White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

April 10, 2001

Kathie L. Olsen, Ph.D.
Chief Scientist
Associate Administrator for Research
Office of Biological and Physical Research
NASA, 8th Floor
300 E Street, SW
Washington, DC 20546

Dear Dr. Olsen:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request certain information in preparation for an upcoming meeting.

The President established the Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at our web site, www.whccamp.hhs.gov.

The Commission will meet May 15 to 16 to discuss areas related to CAM research, research training, as well as the evaluation of and publication of CAM research results. As part of its deliberations, the Commissioners will be considering the questions listed below and would appreciate your guidance and input regarding the topics covered in the questions. In developing your response, please feel free to provide us with the any additional information you may consider important.

Questions

How can coordination of research on CAM be established or strengthened among and between Federal agencies that have research and research-related responsibilities, and how can it be enhanced with the not-for-profit and private sectors?

What are the obstacles (conceptual or otherwise) and possible solutions to accomplishing integration of CAM into mainstream research?

Does NASA support any research or research-related activities on CAM practices and products? Are there areas of research related to CAM that NASA considers promising?

What policy recommendations can your agency offer regarding research on CAM for the Commission's consideration as it develops its report to the President and Congress?

For your reference, I have attached a list of CAM health care modalities. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be nontraditional and wish to include with your response, please do so.

We would appreciate your response **by May 1** either by email or fax so that the Commissioners will have time to review it before the May meeting. Please email your response to Ms. Geraldine Pollen at polleng2@mail.nih.gov, or send it by fax to Ms. Pollen at 301-480-1691. Her telephone number is 301-435-6233.

Thank you for your attention to this request. I look forward to your response.

Sincerely,

Stephen C. Groft

Stephen C. Groft, Pharm. D.
Executive Director

Attachment

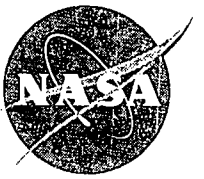
Common CAM Therapies

Acupuncture
Acupressure
Alexander Technique
Applied Kinesiology
Anthroposophic Medicine
Aromatherapy
Autogentic Training
Ayurvedic Medicine
Energy Medicine
Chiropractic
(Sacral) Cranial Osteopathy
Environmental Medicine
Herbal Medicine
Homeopathy
Hypnosis
Imagery
Massage
Meditation
Naturopathy
Nutritional Therapy (Nutrition)
Osteopathy
Reflexology
Relaxation and Visualization
Shiatsu
Spiritual Healing
Therapeutic Touch
Yoga

Adapted from Zollman C, Vickers A. What is Complementary Medicine? British Medical Journal 1999, 319; 693-696

National Aeronautics and
Space Administration

Headquarters
Washington, DC 20546-0001



Reply to Attn of: U

MAY - 1 2001

Mr. Stephen C. Groft, Pharm.D.
Executive Director
White House Commission on Complementary
and Alternative Medicine Policy
6701 Rockledge Drive
Bethesda, Maryland 20817

Dear Dr. Groft:

This is in response to your letter of April 10, 220 requesting information for the Commission on Complementary and Alternative Medicine.

Question #1: I suggest that the Federal Agencies develop Memoranda of Understanding in order to mutually support research furthering the goals of each Agency. For example, NASA has MOU's with NIH, NSF, DOE, and DOD addressing our common research goals.

Question #2: The main obstacle to overcome in integrating CAM research in to the mainstream is to ensure that the research is conducted using the strictest scientific standards in accordance with "mainstream" NIH-type methods. This includes research with adequate controls. An example of this is prospective, double-blinded studies of drug efficacy. It is also important that the funds for the research be awarded in a national competition for investigator-initiated, peer-reviewed grants. It is also important that the peer review panels have broad-based representation from the CAM and traditional scientific communities.

Question #3: NASA does not currently support any CAM research. However, we have medical issues regarding space flight that are the subject of our biomedical research program. These problems are identified in our Critical Path document (http://criticalpath.jsc.nasa.gov/NS_main.asp) and the Institute at NASA responsible for developing countermeasures to the physiological changes in space flight is the National Space Biomedical Research Institute (http://www.nsbri.org/).

Question #4: I recommend that your Commission support high quality scientific research performed by commonly accepted scientific methods and that this research be nationally competed among the research community (see answer to #1).

Sincerely,

Kathie L. Olsen

Kathie Olsen, Ph.D.
Acting Associate Administrator for
Biological and Physical Research

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
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April 10, 2001

James F. Decker, Ph.D.
Acting Director, Office of Science
U.S. Department of Energy, Room 7B058
1000 Independence Avenue, SW
Washington, DC 20585

Dear Dr. Decker:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request certain information in preparation for an upcoming meeting.

