teach future health care professionals about CAM therapies.
- Create an easily accessible, evidence-based data resource on CAM therapies designed for health professions educators [and clinicians].

Conventional Health Care Professionals:

Undergraduate Education:

- Convene education leadership conferences to develop standards of CAM education and position Titles VII and VIII of the PHS Act as vehicles for faculty development and curriculum development initiatives.
- Expose students to CAM early and have CAM practitioners/professionals introduce the philosophy and underlying concepts of CAM.
- Provide joint training opportunities for conventional and CAM students.
- Include CAM on national board examinations

Graduate Education:

- While CAM education should be foundational at the undergraduate level, CAM education at the graduate level should provide opportunities for developing more sophisticated CAM skills in an interdisciplinary environment.
- Provide joint (i.e., both conventional and CAM) graduate education training opportunities.

Continuing Education (CE):

- Develop CE for conventional health care professionals to provide a basic understanding of CAM and its ability to complement conventional treatment.

- Include CAM in health professions continuing education but consider financial barriers to CE.
- Require all health care professionals to receive some form of education in herbal therapies
- Involve CAM practitioners and educators in creating sources of complete information on herbs and drug interactions.
- Require course materials on herbal remedies to include the history of botanical medicines and extent of regulation of herbal products.

CAM

Undergraduate Education:

- Provide comparable access to funding and resource opportunities available to conventional health professions.
- Allow CAM students to participate in scholarship and loan repayment/forgiveness programs.
- Provide joint training opportunities for CAM and conventional students.

Graduate Education:

- Provide comparable access to funding and resource opportunities available to conventional health professions.
- Require minimum levels of post-graduate education (such as residencies) for all non-allopathic and non-osteopathic physicians, leading to state certification or licensure.
- Provide joint (i.e., both CAM and conventional) graduate education training opportunities.

Continuing Education (CE):

- Develop and provide appropriate CE for CAM practitioners.

Credentialing and Licensure (and more):

- Articulate the following five principles to help guide states in developing regulations: (1) many providers want licensure to gain legitimacy and avoid criminal liability under medical license laws; (2) licensure is largely a matter of state law--states rely on the professional organizations to set standards and structures; (3) licensure has a potential dark side, in terms of diminishing the heart and soul of CAM practice; (4) several licensed CAM professions may share legal authority to practice a given modality; and (5) adopt one of several different models for licensing CAM providers based on the state's interest: (a) mandatory licensure, (b) title licensure, (c) registration, (d) exemption, (the Minnesota model), or (e) some variation or combination of the first four.
- Promote state licensure or certification of CAM practitioners to regulate and provide a common standard of practice.
- Do not promote licensure, certification, or regulation of CAM practitioners.
- Develop consistent educational standards for CAM practitioners and accountability within the licensing and credentialing process.
- Develop national standards for CAM health care that are comprehensive, evidence-based, updated regularly, and accessible to everyone.

- Fund confidential, non-discoverable CAM quality improvement and peer review to enhance the quality of care.
- Develop incentives and an easy-to-use method(s) of reporting adverse reactions, interactions, and /or events associated with CAM products and practices and communicating this information to conventional and CAM providers as well as consumers.
- Require adequate record keeping of all providers of CAM products and practices so that outcomes can be complied and evaluated.
- Encourage full disclosure by all practitioners of their qualifications to provide CAM products and practices.

Information Development and Dissemination

A. Internet, Radio, Television, and Print Media

Issue 1: The internet has emerged as a major source of health care information, including information related to CAM, for both consumers and providers. The NCCAM website reports receiving over half a million hits per month[1], the Ask Dr.Weil site reports up to 5 million page views per month[2], AlternativeMedicine.com reports 2 million hits per months[3], and WebMD reports 4.7 unique visits last December[4]. In addition to the many CAM sites, there are numerous general health information sites that include CAM information.

The quality, accuracy, accessibility, and timeliness of the information varies greatly. Some sites provide accurate and current information, while many others contain inaccurate, misleading, or outdated information. The ability to control the quality of information on the internet is extremely limited, due to both the nature of the technology and the First Amendment protection of free speech.

Recommendations:

A) Bring together leaders in the field of CAM internet information, including for- profit, non-profit, academia, researchers, clinicians, state and local sponsors of CAM internet sites and general health information sites, and other interested parties, for a public-private partnership to develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM internet sites. These standards should include disclosure of

[1] - Irene Lui, WHCCAMP testimony, March 26, 2001, p16

[2] - Andrew Weil, WHCCAMP testimony, March 26, 2001, p56

[3] - Burton Goldberg, WHCCAMP testimony, March 26, 2001, p

[4] - Susan Detwiler, WHCCAMP testimony, March 26, 2001, p210

any conflict of interest.

Once the voluntary standards are established, develop a process to review sites based on the established criteria. This could be done through a government- sponsored advisory board, with public members rotating for a specified period of time. No site will not be required to have a rating, and sites that have been reviewed and found in compliance with the criteria can state so on their site (similar to the American Heart Association labels or the Good Housekeeping Seal of Approval). This would be an ongoing system with periodic reviews of sites to assure that they continue to be consistent with the standards.

B) Conduct a public education campaign that teaches people how to evaluate CAM information on the internet. This would be part of a larger public education campaign on CAM.

Discussion: There are several organizations that have developed standards for health sites on the internet. A non-profit membership organization called Hi-Ethics, Inc. has defined a set of criteria for health information on the internet that addresses quality, privacy, and disclosure. Membership is $20,000 annually, although membership will not be required to participate in their upcoming "E-Health Seal" program. Health on the Net, a Swiss -based organization, also has a list of ethical standards for health sites that address issues such as advertising, sponsorship, etc. and does not charge for membership. The Internet Healthcare Coalition charges $50 per year for membership and has more emphasis on the quality of the information. However, none of their Board of Directors or Advisory Board members listed on their internet site have any CAM credentials.

A public-private partnership between the government and industry to develop and implement voluntary standards is proposed because 1) many of the sites that are listed as members of one or more of these groups are the very sites that have been used as examples of the problems in CAM related web sites such as quality, accuracy, accessibility, timeliness, etc.; 2) these programs have not made an impact on consumers; and 3) most of these programs are focused on ethics related issues such as privacy, financial sponsorship, etc. and not on content, and the one that does address content is composed exclusively of representatives from conventional medicine. A government sponsored partnership could bring more exposure, credibility, and balance to this effort and bring more focus to CAM. These organizations could participate in this effort.

A public education campaign is also necessary because, regardless of all efforts to improve the quality of CAM information on the internet, there will always be some information that is inaccurate, misleading, or out of date. Consumers need to be able to recognize indications that a site is less than reputable, and individuals have a responsibility to evaluate or validate the information they get on the internet.

Issue 2: About 60 million American adults have used the internet for health information[5]. Some studies show that 70 % of health seekers search for illness-related information, compared to only 13% for health or wellness related information[6]. There is concern that employers or insurance companies can track which sites a person visits and could use this information to make decisions regarding health insurance coverage, employment opportunities, etc. Some 85% of health seekers on the internet say they are concerned about

[5] - Harrison Lee Raine, WHCCAMP testimony, March 26, p195

[6] - Susan Detwiler, WHCCAMP testimony, March 26, p204

their insurance company finding out such information and changing their insurance status or rates[7]. While there is no documented evidence that this is occurring, the possibility exists and steps should be taken to prevent this from becoming a problem.

Recommendations:
A) Encourage CAM sites to disclose if users are tracked and what how that information is utilized.

B) Explore the necessity of developing or amending current legislation or regulations to assure the protection of privacy of CAM health information seekers on the internet.

Discussion: Concerns about the privacy of health information has been a priority in Congress and the DHHS. Some of the organizations previously mentioned were formed in response to either the need for standards or the fear of restrictive legislation. Current legislation and regulations should be reviewed to determine if they are adequate to protect the privacy of health information seekers on the internet, and if these protections extend to users of CAM internet sites.

Issue 3: As part of its 1998 legislative mandate, NCCAM contracts with a clearinghouse to provide information on research findings to the public. However, there is no other centralized source of CAM information in the Federal government that provides information on other CAM topics such as training, licensure, access, reimbursement, wellness, self-care, herbs, botanicals, legislation, diseases, etc.

Recommendations:
A) Form a task force to determine how the Federal government could provide comprehensive CAM information to the public. This may include:

i) Expanding the scope of NCCAM's clearinghouse activities;
ii) Requiring other agencies such as the FDA, CDC, HRSA, etc. and other Departments such as the Department of Education and the Department of Agriculture to provide CAM information relevant to the mission and activities of those organizations;
iii) Establishing a centralized source of CAM information in DHHS to coordinate and develop CAM information for the public; etc.

Discussion: In several of the Town Hall meetings, people have recommended the establishment of a government clearinghouse for information on CAM. NCCAM has invested a substantial amount of time and resources to develop a clearinghouse for CAM information related to research. Other agencies, such as the FDA, also have a clearinghouse for consumer information, but doesn't specifically address CAM. The task force should look at what approach would be in the best interests of the public to provide comprehensive CAM information, either through expanding the current NCCAM clearinghouse or establishing another, more comprehensive clearinghouse, or creating a link between the NCCAM clearinghouse and other government clearinghouses specifically addressing CAM.

Issue 4: Media coverage of CAM benefits and cautions is often uneven, incomplete, or biased, and the

[7] - Harrison Raine, WHCCAMP testimony March 26, p201

availability of objective, comprehensive information about CAM from the Federal government is hampered because the government does not have a central place for the media to contact for information on CAM.[8]

Recommendations:.
A) Create a centralized office in the Office of the Secretary, DHHS, for information on CAM, with links to other resources such as the NCCAM.

Discussion: The news media works on very short timelines and when they have a breaking story related to CAM, they need to have a centralized source in the government to verify the information and provide balance to their stories. This would also include referrals to experts in different areas of CAM.

Issue 5: While the use of the internet has proliferated, there are still many people, especially elderly and low income people, who do not have personal access to the internet or knowledge of how to use the internet for CAM information. Public libraries exist in most communities and are a source of both internet access and guidance. However, many librarians lack training on how to access CAM information on the internet.

Recommendations:
a) In partnership with the National Library of Medicine and the American Library Association, develop training materials to assist librarians in guiding people to find CAM information on the internet.

Discussion: The NLM has begun working directly with public libraries through the ALA to train local librarians to use the internet to find health information[9]. This effort could be enhanced to include more training and more focus on CAM.

Note: See also "Access"

Issue 6: According to the 1992 National Adult Literacy Survey, 48% of U.S. adults, or close to 100 million Americans, have very limited literacy skills[10]. Factors that contribute to this are 1) lack of English skills, 2) reading disabilities, and 3) under-education[11]. While the use of CAM among this population is unknown, it is believed that a substantial number use CAM.[12].

Recommendations:
A) Promote the development of CAM information materials at a level that the general public can

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[8] - David Schardt, WHCCAMP testimony, March 26, p.228

[9] - Sheldon Kotzin, WHCCAMP testimony March 24, p28

[10] - U.S. Department of Education, National Center for Education Statistics,1992

[11] - ibid

[12] - Elmer Huerta, WHCCAMP testimony March 26, p.142, and Frances Brisbane, WHCCAMP testimony, March 27, p191

understand and utilize.

Issue 7: Even for those without difficulty reading, there is a lack of CAM information that is targeted to specific population groups, despite the numerous indications that there is great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups.

Recommendations:
A) Promote the development of CAM information that is targeted to different population groups.

Note: See also "Access"

Issue 8: There are many government agencies that provide information on diseases, conditions, or products and do not include any information on CAM in their fact sheets or internet sites.

Recommendations:
A) Have the Secretary, DHHS, direct all government agencies involved with health to include CAM- related information on their fact sheets and internet sites as appropriate. This could include information on wellness and CAM, CAM preventive and therapeutic measures, information relevant to specific diseases or conditions where appropriate, advise for patients to tell their physicians about any vitamins, herbals or botanicals they may be taking, etc. This information should emphasize CAM as part of the whole person wellness and healing process in concert with conventional care.

B) Where appropriate, encourage government sites that provide CAM information to describe both benefits and cautions.

Discussion: There has been some discussion to having the government develop a new web site that would list pros and cons of various therapies and interventions, much like a voter pamphlet provides both sides of an issue. While the concept has some merit, it may be more cost-effective and acceptable to have existing government web sites utilize this format to provide balanced information.

Issue 9: Consumers have no easy way of determining the training and quality of people offering CAM services or products.

Recommendations:
A) Government internet sites should provide information describing the training and certification requirements of CAM professionals, and link to states to provide information on licensure.

A) Government internet sites should have links to state licensing and disciplinary information sites.

Note: See also "Education and Training"

Discussion: There are numerous types of CAM providers with different levels of training and it is difficult for the public to understand the differences between them and make informed choices. This is due to several factors, including the variability of state scope of practice acts, the lack of

definition of some professions (e.g. "Herbalist"), and the use of the same title by people of different levels of training (e.g. professional acupuncturists and physicians can both be called "acupuncturist"). To help assure public safety, information should also be available on any disciplinary actions against a practitioner.

Issue 10: Lack of information on effectiveness of CAM therapies is often cited as reason to not provide or reimburse for these services, but there is a significant amount of high quality CAM information published in other countries that is not available in English.

Recommendations:
A) Provide funding to i) identify barriers to identifying and translating relevant articles, reports, and other materials, ii) develop a strategy to overcome these barriers

Note: See also "Research"

B. Advertising, Marketing, and Labeling

Issue 1: The Federal Trade Commission (FTC) oversees advertising of products and services and brings actions against false and deceptive claims in the marketplace. To address what they call "an epidemic of health fraud on the internet"[13], the FTC established Operation Cure.all, an ongoing project specifically targeting deceptive health marketing claims on the internet. Yet, they are only able to pursue a small percentage of the fraudulent claims identified.

Recommendation:
A) Provide additional support to the FTC to identify false and deceptive CAM-related health claims on the internet and to take appropriate action to minimize the occurrence of these claims.

Discussion:
Operation Cure.all is not looking exclusively at CAM related health sites, but many of the fraudulent claims are related to CAM products and services, often claiming to cure cancer, AIDS, and other diseases. In one afternoon of internet surveillance, 400 clearly fraudulent health claims were identified. After sending an email warning, 80 of these sites either dropped the questionable claim or took down the site down. Of the 320 that did not respond to the email warning, the FTC

[13] - Michele Rusk, WHCCAMP testimony, March 26, p.276

was able to take action on only 2. If the perception exists that less than one percent of identified fraudulent claims are pursued, it is likely that there will be even more deceptive CAM advertising.

Issue 2: Some populations, such as the recently arrived Hispanic immigrant population, other immigrants and non-English speaking persons, the elderly, etc. are especially vulnerable to the unscrupulous sales of herbs, tonics, vitamins, and other products in the media, particularly on Spanish language radio and television.[14]

Recommendations:
A) Provide additional support to the FTC to monitor the Spanish media and other English and non-English advertising outlets, especially radio and television, that target vulnerable populations.

B) Bring together national and local leaders of communities of special populations to identify strategies to protect their constituency from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

Discussion: Due to limited language skills, cultural isolation, poverty, unfamiliarity with or lack of access to the health care system, and other similar factors, certain populations are particularly susceptible to advertisements of CAM products or services that promise to cure health and other problems that are not being addressed through the conventional health care system or through legitimate CAM providers. This not only takes money away from people who have very little, but also can delay treatment of serious conditions until they become emergencies. The involvement of community leaders that are trusted by the populations they represent is essential to successfully educate vulnerable consumers and develop strategies to prevent their exploitation.

Note: See also "Access"

Issue 3: Legitimate companies that comply with current anti-deception and substantiation standards can lose market share and suffer financially as a result of companies using deceptive advertising[15].

Recommendation:
A) Provide adequate funding to the FTC to enforce current requirements for substantiation of advertising and marketing claims.

B) Increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising.

Discussion: Companies that invest their resources to comply with FTC regulations and provide truthful information to the public should not be put at a disadvantage in the marketplace.

Issue 4: People providing CAM therapies can have significant differences in their level and type of training and it is difficult for consumers to understand the differences and make informed choices.

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[14] - Elmer Huerta, WHCCAMP testimony March 26, p.145

[15] - Sara Taylor, WHCCAMP testimony, March 26, p.288

Recommendation:
A) Require health professionals to clearly post information that explains their level and scope of training so that consumers understand and can make informed choices.

B) Encourage States and local governments to make information on state guidelines, requirements, and licensure of CAM providers readily available to the public.

Discussion: People can advertise themselves as a practitioner of a CAM therapy, yet licensing requirements, certification, scope of practice, regulations, and even definitions vary considerably from state to state. An herbalist may have years of training or no training at all. Acupuncture can be practiced in some states by practitioners of other health modalities (e.g. physicians, dentists, podiatrists, etc.) with no additional training, or by someone who has spent several years in acupuncture-specific training. Some practices require licensure, others do not. Information that explains a person's level and scope of training will help consumers to make informed choices in their selection of a practitioner.

Note: See also "Education and Training"

Issue 5: The Dietary Supplement Health and Education Act (DSHEA) of 1994 gave the FDA authority to take enforcement action against dietary supplements that are misbranded, adulterated, or found to be a significant or unreasonable risk to consumers. To do this, the FDA relies mostly on its adverse event reporting system to identify safety problems. The system is entirely voluntary, and events can be reported by both consumers and health professionals. However, the a recent study shows that the FDA receives reports on less than 1 percent of all adverse events associated with dietary supplements[16].

Recommendation:
A) Strengthen the adverse event reporting system so that serious or clinically significant adverse events[17] related to dietary supplements can be identified and contained in a timely manner and associated morbidity and mortality can be reduced. This may include requiring dietary supplement manufacturers to report serious adverse events to the FDA (similar to the requirements for OTC drugs), requiring manufacturers to register with the FDA so that the FDA can identify and contact them if an adverse event is reported, developing a data base of manufacturers and product ingredients, etc.

B) Strengthen outreach activities to health professionals and consumers regarding the importance of reporting adverse events and how to use the system.

Discussion: In April, 2001, the Office of the Inspector General, DHHS, issued a report on adverse event reporting for dietary supplements, calling it "an inadequate safety valve". This report describes in detail the limitations of the current system in detecting serious adverse events related to dietary supplements and provides numerous recommendations to improve the system. Some of these recommendations are included in the FDA's 10- year strategic plan. Recommendations to require manufacturer and product registration and mandatory manufacturer

[16] - DHHS, OIG, Adverse Event Reporting for Dietary Supplements, April 2001

[17] - These terms are defined under Medwatch and in the FDA's Standard Operating Procedures of 1999.

reporting of adverse events may require legislative authority, while most recommendations can be implemented administratively with additional funding. The recommendations do not appear to be in conflict with the intent of DSHEA, and would be beneficial in protecting public health and safety.

Note: See also "Research"

Issue 6: Some dietary supplements do not contain the ingredients listed on the label, or do not contain the ingredients in the amount listed on the label, or contain ingredients other than those listed on the label. If the labels are not accurate, consumers may be getting more, less, or something other than what they think they are getting, and this could have negative health consequences, and erode consumer confidence.

Recommendations:
A) The FDA's Good Manufacturing Practices (GMP) for quality control, standardization, accurate labeling, should be issued and implemented.

B) Support programs (e.g.U.S. Pharmacopoeia) to assess the quality of dietary supplements and develop standards for certification of composition, quality, consistency, and safety.

Discussion: ConsumerLab testing of 25 echinacea products found that only 14 (56%) had the amount and type of echinacea and phenol levels that they claimed the product contained.[18] Testing of 13 SAMe products showed that 6 had less than half of the amount listed on the labels (one of which had no detectable level).[19] Aristolochic acid, which has been associated with serious health hazards such as cancer, renal failure, and neuropathy when improperly used, has been identified in various dietary supplements, prompting recalls of products by several companies[20]. There are numerous other examples of dietary supplements that have failed laboratory testing of the identity, quantity, quality, and amount of the ingredients listed on the labels. The GMPs developed by the FDA are widely supported by industry and seen as a minimum standard for the safety and integrity of dietary supplements. The GMPs are currently in OMB.

Issue 7: Some dietary supplements have been found to be contaminated with pesticides or infectious organisms such as salmonella..

Recommendations:
A) The FDA's Good Manufacturing Practices (GMP) for quality control, standardization, accurate labeling, should be issued and implemented.

B) Work with the Department of Agriculture and the Environmental Protection Agency, to inspect and identify sources of contamination.

C) Work with the World Health Organization to establish guidelines for to help assure the purity

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[18] - ConsumerLab.com, September 2000

[19] - ConsumerLab.com, January 2000

[20] - FDA

of herbal ingredients[21].

Discussion: In both imported and domestically produced products, contamination by pesticides and infectious organisms have been found. In April, 2001, Solgar Vitamin and Herb Company recalled some dietary supplements due to salmonella contamination of raw materials supplied by American Laboratories. In May 2001, Natural Organics recalled several dietary supplements, also due to salmonella contamination of raw materials supplied by American Laboratories. The University of California, Cooperative Extension, has found toxic levels of mercury in some pills from China[22]. While the extent of contamination of dietary supplements is not known, steps should be taken to assure that these products are free of contaminants.