The President established the Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at our web site, www.whccamp.hhs.gov.

The Commission will meet May 15 to 16 to discuss areas related to CAM research, research training, as well as the evaluation of and publication of CAM research results. As part of its deliberations, the Commissioners will be considering the questions listed below and would appreciate your guidance and input regarding the topics covered in the questions. In developing your response, please feel free to provide us with the any additional information you may consider important.

Questions

How can coordination of research on CAM be established or strengthened among and between Federal agencies that have research and research-related responsibilities, and how can it be enhanced with the not-for-profit and private sectors?

What are the obstacles (conceptual or otherwise) and possible solutions to accomplishing integration of CAM into mainstream research?

Does the DOE support any research or research-related activities on CAM practices and products? Are there areas of research related to CAM that the DOE considers promising?

What policy recommendations can your agency offer regarding research on CAM for the Commission's consideration as it develops its report to the President and Congress?

For your reference, I have attached a list of CAM health care modalities. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be nontraditional and wish to include with your response, please do so.

We would appreciate your response **by May 1** either by email or fax so that the Commissioners will have time to review it before the May meeting. Please email your response to Ms. Geraldine Pollen at polleng2@mail.nih.gov, or send it by fax to Ms. Pollen at 301-480-1691. Her telephone number is 301-435-6233.

Thank you for your attention to this request. I look forward to your response.

Sincerely,

Stephen C. Groft

Stephen C. Groft, Pharm. D.
Executive Director

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Therapeutic Touch
Yoga

Adapted from Zollman C, Vickers A. What is Complementary Medicine? British Medical Journal 1999, 319; 693-696

Pollen, Geraldine (NCCAM)

From: Viola, Michael [Michael.Viola@science.doe.gov]
Sent: Thursday, May 03, 2001 4:27 PM
To: Pollen, Geraldine (NCCAM)
Cc: Betson, Sharon; Holmes, Kathy
Subject: White House Commission on CAM

Dear Ms. Pollen- The Office of Science of the Department of Energy is not involved in support of research on complementary and alternative medicine products or methodologies, in education or dissemination of CAM information to health professionals or to the general public. In the biomedical field our primary mission is the medical application of advanced technology, particualrly medical imaging, developed in the DOE National Laboratories. However, if there is more information we can supply to your office please do not hesitate to get in touch with me.

Michael V. Viola, M.D.
Director, Medical Sciences Division
Office of Science, OBER
U.S. Dept. of Energy
Germantown , MD 20874-1290
301-903-5346
fx 301-903-0567
michael.viola@science.doe.gov <mailto:michael.viola@science.doe.gov>

White House Commission on Complementary and Alternative Medicine Policy

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April 10, 2001

Rita Colwell, Ph.D.
Director
National Science Foundation
4201 Wilson Boulevard, Suite 1205
Arlington, VA 22230

Dear Dr. Colwell:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request certain information in preparation for an upcoming meeting.

The President established the Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at our web site, www.whccamp.hhs.gov.

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What are the obstacles (conceptual or otherwise) and possible solutions to accomplishing integration of CAM into mainstream research?

Does NSF support any research related to CAM practices and products? What can CAM perspectives and approaches contribute to research in the biological, physical, social, and behavioral sciences? Are there areas of research related to CAM that NSF considers promising?

What policy recommendations can your agency offer regarding research on CAM for the Commission's consideration as it develops its report to the President and Congress?

For your reference, I have attached a list of CAM health care modalities. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be nontraditional and wish to include with your response, please do so.

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Sincerely,

Stephen C. Groft

Stephen C. Groft, Pharm. D.
Executive Director

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April 10, 2001

Orville Levander, Ph.D.
Research Chemist
Nutrient and Functions Lab (NRFL), BHNRC, ARS, USDA
10300 Baltimore Avenue
Room 201A, Building 307, BARC East
Beltsville, MD 20705

Dear Dr. Levander:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request certain information in preparation for an upcoming meeting.

The President established the Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at our web site, www.whccamp.hhs.gov.

The Commission will meet May 15 to 16 to discuss areas related to CAM research, research training, as well as the evaluation of and publication of CAM research results. As part of its deliberations, the Commissioners will be considering the questions listed below and would appreciate your guidance and input regarding the topics covered in the questions. In developing your response, please feel free to provide us with the any additional information you may consider important.

Questions

How can coordination of research on CAM be established or strengthened among and between Federal agencies that have research and research-related responsibilities, and how can it be enhanced with the not-for-profit and private sectors?