Issue 8: Dietary supplements can make structure and function claims, but only approved drugs can make claims about preventing, treating, curing, or mitigating a disease. Since drug approval is a labor intensive process that requires substantial research, time, and money, most manufacturers of dietary supplements do not seek drug status for their products. The unintended effect is that in some instances where there is research supporting a claim for preventing, treating, curing, or mitigating a disease, claims are still limited to structure and function, unless they already have an approved health claim under Nutrition Labeling and Education Act of 1990 (NLEA). Information that may be beneficial to consumers is therefore limited and sometimes confusing.

Recommendations:
A) Include package inserts that explain current information on the product, as well as the limitations of that information.

Discussion: The NLEA has authorized claims for calcium and reduced risk of osteoporosis, psyllium and reduced risk of heart disease, reduced sodium and reduced risk of high blood pressure, reduced fat and reduced risk of cancer, etc. However, glucosamine, which has had numerous controlled studies published in peer-reviewed journals showing it is effective for osteoarthritis, can only claim that it helps to maintain joint health because it is distributed as a dietary supplement instead of a drug. Statements of nutritional support can use terms such as stimulate, maintain, support, regulate, or promote, but cannot claim to "diagnose, treat, prevent, cure, or mitigate" a disease. The cost of preparing a drug application is prohibitive to many companies, the extensive time required for drug approval is a deterrent , and any realized benefits will apply to all manufactures, not just the one who prepared the application. While consumers need to have accurate and truthful information, they should also have access to available data to assist them in their decision making.

The U.S. Court of Appeals for the District of Columbia, in the matter of *Pearson v. Shalala*, ordered the FDA to clarify its significant scientific agreement (SSA) standard, reevaluate some previously denied claims, and permit health claims that do not meet the SSA standard if a disclaimer can ensure that the claim will not mislead consumers. It is too early to assess how this will change health claims information.

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[21] - Dennis Awang, WHCCAMP testimony, December 3 2000

[22] - University of California, Cooperative Extension, Environmental Toxicology Newsletter, Vol. 19, No.1, 1999

Issue 9: Consumers may be unaware of possible risks of using one or more dietary supplements.

Recommendations:
A) Include warnings in dietary supplements regarding interactions with other dietary supplements, drugs, OTCs, foods, or other products with which interactions may occur, or with certain health conditions. If this information is not available, the labels should state so.

B) Warnings for pediatric use, use by pregnant or nursing women, and those whose immune system is compromised should be included.

Discussion: Many people have the misconception that so-called "natural" products are inherently safe. While much information is not known about safety, interactions with other drugs or foods, or the effect on various conditions or diseases, consumers should be made explicitly aware that these are all possibilities until proven otherwise. However, even when information becomes known, such as St. John's Wort decreasing the efficacy of some drugs, that information is not included in the product.

Issue 10: Oversight of the composition, quality, safety, labeling, and adverse events of botanical products should be performed by professionals with expertise in botanical products.

Recommendations:
A) Assure an adequate staff of professionals within the FDA with expertise in botanical products. This could include hiring people with these specific skills, and/or providing training to current staff.

Discussion: There have been recommendations to establish an Office of Botanical Products within FDA, and recommendations to establish an Office of Botanical Products outside of FDA. These recommendations stem largely from real or perceived concerns that the FDA will either not do its job in a timely, effective, or fair manner, or that it will overstep its authority and limit the access and availability of these products. Establishing another office within or outside of FDA would not address the lack of sufficient expertise in the government oversight of botanical products. The use of all dietary supplements, including botanicals, has grown remarkably since DSHEA was enacted in 1994, yet the FDA has not received appropriations commensurate with its new responsibilities. To provide greater leadership in the oversight of botanical products, FDA needs additional funds to hire qualified expertise and train existing staff to meet the increasing and ongoing demands of assuring both public access to and safety of botanical products.

Access to and Delivery of CAM Practices and Products

Conventional medicine and practicing physicians' resistance to and lack of acceptance of CAM is cited as the basis for non-disclosure of CAM use by patients and as a barrier to access to CAM services. While the current reimbursement system is influenced by an evidenced-based approach, CAM generally lacks the type and amount of western scientific evidence on safety, indications, clinical effectiveness, and cost effectiveness sought by the current reimbursement system. Moreover, data on systems of care, multiple modalities, combination therapies, various delivery systems, and diverse populations are not available. The balance of consumer choice and public safety is evident in utilization of CAM as part of self-care, particularly in women's health, and is dependent on information which can be difficult to obtain, contradictory, and of questionable accuracy. Access to CAM by special populations such as HIV/AIDS, elderly, pediatrics, and cancer patients is characterized by more numerous and significant barriers than the general population. Cultural and linguistic barriers to access to CAM are associated with recent immigrants, native peoples, and an increasingly diverse population especially in the context of traditional healing.

Although there is strong support for integrating CAM practices and conventional or western medicine to form what is frequently termed "integrative medicine," there also is strong interest in maintaining CAM as a separate system of care. The CAM community is fragmented and does not possess unifying infrastructure or global consensus. Many of the problems of CAM service delivery are magnified by the challenges of service delivery to the growing numbers of uninsured and underinsured.

6 June 2001 DRAFT Recommendations on
Access and Delivery

Recommendations Related to Conventional Medicine and Physician Resistance to CAM:

- Direct educational resources to training all conventional health professions in clinical and cost effectiveness of CAM approaches (especially nutrition), relationship-centered care, and how to interrelate with CAM practitioners.
- Train CAM practitioners how to interrelate with conventional health care professions.

Recommendations Related to Reimbursement, Coverage and Cost Issues:

Please note that because of an evidenced-based approach to reimbursement, research recommendations were categorized under the rubric of reimbursement, coverage, and costs issues.

- Create access to CAM therapies that are considered to be safe. However, embrace reimbursement only for those therapies that have strong evidence supporting their effectiveness.
- Determine the most common guidelines for setting limits for access and apply them to CAM.

- Insert language for CAM in Federal entitlement acts, such as Medicare, Medicaid, Indian Health Service, and CHAMPUS.
- Place a major focus on wellness and recommend policies for reimbursing CAM providers for health promotion.

- Promote the incorporation of new codes into Federally funded CAM research so that cost-effective CAM treatments can be identified as a solution to escalating health care expenses, especially where these procedures could have an impact on Medicare/Medicaid recipients.
- Promote research with side-by-side comparison of conventional health care and CAM to determine which gets better results and at lower costs.

Recommendations Related to Balance of Consumer Choice and Public Safety:

- Allow use of any medical treatment that has been in use in another country without evidence of harm.

- Encourage the FDA to require nutritional supplement and herbal remedy manufacturers to label their products with warning against possible adverse effects or toxicity, and recommendations for proper usage.

- Institute a system, such as that proposed by the World Health Organization, to establish guidelines for the assessment of herbal products to ensure proper identity and quality of both raw materials and finished products.
- Involve well-trained herbalists in the scientific study of safety and efficacy of herbs.

Recommendation Related to Needs of Special Populations:

- Develop demonstration projects that will allow hospice programs to provide care without a reimbursement, criteria, or prognostic cap.

Recommendations Related to Cultural and Linguistic Challenges (Including Traditional Healing):

- Require the FDA to recognize a "traditional medicines" category that would take into account the historical and traditional uses of herbs and permit manufacturers to put this information on the label.
- Develop "peer" education programs to disseminate credible information on CAM to minority and ethnic communities.

Recommendations Related to Integration of CAM vs. CAM Separatism:

- Break down barriers to collaboration of conventional health care with CAM practitioners.
- Develop a 20-year plan to integrate conventional medicine into patient-centered, whole-person health care.

- Do not fully integrate CAM therapies into mainstream medicine.

Recommendations Related to Models of Service Delivery

- Provide access for all populations to nutritional programs such as the Dean Ornish program.
- Use nurses as a resource to integrate CAM into conventional medicine and serve as a bridge to help educate doctors.
- Develop a system of integrative medicine in which a cadre of CAM and conventional health care practitioners, each with his/her own scope of practice and tools, coordinate care, cross-refer, and co-manage patients.
- Fund and coordinate systematic reviews of specific CAM methods organized by clinical conditions.
- Increase research by CAM practitioners and experienced clinical researchers on clinical implementation of specific CAM treatments for specific conditions.

Recommendations Related to CAM Service Delivery to Uninsured and Underinsured:

- Link school loan forgiveness programs for CAM practitioners to service to underserved populations.
- Facilitate inclusion of underserved populations in CAM clinical research and require provision of standard conventional care instead of placebo.
- Include a service component to uninsured, underinsured, and underserved populations in Federally-supported CAM training and research grants.
- Include CAM in all Federal programs to reduce health disparities.
- Fund Community and Migrant Health Centers to use their unique abilities to deliver CAM and educate uninsured and underinsure populations about CAM in culturally competent ways.

Coverage and Reimbursement of CAM Practices and Products

The authority to decide what health care services are covered and reimbursed is spread among a number of purchasers. Employers, in conjunction with insurance and managed care companies, determine what health benefits are covered for most Americans. The Federal government, with Congressional approval, makes decisions regarding the health benefits for Medicare, Medicaid (although this authority is shared with States), the military, veterans, Federal employees, and others. These benefits help provide a safety net for the uninsured and underinsured. States enhance the benefits available under Medicaid and for the medically indigent.

Payers and purchasers generally expressed openness to coverage of CAM services that demonstrate several factors:

- The services or products were no longer investigational;
- The services or products were proven safe and of consistent high quality;
- Criteria were available to determine when such services or products should be paid, such as medical necessity criteria; and
- Standards of practice were available for the service or product (not only for guiding utilization and treatment plans, but as a prospective defense against potential malpractice/medical liability suits).

Major considerations of practitioner qualification for coverage and reimbursement are related to education, training, licensure/certification, and credentialing discussed in another section of this report.

Another common thread identified to address the issue of coverage and reimbursement was the need for not only biomedical research but more clinical research, health services research, and health services demonstration projects, particularly on the cost effectiveness of CAM services, comparative studies with allopathic medicine, and the value of health, wellness(non-disease oriented), and prevention regimens.

CAM in Wellness, Self-Care and Prevention

The role of CAM in self-care, wellness, and prevention, like the role of CAM in illness and disease management, is an evolving phenomenon with boundaries that are sometime difficult to define. The areas where CAM in self-care, wellness, and prevention merge can have important consequences for the health and well-being of individuals, and can greatly impact the way that health care is delivered in this country.

The current health care system is disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating disease. Self-care, wellness, or prevention activities that are incorporated into the conventional health care system are, for the most part, disease screening (e.g. pap smears, mammograms, etc.), or offered in response to an already identified illness or condition (e.g. physical therapy, nutrition counseling, etc.) Self-care, wellness, and prevention activities frequently take

place outside of the conventional health care system, and are reliant upon a person's initiative and ability (education, finances, availability of resources, etc.) to access and incorporate them into their life.

Many CAM therapies come from a holistic tradition of integrating body, mind, and spirit, and focus on optimal functioning to prevent, deter, or minimize illness and disease, and maximize one's potential to live life to the fullest. These qualities are the foundation of much of the interest in self-care, wellness, and prevention, which cover a wide range of activities such as support groups for people with cancer; meditation, yoga, or tai chi for relaxation and stress reduction; foods and dietary supplements to retain and enhance function and vitality; palliative care for the end of life; etc. All of these have a CAM component whose benefit is just beginning to be realized.

CAM-related self-care, wellness, and prevention activities need to be taught, promoted, and encouraged at all levels of the education spectrum, including the workplace, as part of a national health and wellness initiative for the entire population.

Schedule of Commission Meetings and Material Subjects Reviewed

July 13-14, 2000 - Planning Meeting

- Discussion of Vision, Issues and Concerns of the Commission Members on Issues Presented in Executive Order
- Development of Meeting Schedule
- Discussion of Website Development and Content

October 5-6, 2000 - Coordination of CAM Research & Achievements, Opportunities, Obstacles and Solutions

- Public Input and Research Priorities
- Federal Support for CAM Research
- Academic Centers and Support for CAM Research
- Research Support and Collaborations at the NIH
- Facilitating CAM Research and Regulatory Challenges
- Research in the Regulatory Framework
- Outcomes Research - Interface between CAM Research and Regulatory Agencies

- Outcomes Research - CAM Research and Experimental Study Design
- Guiding Principles of CAM Perspectives and Practices
- Support for CAM Research - The Not-for-Profit Sector
- Support for CAM Research - The Private Sector
- Support for CAM Research - Federal Agency Support

December 4-5, 2000 - Access and Delivery of CAM Services

- Utilization of CAM Services and Products
- Cost Effectiveness of Selected CAM Services
- Clinical Effectiveness of Selected CAM Services
- Use of CAM for Selected Health Conditions
- Issues in Integrating CAM in Service Delivery
- Meeting Public Needs: Systems of CAM Delivery at Community Health Clinics, in Private Practice and Hospital Based Centers, in Hospice Care, at Academic Research Centers and in Managed Care Organizations.

February 22–23, 2001 - Training, Education, Credentialing and Licensing of CAM Practices

- CAM Education and Training: Establishing Educational Programs
- Continuing CAM Education and Training - Building Knowledge and Skills
- CAM Credentialing and Licensure - Assuring Quality and Accountability in CAM Practices

March 26-27, 2001 - Development and Dissemination of CAM Information

- CAM in the Media - Newspapers, Magazines, Television and Radio
- CAM in the Media - The Internet
- Evaluation of available CAM Information
- Marketing and Advertising of CAM Services and Products

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities
- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

- Not-for-Profit Support for CAM Research
- Investigating the Scientific Bases of CAM Practices
- Approaches to Evaluating CAM Research Literature
- Challenges of CAM Research and Research Training
- Peer Reviews of CAM Research Results in the Published Literature

May 15-16, 2001 - Coverage and Reimbursement of CAM Services

- Health Care Financing in the United States
- Federal Purchasers
- State Perspectives
- Employer Coverage
- The Underinsured, Uninsured and Minorities
- Health Plans and CAM Benefits
- Healthcare Insurance - Providers Perspectives
- Evolving Health Care Systems

Town Hall Meetings

September 8, 2000 - San Francisco, CA
October 30-31, 2000 - Seattle, WA
January 23, 2001 - New York City, NY
March 16, 2001 - Minneapolis, MN

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems
- Dietary Supplements and Herbal Products
- Education of CAM Providers
- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

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Research

(Regulations
separated)
per Info
— DBS

Geri Polka
6/12

DRAFT RECOMMENDATION ON COLLABORATIVE RESEARCH ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

MORE EVIDENCE BASED ON RESEARCH IS NEEDED ON CAM PRODUCTS AND PRACTICES.

Because the public in large numbers is using complementary and alternative medicine (CAM), research on CAM products and practices is an important public health and safety issue. To address the need for dependable information on CAM products and procedures, research that meets high standards of design and execution is required. For many CAM products and practices there is little reliable information about safety and efficacy. Anecdotes, observations by individual practitioners, and small studies are important first steps in pursuing the development of the critical mass of objective, high quality data on the safety and efficacy of CAM practices and products.

PUBLIC SAFETY REQUIRES IMPROVED DIALOGUE AND COOPERATION BETWEEN THE CONVENTIONAL MEDICAL COMMUNITY AND THE CAM COMMUNITY.

Greater communication, understanding, and cooperation need to be fostered between the conventional medical community and the CAM community. The conventional medical research community and the CAM community should:

(1) reduce negative stereotyping;
(2) work on strengthening the dialogue between them;
(3) increase collaboration; and
(4) include each other on interdisciplinary advisory committees and at conferences designed to facilitate communication.

Because CAM is important to many members of the public, the conventionally-trained medical community needs to:

(1) be better trained and more knowledgeable about CAM;
(2) discuss patients' use of CAM products and procedures to be better informed about patients' total care and to avoid adverse reactions and drug/herb interactions; and
(3) be open and receptive to communication with CAM practitioners in a joint interest to improve patient care.

The CAM community needs to:

(1) understand the concerns of members of the conventional medical community about CAM practices and products;
(2) strengthen their professional organizations in the areas of training and credentialing;
(3) improve their ability to recognize complications and adverse interactions; and
(4) pursue the skills needed to collect reliable, objective data; serve on research teams, and learn the research skills and rigorous requirements of competing for research dollars,

AS IS THE CASE WITH CONVENTIONAL MEDICAL RESEARCH, GOOD SCIENTIFIC EVIDENCE ABOUT CAM MODALITIES REQUIRES CREATIVITY IN RESEARCH METHODOLOGY AND FLEXIBILITY IN IDENTIFYING PRELIMINARY DATA.

Randomized, controlled clinical trials (RTC) should be the method of choice whenever possible. As in challenges posed by conventional medical research questions, methodological adjustments to the study of CAM questions are possible, few are insoluble. CAM studies may be different in detail and types of complexity, but should adhere to the same basic elements–a hypothesis that can be tested, a good study design and research team, verifiable data, and objective conclusions. Findings should be as reproducible as possible. Individualized therapy and practitioner affect on outcome can be examined inside studies.

Pursue follow-up studies to increase the strength of the evidence.

Use a broad spectrum of data when studying herbs. Consider historical data in addition to practice-based and other more current data sources. (Also see section on industry below.)

Pursue ways to access international data (European and Asian), but evaluate the quality and objectivity of the data.

RESEARCH ON THE SCIENTIFIC BASIS OF CAM AND THE DEVELOPMENT OF AN ADEQUATE POOL OF WELL-TRAINED CAM RESEARCHERS REQUIRES STRONG COMMITMENT BY THE FEDERAL GOVERNMENT.

The Federal government should:

continue to strengthen support for

(1) rigorous research on the scientific basis of CAM and the training of conventional researchers to develop well designed and conducted studies;
(2) the training of CAM professionals to collect reliable and objective data, serve as members of collaborative research teams, and become fully trained investigators; and
(3) the infrastructure needed to carry out CAM research and the training of CAM researchers at both conventional medical research institutions and state-approved CAM educational facilities, and to stimulate cooperation between the conventional researchers and credentialed, licensed members of the CAM community. (Also see section below on academic health centers.)

ensure the appropriate inclusion of experts on CAM practices and products on peer review and advisory committees and institutional review boards (IRBs).

encourage more NIH Institutes to collaborate with the National Center for Complementary and Alternative Medicine (NCCAM), as good grant application opportunities arise, and to develop programs similar to the best case series program of the National Cancer Institute (NCI).

give strong support to the Office of Dietary Supplements (ODS), NIH, which is supporting studies in such areas as the synergistic properties of blended compounds, and encourage collaboration with NIH Institutes, such as the collaborations between the ODS and the National Institute of Environmental Health Sciences (NIEHS).

create incentives to motivate basic scientists to partner with CAM practitioners in areas relevant to both, such as the mechanisms of action of acupuncture or the study of complete biological systems.

support clinical research on promising products and modalities that are not patentable and are therefore not likely to attract the expenditure of research dollars by the pharmaceutical, biotechnology, or medical device industries. (Also see section on government agencies below.)

fund research on the top 20 most popular herbs, first to establish their safety and then in more depth to establish their efficacy.

revisit Medicare rules barring payment for treatments not normally covered, including many CAM modalities, which pose a significant obstacle for including elderly people on Medicare in CAM clinical trials.

invite the public to give their views in setting CAM research priorities, and invite CAM professionals to be included in research policy efforts.

leverage funds through collaboration with philanthropic and private organizations; invite representatives from these two sectors as well as CAM professionals to join advisory committees considering CAM research activities; and issue a list of meritorious grants that have not received support. (Also see section on private and philanthropic organizations below.)

increase opportunities to study CAM approaches to improving lifestyle, disease prevention, and quality of life, especially given an aging society, the prevalence of chronic diseases, and the need to strengthen health maintenance in younger people. Many people with chronic disorders turn to CAM.

encourage funding to universities to develop or strengthen programs that bring CAM clinical research into academic health centers, such as those at the University of Pennsylvania, Harvard, Duke, and the University of Maryland. (Also see academic health centers below.)

MAKE CAM PART OF THE MISSION OF ALL RELEVANT FEDERAL AGENCIES.

Strengthen CAM-related activities among the Federal agencies through a government-wide interagency committee that considers all aspects, other than research, that are relevant to the integration of CAM and collaborations with the private and not-for-profit sectors.

STRENGTHEN SUPPORT FOR CAM RESEARCH AS APPROPRIATE IN ALL AGENCIES WITH RESEARCH-RELATED RESPONSIBILITIES IN THEIR MISSION.

Adequately support CAM-related surveillance programs on utilization (CDC, HRSA) and adverse reactions (CDC, FDA), demonstration projects (NIH, HRSA, VA), and health services and cost effectiveness studies (HRSA, HCFA, AHRQ) and by other appropriate Federal agencies.

For example, support demonstration projects or outcomes studies to answer questions about the clinical effectiveness and cost effectiveness of CAM modalities as compared to conventional care.

Use a mechanism, similar to the Centers of Excellence Program in the Health Services and Resources Administration's Bureau of Health Professionals to help jumpstart the research efforts of licensed CAM professionals and institutions.

Support schools of public health to carry out research on CAM services.