What are the obstacles (conceptual or otherwise) and possible solutions to accomplishing integration of CAM into mainstream research?

Does USDA support any research or research-related activities on CAM practices and products? Are there areas of research related to CAM that USDA considers promising?

What policy recommendations can your agency offer regarding research on CAM for the Commission's consideration as it develops its report to the President and Congress?

For your reference, I have attached a list of CAM health care modalities. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be nontraditional and wish to include with your response, please do so.

We would appreciate your response **by May 1** either by email or fax so that the Commissioners will have time to review it before the May meeting. Please email your response to Ms. Geraldine Pollen at polleng2@mail.nih.gov, or send it by fax to Ms. Pollen at 301-480-1691. Her telephone number is 301-435-6233.

Thank you for your attention to this request. I look forward to your response.

Sincerely,

Stephen C. Groft

Stephen C. Groft, Pharm. D.
Executive Director

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E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

April 11, 2001

Elizabeth James Duke, Ph.D.
Health Resources and Services Administration
5600 Fishers Lane, Room 1405
Parklawn Building
Rockville, MD 20857

Dear Dr. Duke:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request information in preparation for an upcoming meeting.

The President established the Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at our web site, www.whccamp.hhs.gov.

The Commission will meet May 15 to 16 to discuss areas related to CAM research, research training, as well as the evaluation and publication of CAM research results. As part of its deliberations, the Commissioners will be considering the questions listed below and would appreciate your guidance and input regarding the topics covered in the questions. In developing your response, please feel free to provide us with the any additional information you may consider important.

Questions

Do any HRSA programs include projects on the evaluation of health services delivery or collaborative research on health services delivery? If yes, does the activity include complementary and alternative medicine (CAM)? What are the obstacles to including CAM in a health services delivery evaluations? What would be the possible solutions or strategies to overcome the obstacles?

Do HRSA programs such as the Community and Migrant Health Centers, 100% Access/0% Disparities Campaign, the Community Access Program, HIV/AIDS programs or others collect data that could be useful in health services delivery evaluations? If yes, is CAM included in any of the data, e.g., utilization data, that are being collected? What are the obstacles to including CAM in a data collection? What would be the possible solutions/strategies to overcoming the obstacles?

How can HRSA programs increase their coordination with: (1) other Federal agencies to conduct health service delivery research or data collection related to CAM; (2) non-Federal organizations? What resources are needed to accomplish this?

How can coordination of research on CAM be established or strengthened among and between Federal agencies that have research and research-related responsibilities, and how can it be enhanced with the not-for-profit and private sectors?

What information regarding health services delivery and CAM would HRSA be interested in having available?

What recommendations can your agency offer regarding research on CAM for the Commission's consideration as it develops its report to the President and Congress?

For your reference, I have attached a list of CAM health care modalities. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be nontraditional and wish to include with your response, please do so.

We would appreciate your response **by May 1** either by email or fax so that the Commissioners will have time to review it before the May meeting. Please email your response to Ms. Geraldine Pollen at polleng2@mail.nih.gov, or send it by fax to Ms. Pollen at 301-480-1691. Her telephone number is 301-435-6233.

Thank you for your attention to this request. I look forward to your response.

Sincerely,

Stephen C. Groft

Stephen C. Groft, Pharm. D.
Executive Director

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White House Commission on Complementary and Alternative Medicine Policy

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E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

April 6, 2001

J. Jarrett Clinton, M.D.
Acting Assistant Secretary of Defense for Health Affairs
ASD-HA Room 3E-1082
1200 Defense Pentagon
Washington, D. C. 20301-1200

Dear Dr. Clinton:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy to request certain information in preparation for an upcoming meeting.

The President established this Commission in March of 2000 through Executive Order 13147. In carrying out its mandate, the Commission is addressing (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at **www.whccamp.hhs.gov**.

The Commission will meet May 14th through the 16th to discuss topic areas related to research as well as to coverage and reimbursement for CAM. As part of its deliberations, the Commissioners need to understand the role of the Department of Defense in these topic areas. To guide you in providing information of interest to the Commission, we have developed the questions outlined below. If in preparing your response you find information not specifically requested but related to the scope of the Commission, please provide us with the additional information.

To assist you, we have enclosed a listing of health care modalities that are generally considered to be CAM to serve as guidance. This list is not intended to be all-inclusive and does not reflect the consensus or opinion of the Commission regarding a definition CAM. If there are other health care practices that you consider to be unconventional and wish to include with your response, please do so.