GOVERNMENT REGULATORY AGENCIES (FEDERAL AND STATE) SHOULD HELP FACILITATE CAM RESEARCH IN THE PUBLIC INTEREST.

State Medical Boards

While recognizing that protecting the public from unqualified practitioners is of the utmost importance, the U.S. Federation of State Medical Boards should develop a process for meeting with CAM practitioners who believe in practice-based research but whose treatments are considered nonstandard to guide them to collaborative research environments that allow thinking outside the box, such as the best-case series program of the National Cancer Institute (NCI). State medical boards might also help researchers involved in CAM/conventional research efforts to navigate the institutional review board process and help IRB's to better evaluate CAM research protocols. (Also see section on academic health centers below.)

Explore what regulatory changes might be made to strengthen such CAM research efforts as the NCI program which can succeed only if practitioners feel secure in sharing their observations with a government entity.

Food and Drug Administration

Increase FDA funding to add adequate staff, who are well-versed in CAM and able to communicate well with the CAM community, in order to address the safe integration of CAM products into the broader regulatory process.

Consider regulatory changes in combination-product regulations to promote CAM research on botanicals. The product that is shown, through scientific evidence, to be clinically effective no

longer has to play the label game. However, the current FDA's drug development system's regulatory framework is tailored to single entity and synthetic drugs and thus poses a barrier to research on CAM products. The FDA guidance document on how to study botanicals and deal with the approval process is a good start, but it takes the single-entity paradigm and overlays it with botanical requirements..

Encourage FDA to promulgate additional chemistry and manufacturing standards to accommodate the reproducibility, stability, and constant dose issues related to CAM products.

Because it is so difficult to give exclusive rights to products that have been used for centuries, there is little research on these products.

In addition to providing support for research on CAM products, the Federal government should provide assistance to CAM companies for drug review costs. Small manufacturers, more often than not, do not have the money to support clinical trials. If the few companies that might be able to support clinical studies did so with positive results, they would be faced with the additional expenses associated either OTC, IND, or NDA reviews. In addition, while manufacturers who took the trouble and went to the expense of gaining approval would have the right to make a medical claim, other manufacturers could sell similar products as dietary supplements. Also, pharmaceutical companies that are increasing their involvement in the sale of dietary supplements are not investing in research on these products.

Establish a mechanism for reviewing problems CAM researchers may have getting INDs. Support a staff at the FDA to assess the appropriate classification of botanicals as treatments, and support more forceful advertising of FDA's health advisories on health interactions.

ACADEMIC HEALTH CENTERS SHOULD OVERCOME TABOOS ABOUT CAM AND HELP BRING ABOUT THE SAFE INTEGRATION OF CAM INTO MEDICAL PRACTICE THROUGH RESEARCH, RESEARCH TRAINING, AND MEDICAL EDUCATION. (negative)

Address education, clinical practice and research in any plan that incorporates CAM, and develop all three simultaneously.

Create steering committees that include individuals knowledgeable about CAM to advise IRB's on applications that require such input.

Integrate core knowledge about CAM modalities into the educational curriculum.

Sponsor meetings with institutions engaged in CAM research that want to exchange ideas and explore cooperation. Address the need to improve research capabilities at CAM institutions by partnering with institutions that have a research focus.

When creating a program or division that will include CAM, invite people representing opposing positions to join the planning panels.

Provide training programs, including pre- and post-doctoral opportunities and career tracks for capable individuals interested in the integration of CAM.

THERE IS A NEED FOR GREATER COVERAGE OF CAM RESEARCH RESULTS IN MEDICAL JOURNALS SO THAT ALL PRACTITIONERS AND THE PUBLIC ARE MORE AWARE OF BOTH THE POSITIVE VALUE OF CAM THERAPY AND ANY HARMFUL EFFECTS.

Mainstream medical journals need to publish carefully and fairly reviewed research results of CAM practices and products because many people use CAM products and visit CAM practitioners and medical students are expressing increased interest in gaining knowledge about CAM.

Recognizing that impartial review and the expectation of the highest research standards are required practice for all quality academic publications, the fine line between these requirements and publication bias must be carefully navigated and, if present, overcome.

Encourage mainstream journal editorial boards to consider the distinction between adhering to sound scientific principles and the design methodology itself in order to allow the flexibility that may be needed in evaluating the examination of a CAM question.

Ensure that the review of CAM research submissions include reviewers with knowledge about CAM.

Peer-reviewed journals should consider papers on any topic relevant to the practice of medicine and their physician/practitioner readers.

Continue to increased Federal support for CAM research and training of CAM researchers so that more high quality research articles are submitted for review.

ENCOURAGE GREATER INVOLVEMENT ON THE PART OF THE PRIVATE AND PHILANTHROPIC SECTORS IN RESEARCH ON CAM. FOR THE CAM INDUSTRY, ADEQUATE FUNDS AND RESEARCH COLLABORATIONS ARE ISSUES. FOR THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES, PROPRIETARY AND MARKET CONCERNS ARE ISSUES. FOR BOTH, REGULATORY ISSUES EXIST.

Create a model for coordination among the Federal, private and philanthropic sectors.

Encourage the CAM industry to

(1) submit studies to peer-reviewed journals; provide data from unpublished studies to assist in the selection of therapies for further study; and contribute to study design;

(2) cosponsor, symposia or conferences to provide networking opportunities for communication among practitioners, researchers, and industry; and
(3) develop a clinical trials guidance document outlining the standard components and proper design of study protocols.

The dietary supplement industry should use NIEHS National Toxicology Program data on the toxicity/carcinogenicity of these complex materials to study some of the untested dietary supplements in commerce. This is important because the basic safety and toxicity information is urgently needed and the NTP is limited in the number of (the many) products in popular use that it can test.

Consider providing pharmaceutical companies with incentives, such as process-use patents, and market protections, such as exclusivity periods, to stimulate investment in research and development of botanicals that meet the highest standards.

Convene meetings between companies and medical journal editorial boards to solicit recommendations for increasing acceptance of papers submitted by industry.

Involve industry early in the discussion and development of regulations that would affect facilitating research and research investment.

Develop a rigorous review process that would include both academic and industry scientists in the evaluation of CAM research proposals.

Increase the use of the NIH Small Business Innovation Research grant mechanism.

Stimulate the philanthropic sector to form a consortium of foundations interested in CAM and the public interest that would pool funds for the support of CAM research, which would reduce the risk for the individual organizations. The endeavor would require a scientific advisory board, a review process, and a mechanism for announcing funding competition up to so many dollars.

Encourage philanthropic organizations to (individually or cooperatively) provide seed money for or pilot studies, research training, coordinated research activities at academic health centers; the publication of research results; and the convening of conferences to assess the state of the science, and workshops on Federal and foundation grant processes and opportunities.

Encourage foundation sponsorship to convene a "think-tank" group of research methodologists and CAM professionals to discuss the methodological issues involved in CAM research.

Consider the advisability of changes in the not-for-profit law to permit grants to individuals.

Invite foundations to host face-to-face meetings with CAM professionals and make site visits to NIH-funded research centers.

GP Draft 6/12

DRAFT RECOMMENDATION ON COLLABORATIVE RESEARCH ON COMPLEMENTARY AND ALTERNATIVE MEDICINE

I. More Clinical evidence based on research is needed on CAM products and practices.

Because the public in large numbers is using complementary and alternative medicine (CAM), research on CAM products and practices is an important public health and safety issue. To address the need for dependable information on CAM products and procedures, research that meets high standards of design and execution is required. For many CAM products and practices there is little reliable information about safety and efficacy. Anecdotes, observations by individual practitioners, and small studies are important first steps in pursuing the development of the critical mass of objective, high quality data on the safety and efficacy of CAM practices and products.

II. Public safety requires improved dialogue and cooperation between the conventional medical community and the CAM community.

Greater communication, understanding, and cooperation need to be fostered between the conventional medical community and the CAM community. The conventional medical research community and the CAM community should:

(1) reduce negative stereotyping;
(2) work on strengthening the dialogue between them;
(3) increase collaboration; and
(4) include each other on interdisciplinary advisory committees, as appropriate, and at conferences designed to facilitate communication.

Because CAM is important to many members of the public, the conventionally-trained medical community needs to:

(1) be better trained and more knowledgeable about CAM and CAM research;
(2) use this knowledge to discuss respectfully with patients their use of CAM products and procedures in order to be better informed about their total care and to avoid adverse reactions and drug/herb interactions; and
(3) to improve patient care, be open and receptive to communication with CAM practitioners and CAM research.

The CAM community needs to:

(1) understand the concerns of members of the conventional medical community about CAM practices and products and the role of research in addressing these concerns;
(2) strengthen their professional organizations in the areas of training and credentialing based on research and stringent practice guidelines;
(3) improve their ability to recognize complications and adverse interactions through knowledge gained from research; and
(4) pursue the skills needed to collect reliable, objective data; serve on research teams, and learn the research skills and rigorous requirements of competing for research dollars,

III. AS IS THE CASE WITH CONVENTIONAL MEDICAL RESEARCH, GOOD SCIENTIFIC EVIDENCE ABOUT CAM MODALITIES REQUIRES CREATIVITY IN RESEARCH METHODOLOGY AND FLEXIBILITY IN IDENTIFYING PRELIMINARY DATA.

Randomized, controlled clinical trials (RTC) should be the method of choice whenever possible. As in challenges posed by conventional medical research questions, methodological adjustments to the study of CAM questions are possible, few are insoluble. CAM studies may be different in detail and types of complexity, but should adhere to the same basic elements–a hypothesis that can be tested, a good study design and research team, verifiable data, and objective conclusions. Findings should be as reproducible as possible. Individualized therapy, practitioner affect on outcome, and the placebo effect can be examined inside studies.

Pursue follow-up studies to increase the strength of the evidence.

Use a broad spectrum of data when studying herbs. Consider historical data in addition to practice-based and other more current data sources. (Also see section on industry below.)

Pursue ways to access international data (European and Asian), but evaluate the quality and objectivity of the data.

IV. RESEARCH ON THE SCIENTIFIC BASIS OF CAM AND THE DEVELOPMENT OF AN ADEQUATE POOL OF WELL-TRAINED CAM RESEARCHERS REQUIRES STRONG COMMITMENT BY THE FEDERAL GOVERNMENT.

The Federal government should:

continue to strengthen support for

(1) rigorous research on the scientific basis of CAM and the training of conventional researchers to develop well designed and conducted studies;
(2) the training of CAM professionals to collect reliable and objective data, serve as members of collaborative research teams, and become fully trained investigators; and
(3) the infrastructure needed to carry out CAM research and the training of CAM researchers at both conventional medical research institutions and state-approved CAM educational facilities, and to stimulate cooperation between the conventional researchers and credentialed, licensed members of the CAM community. (Also see section below on academic health centers.)

ensure the appropriate inclusion of experts on CAM practices and products on peer review and advisory committees and institutional review boards (IRBs).

encourage more NIH Institutes to collaborate with the National Center for Complementary and Alternative Medicine (NCCAM), as good grant application opportunities arise, and to develop programs similar to the best case series program of the National Cancer Institute (NCI).

give strong support to the Office of Dietary Supplements (ODS), NIH, which is supporting studies in such areas as the synergistic properties of blended compounds, and encourage collaboration with NIH Institutes, such as the collaborations between the ODS and the National Institute of Environmental Health Sciences (NIEHS).

create incentives to motivate basic scientists to partner with CAM practitioners in areas relevant to both, such as the mechanisms of action of acupuncture or the study of complete biological systems.

support clinical research on promising products and modalities that are not patentable and are therefore not likely to attract the expenditure of research dollars by the pharmaceutical, biotechnology, or medical device industries. (Also see section on government agencies below.)

fund research on the top 20 most popular herbs, first to establish their safety and then in more depth to establish their efficacy.

revisit Medicare rules barring payment for treatments not normally covered, which include many CAM modalities. These rules have posed a significant obstacle to research by excluding elderly people on Medicare from CAM clinical trials.

invite the public to give their views in setting CAM research priorities, and invite CAM professionals to be included in research policy efforts.

leverage funds through collaboration with philanthropic and private organizations; invite representatives from these two sectors as well as CAM professionals to join advisory committees considering CAM research activities; and issue a list of meritorious grants that have not received government support. (Also see section on private and philanthropic organizations below.)

increase opportunities to study CAM approaches to improving lifestyle, disease prevention, and quality of life, especially given an aging society, the prevalence of chronic diseases, and the need to strengthen health maintenance in younger people. Many people with chronic disorders turn to CAM.

encourage funding to universities to develop or strengthen programs that bring CAM clinical research into academic health centers, such as those at the University of Pennsylvania, Harvard, Duke, and the University of Maryland. (Also see academic health centers below.)

V. STRENGTHEN SUPPORT FOR CAM RESEARCH, AS APPROPRIATE, IN ALL AGENCIES WITH RESEARCH-RELATED RESPONSIBILITIES IN THEIR MISSION.

Adequately support health care delivery research including such activities as CAM-related studies on utilization (HRSA) and surveillance of adverse reactions (CDC, FDA), demonstration projects (NIH, HRSA, VA), and health services and cost effectiveness studies (HRSA, HCFA,

AHRQ) and by other appropriate Federal agencies.

For example, support demonstration projects or outcomes studies to answer questions about the clinical effectiveness and cost effectiveness of CAM modalities as compared to conventional care.

Use a mechanism, similar to the Centers of Excellence Program in the Health Services and Resources Administration's Bureau of Health Professionals to help jumpstart the research efforts of licensed CAM professionals and institutions.

Support collaboration with schools of public health to carry out health services delivery research.

VI. GOVERNMENT REGULATORY AGENCIES (FEDERAL AND STATE) SHOULD HELP FACILITATE CAM RESEARCH IN THE PUBLIC INTEREST.

State Medical Boards

While recognizing that protecting the public from unqualified practitioners is of the utmost importance, the U.S. Federation of State Medical Boards should develop a process for meeting with CAM practitioners who believe in practice-based research but whose treatments are considered nonstandard to guide them to collaborative research environments that allow thinking outside the box, such as the best-case series program of the NCI. State medical boards might also help researchers involved in CAM/conventional research efforts to navigate the institutional review board process and help IRB's to better evaluate CAM research protocols. (Also see section on academic health centers below.)

Explore what regulatory changes might be made to strengthen CAM-related research programs, such as the NCI program, that can succeed only if practitioners feel secure in sharing their observations with a government entity.

Food and Drug Administration

Ensure that FDA has an adequate staff, who are well-versed in CAM and CAM research and able to communicate well with the CAM community, in order to address the safe integration of CAM products into the broader regulatory process.

Consider regulatory changes in combination-product regulations to promote CAM research on botanicals. The product that is shown, through scientific evidence, to be clinically effective no longer has to play the label game. However, the current FDA's drug development system's regulatory framework is tailored to single entity and synthetic drugs and thus poses a barrier to research on CAM products. The FDA guidance document on how to study botanicals and deal with the approval process is a good start, but it takes the single-entity paradigm and overlays it with botanical requirements. To promote research on CAM, more attention needs to be paid to

product combinations.

Support a staff at the FDA to assess the appropriate classification of botanicals as treatments.

Because it is so difficult to give exclusive rights to products that have been used for centuries, there is little research on these products.

Small manufacturers, more often than not, do not have the money to support clinical trials and, if the companies that were able to conduct clinical studies did so with positive results, they believe they face additional expenses associated with OTC, IND, or NDA reviews. To stimulate more research on CAM modalities, in addition to providing research support, the Federal government should consider waiving the costs to CAM companies for regulatory reviews.

In addition, while manufacturers who go to the trouble and expense of gaining approval would have the right to make a medical claim, other manufacturers could sell similar products as dietary supplements. Also, pharmaceutical companies that are increasing their involvement in the sale of dietary supplements are not investing in research on these products. (See section on private and philanthropic sectors below)

Establish a mechanism for reviewing problems CAM researchers may have getting INDs and make it more widely known that FDA staff are available to help.

VII. INSERT FDA #2: Please see Appendix to this document.

VIII. ACADEMIC HEALTH CENTERS SHOULD OVERCOME TABOOS ABOUT CAM AND HELP BRING ABOUT THE SAFE INTEGRATION OF CAM INTO MEDICAL PRACTICE THROUGH RESEARCH, RESEARCH TRAINING, AND MEDICAL EDUCATION.

Address education, clinical practice and research in any plan that incorporates CAM, and develop all three simultaneously.

Create steering committees that include individuals knowledgeable about CAM to advise IRB's on applications that require such input.

Integrate core knowledge about what is learned from research on CAM modalities and approaches into the educational curriculum.

Sponsor meetings with institutions engaged in CAM research that want to exchange ideas and explore cooperation. Address the need to improve research capabilities at CAM institutions by partnering with institutions that have a research focus.

When creating a program or division that will include CAM, invite people representing opposing positions to join the planning panels.

Provide training programs, including pre- and post-doctoral opportunities and career tracks for capable individuals interested in the integration of CAM.

IX. THERE IS A NEED FOR GREATER COVERAGE OF CAM RESEARCH RESULTS IN MEDICAL JOURNALS SO THAT ALL PRACTITIONERS AND THE PUBLIC ARE MORE AWARE OF BOTH THE POSITIVE VALUE OF CAM THERAPY AND THE HARMFUL EFFECTS.

Mainstream medical journals need to publish carefully and fairly reviewed research results of CAM practices and products because many people use CAM products and visit CAM practitioners, and medical students are expressing increased interest in gaining knowledge about CAM.

Recognizing that impartial review and the expectation of the highest research standards are required practice for all quality academic publications, the fine line between these requirements and publication bias must be carefully navigated and, if present, overcome.

Encourage mainstream journal editorial boards to consider the distinction between adhering to sound scientific principles and the design methodology itself in order to allow the flexibility that may be needed in evaluating the examination of a CAM question.

Ensure that the review of CAM research submissions include reviewers with knowledge about CAM.

Peer-reviewed journals should consider papers on any topic relevant to the practice of medicine and their physician/practitioner readers.

Continue to increased Federal support for CAM research and training of CAM researchers so that more high quality research articles are submitted for review.

X. ENCOURAGE GREATER INVOLVEMENT ON THE PART OF THE PRIVATE AND PHILANTHROPIC SECTORS IN RESEARCH ON CAM. FOR THE CAM INDUSTRY, ADEQUATE FUNDS AND RESEARCH COLLABORATIONS ARE ISSUES. FOR THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES, PROPRIETARY AND MARKET CONCERNS ARE ISSUES. FOR BOTH, REGULATORY ISSUES EXIST.

Create a model for coordination among the Federal, private and philanthropic sectors.

Encourage the CAM industry to

(1) submit studies to peer-reviewed journals; provide data from unpublished studies to assist in the selection of therapies for further study; and contribute to study design;
(2) cosponsor, symposia or conferences to provide networking opportunities for communication among practitioners, researchers, and industry; and
(3) develop a clinical trials guidance document outlining the standard components and

proper design of study protocols.

The dietary supplement industry should use NIEHS National Toxicology Program data on the toxicity/carcinogenicity of these complex materials to study some of the untested dietary supplements in commerce. This is important because the basic safety and toxicity information is urgently needed and the NTP is limited in the number of products in popular use that it can test.

Consider providing pharmaceutical companies with incentives and market protections, such as exclusivity periods, to stimulate investment in research and development of botanicals that meet the highest standards.

Convene meetings between companies and medical journal editorial boards to solicit recommendations for increasing acceptance of papers submitted by industry.

Involve industry early in the discussion and development of regulations that would affect facilitating research and research investment.

Develop a rigorous review process that would include both academic and industry scientists in the evaluation of CAM research proposals.

Increase the use of the NIH Small Business Innovation Research grant mechanism.

Stimulate the philanthropic sector to form a consortium of foundations interested in CAM and the public interest that would pool funds for the support of CAM research, which would reduce the risk for the individual organizations. The endeavor would require a scientific advisory board, a review process, and a mechanism for announcing funding competition up to so many dollars.

Encourage philanthropic organizations to (individually or cooperatively) provide seed money for or pilot studies, research training, coordinated research activities at academic health centers; the publication of research results; and the convening of conferences to assess the state of the science, and workshops on Federal and foundation grant processes and opportunities.

Encourage foundation sponsorship to convene a "think-tank" group of research methodologists and CAM professionals to discuss the methodological issues involved in CAM research.

Consider the advisability of changes in the not-for-profit law to permit grants to individuals.

Invite foundations to host face-to-face meetings with CAM professionals and make site visits to NIH-funded CAM research centers.

June 13, 2001
Corinne Axelrod

CAM in Self-Care, Wellness, and Prevention (SWAP)

The role of CAM in self-care, wellness, and prevention (SWAP), like the role of CAM in illness and disease management, is an evolving phenomenon with boundaries that are sometime difficult to define. While not all CAM is SWAP, and not all SWAP is CAM, the areas where they merge can have important consequences for the health and well-being of individuals, and can greatly impact the way that health care is delivered in this country.

The current health care system is disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating disease. Self-care, wellness, or prevention activities that are incorporated into the conventional health care system are, for the most part, disease screening (e.g. pap smears, mammograms, etc.), or offered in response to an already identified illness or condition (e.g. physical therapy, nutrition counseling, etc.) SWAP activities usually take place outside of the conventional health care system, and are reliant upon a person's initiative and ability (education, finances, availability of resources, etc.) to access and incorporate them into their life.

Many CAM therapies come from a holistic tradition of integrating body, mind, and spirit, and focus on optimal functioning to prevent, deter, or minimize illness and disease, and maximize one's potential to live life to the fullest. These qualities are the foundation of much of the interest in self-care, wellness, and prevention, which cover a wide range of activities such as support groups for people with cancer; meditation, yoga, or tai chi for relaxation and stress reduction; foods and dietary supplements to retain and enhance function and vitality; palliative care for the end of life; etc. All of these have a CAM component whose benefit is just beginning to be realized.

The following recommendations have been made at the WHCCAMP meetings:

<u>CAM in the Schools</u>

CAM activities should begin in elementary school, as part of health education. Teachers and students should learn meditation and relaxation techniques, and information should be provided about the ancient civilizations and diverse cultures which gave rise to many of these health traditions.

Outlaw corporate/school relationships where corporate contributions of computers and resources are tied to the presence of soft drink machines in schools.

Create programs in schools that help educate children about how to care for their bodies throughout their lives, and teach nutrition.

CAM and Conventional Health Care

Measurements of health must be more than the absence of disease, and include qualities such as greater levels of energy, vitality, creativity, and overall well being.

CAM should be incorporated into well child care and pediatric practice.

Increased funding should be directed to research in self-care, wellness, and prevention, including the role of spirituality.

Encourage more communication between medical practitioners and spiritual leaders to address issues such as spiritual assessment, referrals, possible conflicts, etc.

Establish a Center of Wellness at the NIH

Encourage the U.S. Surgeon-General to send a letter to the nation's doctors reporting briefly on those CAM approaches that have been validated by clinical research within the last five years.

Support funding for research and education on the effectiveness of CAM for both prevention and recovery, with diet and lifestyle at the base and establish a pilot plan for clinical trials in some hospitals and health care centers.

Encourage hospitals, clinics, health care facilities, and medical schools to add dietary and wellness studies, counseling, cooking classes, and serving facilities with healthful menus.

Clinical nutrition and nutritional supplementation needs to be taught in medical school courses, and clinical competency courses are needed for practitioners.

Provide additional training for doctors and nurses to include: the role of spirituality in health and in end-of-life care; how to address patients' spiritual needs; how to recognize spiritual suffering; how an interdisciplinary approach to care can build communities of caring.

Train health care professionals, as well as faith and other social communities, to recognize the importance of spiritual care, particularly at the end of life, and how to work within the health care system.

Shift reimbursement codes from the ICD-9/CPT disease-based model to one that is based on health promotion and change our focus on acute and terminal care to focusing on early assessment and intervention to prevent and diagnose and treat and optimize health.

CAM and the Workplace

Offer employers incentives to start new workplace health and wellness programs that incorporate appropriate CAM modalities.

CAM and Special Populations

Support studies of CAM usage among different racial/ethnic populations.

Integrate CAM providers into traditional geriatric health provider teams in hospitals, the community, assisted living facilities, nursing homes, etc.

Promote self-care and wellness in older adults, and provide Medicare reimbursement for CAM.

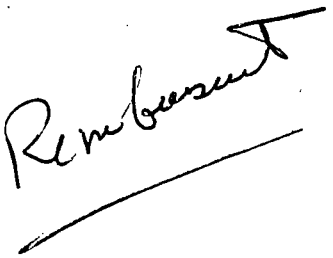
Help facilitate the use of a proper diet and wellness plan in government programs, such as Meals On Wheels for seniors, and in prisons.

Extend the hospice benefit so that someone who is diagnosed with a potentially life-threatening illness could immediately be eligible for palliative care support.

CAM and the Environment

Encourage the avoidance of daily consumption of food and water which are overly artificialized, chemicalized, irradiated. Encourage the proper evaluation of genetic modification, and encourage more respect for natural, organic, and traditional quality of food and drinks.

Promote improvements to secure a more clean, natural environment of our air, water, and soil, and encourage avoidance of technology that is environmentally harmful.


Rembrandt

M. Miller
6/12

Recommendations on Coverage and Reimbursement of CAM Services

The authority to decide what health care services are covered and reimbursed is spread among a number of "purchasers." Employers, in conjunction with insurance and managed care companies, determine what health benefits are covered for most Americans. The federal government – often only with Congressional approval -- makes decisions regarding the health benefits for Medicare, Medicaid (although this authority is shared with States), the military, veterans, Federal employees, etc. and helps provide a safety net for the uninsured and underinsured. States enhance the benefits available under Medicaid and for the medically indigent.

Presentations at the recent meeting on coverage and payment identified key issue areas and recommendations. Payers and purchasers generally expressed openness to coverage of CAM services that demonstate several factors:

- The services or products were no longer investigational
- The services or products were proven safe and of consistent high quality
- Criteria were available to determine when such services or products should be paid, such as medical necessity criteria
- Standards of practice were available for the service or product (not only for guiding utilization and treatment plans, but as a prospective defense against potential malpractice/medical liability suits).

Related to these are issues of practitioner qualification for coverage and reimbursement: education, training, licensure/certification, and credentialing.

Another common thread among the presenters was the need for more research not only biomedical research but more clinical research, health services research, and health services demonstrations, particularly on the cost and efficacy of CAM services, comparative studies with allopathic medicine, and the value of health (non-disease oriented) regimens.

The topic areas being considered ~~recommendations~~ that follow were drawn from the May meeting as well as other Commission meetings and Town Hall meetings.

Health Services/Cost Effectiveness Research and Demonstrations

Congress could instruct public agencies (e.g., NIH, AHRQ, HCFA, DOD, VA, HRSA) to fund research and demonstrations on the clinical effectiveness of various CAM approaches and on the relative costs of more conventional allopathic treatments and of CAM treatments for the same condition.

- Investigate the outcomes and value of CAM networks and the use of complementary/integrative teams of practitioners.

Develop a unified data tracking system for clinical outcomes and costs that allows research from public and private sectors to be aggregated across institutions.

Fund the needed clinical and health services research/demonstrations from both public and private sources. For example: NIH, AHRQ, CDC, FDA, HCFA, DOD, VA, insurance companies, managed care companies, employers, health care business entities (such as pharmaceutical companies) associations, foundations, etc.

Encourage HCFA to develop a HCFA demonstration project with selected HMOs:

- Cover reimbursement for evidence-based CAM procedures as part of comprehensive case management of persons with chronic disease
- Utilize Medicare+Choice organizations (M+COs) – i.e., Medicare HMOs – and Medicaid managed care plans, selecting those HMOs whose physician leadership has demonstrated a commitment to evidence-based medicine and pursuit of excellence in high quality case management.
-

WHCCAMP and Congress could encourage one or more Fortune Top 50 companies to collaborate with HCFA by creating its own demonstration project, examining the feasibility of using this approach with a broad-based employee population and testing the impact on overall medical costs.

WHCCAMP and Congress could encourage HCFA to set up an additional 5-year demonstration project that reimburses Medicare enrollees within a single state or area of a state for costs of services provided by certified CAM practitioners or for herbs and supplements. There would be a cap on reimbursements equivalent to current proposals for prescription drug relief. The project would compare total Medicare costs for that demonstration area with costs incurred by an equivalent Medicare population of similar size elsewhere.

Conduct research to evaluate the effectiveness of CAM services in improving health outcomes. The impact of CAM services on improving health and moderating costs must be studied and proven to be of value, based on clinical evidence. Such studies should use metrics that will withstand the legal and professional scrutiny to which plans are subject.

- Study how CAM care relates to and supports conventional biomedical services. Can CAM services substitute appropriately for some biomedical services, or will CAM always be additive?
- The impact of CAM services on improving health and moderating health care costs should be studied before consumers become entrenched in new patterns of care.

Federal and State Initiatives

Establish within the federal bureau that funds [community] health centers an Integrative Medicine and Alternative Health Practices – or IMAHP Initiative to

provide information and track the use of alternative therapies within these health centers.

Address the funding barrier. At DHHS, increase funding and/or earmark funds for identified populations to benefit from CAM therapies, not only at the Bureau of Primary Health, but also the Indian Health Service, Maternal and Child Health Program, Ryan White AIDS Program, among others.

- Open the National Health Service Corps to CAM practitioners.

Medicaid and the Child Health Insurance Program should provide coverage for appropriate CAM therapies.

CAM practitioners should apply to become members of various committees, working groups, professional panels, etc. (such as the Medicare Coverage Advisory Committee) in order to assure that CAM interests are represented and to help influence coverage, payment, and research decisions within the broader health care industry.

Explore approaches to expanding Medicare coverage other than through demonstrations or national coverage decisions, e.g., work with local carrier review committees, explore coverage under Medicare's "incident to" policy.

Explore approaches to expanding coverage for federal employees under FEHBP, the military, and veterans to clinically effective CAM services.

Creating a Level Playing Field

Information [on the clinical and cost effectiveness of various allopathic and CAM treatments for the same condition], supplemented by other information found in peer-reviewed journal, should be brought together and made available in an easily accessible website.

- The website should be updated constantly as new data becomes available.
- The public agency responsible for this website should be instructed to draw this information to the attention of insurance companies, managed care organizations, HCFA, and the continuing medical education programs of medical schools on an ongoing basis.
- Information should be made available not only for professionals, but also for consumers.

Congress could amend the tax laws to allow performance-based tax credits to businesses that provide disease-prevention and health-improvement programs to their employees. As part of this legislation, Congress could encourage work-site wellness programs to include relevant complementary and altenatitive health ingredients as part of these wellness services.

Develop tax policy that gives consumers of CAM therapies an equivalent "pre-tax benefit" as consumers have with health insurance.

Insurers and "purchasers" of health plans (e.g. employers, Medicare, Medicaid, etc.) should be educated in CAM and encouraged to treat CAM practitioners and CAM services equitably with conventional practitioners and allopathic medicine.

Address appropriately the obstacles to including CAM services in health plan packages.

- Contracted benefits must be clinically and legally defensible. Does the CAM service(s) meet contractual definitions, or investigational and medical necessity criteria? This would require outcome measures and data, expert consensus panels, and criteria on the indications for particular services (usually developed by professional organizations, government bodies such as NIH or AHRQ, academic centers, or consulting organizations).
- Are there data on local CAM providers and the substitution between biomedical and CAM services that would be necessary to project a premium for an open-ended benefit?
- For coordinated, high quality care, how would CAM utilization information be shared with allopathic physicians (e.g., a PCP)?
- How do licensure and scope of practice laws affect coverage of CAM? What is the health plan liability associated with credentialing unlicensed CAM providers for network participation?

Analyze the coding issues for CAM services, including the impact of HIPAA. (These coding issues affect progress on research and demonstrations, as well as reimbursement.) The coding system should recognize the time, training, and experience of CAM providers and CAM approaches to health care, and should not be solely based on allopathic parameter or disease-based diagnoses.

Develop strategies for achieving consistent national standards for education, training, and licensure that are appropriate for the various CAM therapies. Develop a strategy for informing purchasers of health care, and health insurers, of progress toward these standards with specific therapies.

Insurers should offer a partial "cash-out" for patients with catastrophic or terminal illnesses (with written consent) to allow them to use CAM services.

Coverage and Reimbursement

Providers and third party payers should consider cultural diversity and standards in their efforts to improve cultural competency of their health care delivery system.

Purchasers of health care (employers, HCFA, OPM, DOD, etc.) and health insurers should consider reimbursement for clinically effective CAM services and products. (Some recommendations were made for specific services such as, second opinions by CAM practitioners, acupuncture and Oriental medicine, non-prescription substances prescribed by licensed providers, etc.)

Access +
Delivery

Note this is from 5-3-01

Joe K. Summary
Joe K
5-3-01

Summary and Analysis of Themes and Recommendations from December 4-5, 2000 WHCCAMP Meeting on Access and Delivery

This is an initial summary and analysis of not only the themes, but also the recommendations made during testimony at the December 4-5, 2000 meeting of the White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) on Access to and Delivery of Complementary and Alternative Medicine (CAM). The intended purpose of this summary and analysis is to facilitate formulation of draft policy recommendation by Commissioners during the discussion group breakout session on Monday, May 14, 2001. Although additional themes and recommendations can be gleaned from town hall and other full Commission meetings testimony, the focus of this summary and analysis is limited to the testimony of the December 4-5, 2000 meeting. Additional themes and suggested recommendations from other sources can be added subsequently to this summary and analysis.

The following Access themes, which can be classified generally as "Barriers," are evident in the December 4-5, 2000 meeting testimony:

- Conventional medicine and physician resistance to CAM
- Reimbursement, coverage, and cost issues
- Balance of consumer choice and public safety (self-care)
- Needs of special populations
- Cultural and linguistic challenges (including Traditional Healing)

Conventional medicine and practicing physicians' resistance to and lack of acceptance of CAM is cited in testimony as the basis for non-disclosure of CAM utilization and as a barrier to access to CAM services. While the current reimbursement system is influenced by an evidenced-based approach, CAM generally lacks the type and amount of western scientific evidence on safety, indications, clinical effectiveness, and cost effectiveness sought by the current reimbursement system. Moreover, data on systems of care, multiple modalities, combination therapies, various delivery systems, and diverse populations are not available. The balance of consumer choice and public safety is evident in utilization of CAM as part of self-care, particularly in women's health, and is dependent on information which can be difficult to obtain, contradictory, and of questionable accuracy. Access to CAM by special populations such as HIV/AIDS, elderly, pediatrics, and cancer patients is characterized by more numerous and significant barriers than the general population. Cultural and linguistic barriers to access to CAM are associated with recent immigrants, native peoples, and an increasingly diverse US population especially in the context of Traditional healing.

Likewise, the following Delivery themes are found in the December 4-5, 2000 meeting testimony:

- Integration of CAM vs. CAM separatism
- Fragmentation of CAM
- Models of service delivery
- Service delivery of CAM to uninsured and underinsured

Although there is ~~interest in~~ strong support for integrating CAM and conventional or western medicine to from what is frequently termed "integrative medicine," there also is strong interest in maintaining CAM as a separate system of care, ~~because of an articulated concern about the potential for CAM to be co-opted or usurped completely by the dominant medical system. However,~~ The CAM community is fragmented and does not possess unifying infrastructure or global consensus. ~~Despite numerous attempts and failures, the best models of CAM service delivery have not been identified yet~~. All of the problems of CAM service delivery are magnified by the challenges of service delivery to the growing numbers of uninsured and underinsured. ~~If CAM services and products improve health status, health disparities in uninsured and underinsured populations without CAM services and products may worsen.~~

The recommendations extracted from the December 4-5, 2000 meeting transcript by James P. Swyers, MA have been grouped according to the above Access and Delivery themes and are summarized on the following pages. While recommendations admittedly can fit in multiple categories, recommendations were placed into only the category in which there appeared to be the best fit, albeit subjective.

Joe K
6/12

6 June 2001 DRAFT Recommendations on Access and Delivery

Recommendations Related to Conventional Medicine and Physician Resistance to CAM:

- Direct educational resources to training all conventional health professions in clinical and cost effectiveness of CAM approaches (especially nutrition), relationship-centered care, and how to interrelate with CAM practitioners.
- Train CAM practitioners how to interrelate with conventional health care professions.

Recommendations Related to Reimbursement, Coverage and Cost Issues:
Please note that because of an evidenced-based approach to reimbursement, research recommendations were categorized under the rubric of reimbursement, coverage, and costs issues.

- Create access to CAM therapies that are considered to be safe. However, embrace reimbursement only for those therapies that have strong evidence supporting their effectiveness.
- Determine the most common guidelines for setting limits for access and apply them to CAM.
- Insert language for CAM in Federal entitlement acts, such as Medicare, Medicaid, Indian Health Service, and CHAMPUS.
- Place a major focus on wellness and recommend policies for reimbursing CAM providers for health promotion.
- Promote the incorporation of new codes into Federally funded CAM research so that cost-effective CAM treatments can be identified as a solution to escalating health care expenses, especially where these procedures could have an impact on Medicare/Medicaid recipients.
- Promote research with side-by-side comparison of conventional health care and CAM to determine which gets better results and at lower costs.

Recommendations Related to Balance of Consumer Choice and Public Safety:

- Allow use of any medical treatment that has been in use in another country without evidence of harm.
- Encourage the FDA to require nutritional supplement and herbal remedy manufacturers to label their products with warning against possible adverse effects or toxicity, and recommendations for proper usage.
- Institute a system, such as that proposed by the World Health Organization, to establish guidelines for the assessment of herbal products to ensure proper identity and quality of both raw materials and finished products.
- Involve well-trained herbalists in the scientific study of safety and efficacy of herbs.

Recommendation Related to Needs of Special Populations:

- Develop demonstration projects that will allow hospice programs to provide care without a reimbursement, criteria, or prognostic cap.

Recommendations Related to Cultural and Linguistic Challenges (Including Traditional Healing):

- Require the FDA to recognize a "traditional medicines" category that would take into account the historical and traditional uses of herbs and permit manufacturers to put this information on the label.
- Develop "peer" education programs to disseminate credible information on CAM to minority and ethnic communities.

Recommendations Related to Integration of CAM vs. CAM Separatism:

- Break down barriers to collaboration of conventional health care with CAM practitioners.
- Develop a 20-year plan to integrate conventional medicine into patient-centered, whole-person health care.
- Do not fully integrate CAM therapies into mainstream medicine.

Recommendations Related to Models of Service Delivery

- Provide access for all populations to nutritional programs such as the Dean Ornish program.
- Use nurses as a resource to integrate CAM into conventional medicine and serve as a bridge to help educate doctors.
- Develop a system of integrative medicine in which a cadre of CAM and conventional health care practitioners, each with his/her own scope of practice and tools, coordinate care, cross-refer, and co-manage patients.
- Fund and coordinate systematic reviews of specific CAM methods organized by clinical conditions.
- Increase research by CAM practitioners and experienced clinical researchers on clinical implementation of specific CAM treatments for specific conditions.

Recommendations Related to CAM Service Delivery to Uninsured and Underinsured:

- Link school loan forgiveness programs for CAM practitioners to service to underserved populations.
- Facilitate inclusion of underserved populations in CAM clinical research and require provision of standard conventional care instead of placebo.
- Include a service component to uninsured, underinsured, and underserved populations in Federally-supported CAM training and research grants.
- Include CAM in all Federal programs to reduce health disparities.
- Fund Community and Migrant Health Centers to use their unique abilities to deliver CAM and educate uninsured and underinsure populations about CAM in culturally competent ways.

White House Commission on Complementary and Alternative Medicine Policy

Jury's Hotel
1500 New Hampshire Ave, NW
Westbury Room, Washington, DC

July 2-3, 2001

PRELIMINARY AGENDA (Staff use only)

DAY ONE: MONDAY, JULY 2, 2001

8:00 – 9:45 a.m. **Breakfast with Commissioners**
Facilitator: Tom Andrews

Discussion Topic I. *(proposed)* Commissioner Expectations and Aspirations for the Final Report

Objective: (1) to elicit Commissioners' expectations for the Report
(2) to discuss the concept of a permanent presence*

Discussion Topic II. *(proposed)* Reality Check: Political and Strategic Pitfalls and Opportunities

** the proposal and concurrence discussion of a permanent presence, if raised here initially, must also be fully addressed later in public sessions...*

10:00 a.m. **Opening Remarks and Introductions**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy

- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

10:10 a.m. **Discussion Session I: Coordinated CAM Research and Regulatory Activities**

Discussion Facilitator:
Staff Lead: Gerry Pollen

12:15 -- 1:30 p.m. Lunch

1:30 – 3:30 p.m. **Discussion Session II: Education, Training, Credentialing and Licensing of CAM Practitioners**

Discussion Facilitator:
Staff Lead: Joe Kaczmarczyk

3:30 – 3:45 p.m. BREAK

3:45 – 5:45 p.m. **Discussion Session III: Information Development and Dissemination**

Discussion Facilitator:
Staff Lead: Corinne Axelrod

6:00 p.m. Adjourn

6:30 p.m. Dinner at Nora's (proposed!)

DAY TWO: TUESDAY, JULY 3, 2001

8:00 a.m. **Opening Remarks**

- *Dr. Stephen C. Groft, Pharm.D., Executive Director*
  White House Commission on Complementary and Alternative Medicine Policy
- *Dr. James S. Gordon, M.D., Chair*
  White House Commission on Complementary and Alternative Medicine Policy

8:05 -- 10:15 a.m. **Discussion Session IV: Access, Delivery and Reimbursement of CAM Services**

Discussion Facilitator:
Staff Leads: Joe Kaczmarczyk, , Maureen Miller

10:15 – 10:30 a.m. BREAK

10:30 -- 12:30 p.m. **Panel Session V: Self-care & Wellness**

Discussion Facilitator:
Staff Lead: Corinne Axelrod

12:30 – 1:30 p.m. LUNCH

1:30 – 3:00 p.m. **Panel Session VI: Interim Report**

Discussion Facilitator: Steve Groft

3:00 – 3:15 p.m. BREAK

3:15 – 4:30 p.m. **Public Comment Session**

4:30 p.m. **ADJOURN**