Questions Related to Research

- Does DoD, or any of the service branches, support any research on CAM practices and programs? If so, please briefly describe the research and describe why these areas of research were selected.

- Does DoD coordinate CAM research efforts 1) across services 2) with other Federal agencies, and 3) with the private sector? What is needed to create or strengthen coordination of research among these sectors?

- What are the most promising areas of research on CAM interventions funded by DoD or its service branches, or elsewhere?

- What is needed to expand DoD efforts to bring CAM practices and products into mainstream medical research, e.g., research support, methodologies, education and training, incentives, etc.?

- What are the obstacles (conceptual or otherwise) and possible solutions to accomplishing integration of CAM into mainstream medical research?

- What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional areas of research, e.g., nutrition, wellness/health promotion and disease prevention, pain management, women's health, self care, care for the terminally ill, etc.?

- What ideas, issues, and concerns regarding research on CAM can DoD offer for the Commission's consideration as it develops its policy recommendations and report to the President and Congress?

Questions Related to Coverage and Reimbursement

- What are the legislative, regulatory, and administrative parameters related to coverage of health benefits for active duty military, retirees, and dependents? How does DoD determine which benefits to add to its military/TRICARE health care programs?

- Does DoD include any CAM services and products at its military treatment facilities, or through the TRICARE program? Describe the history and use of chiropractic medicine in DOD.

- Does DoD have plans to incorporate new or additional CAM benefits? Explain. Does DOD, or any of its branches of service, cover or include on a formulary any herbs or dietary supplements?

- What does DoD consider as the most promising areas of CAM practice to incorporate into military/TRICARE health care programs? Explain.

- For CAM services provided at or through a military treatment facility, how are the costs of such services addressed? Describe any pertinent payment policies, payment procedures, budgeting, etc.

- For any CAM service provided outside of a military treatment facility, does DoD (or TRICARE or another contractor) determine whether the service is covered? Explain.

- For CAM services provided outside of a military treatment facility, how is the amount of payment determined? Describe any pertinent payment policies and procedures used by DoD or its service branches.

- What ideas and suggestions does DoD have for health services research related to access, coverage, and payment for CAM services and products?

- For CAM services covered, has DOD or its service branches established standards (e.g., education, training, licensure, certification) for the practitioners providing such services? Are any other quality monitors utilized?

- Does DoD or any of its service branches have any criteria, standards, or policies for the selection of dietary supplements available in the commissary and exchange system?

- Does DoD have any comment on the use of CAM products and services by active duty personnel?

- What ideas, issues, and concerns regarding coverage and payment for CAM can DoD provide the Commission as it develops its policy recommendations and report to the President and Congress?

We would appreciate your response **by May 7** either by email or fax so that the Commissioners will have time to review it before the May meeting. You may email me at GroftS@mail.nih.gov or send a fax to 301-480-1691. Specific questions may be addressed to:

Research	Geraldine Pollen	301-435-6233
Coverage/Reimbursement	Maureen Miller	301-435-7592

Thank you for your attention to this information request.

Sincerely,

Stephen C. Groft

Stephen C. Groft, Pharm. D.
Executive Director

Enclosure

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Traditional Chinese and Oriental Medicine
Yoga

Adapted from Zollman C, Vickers A. What is Complementary Medicine?
British Medical Journal 1999, 319; 693-696

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: Access and Delivery

Breakout Session One

May 14, 2001

Access to CAM Products and Practices

Executive Order: "The recommendations shall address the following... (d) guidance for appropriate access to and delivery of complementary and alternative medicine."

Question: How can access to CAM products and practices be improved? Please answer this question with one or two draft policy recommendations to overcome the barriers to access to CAM products and practices.

Consideration should be given to discussing:

1. Access to CAM products and practices as two separate issues
2. Overcoming barriers identified in previous testimony:
    - Conventional medicine and physician resistance to CAM
    - Balance of consumer choice and public health/safety
    - Needs of special populations (e.g., women, children, elderly, cancer, HIV/AIDS, immigrants, native peoples)
    - Cultural and linguistic challenges (including Traditional medicine)
3. Role of Community Health Centers (CHCs)
4. Reduction of health disparities

Any reimbursement-related topic or issue should be averted since this which will be covered in a subsequent breakout session. Practice effective time management, since the session will be limited to 60 minutes.

Breakout Session One

May 14, 2001

Delivery of CAM Products and Practices

Executive Order: "The recommendations shall address the following... (d) guidance for appropriate access to and delivery of complementary and alternative medicine."

Question: How can delivery of CAM products and practices be improved? Please answer this question with one or two draft policy recommendations that incorporate the themes articulated in previous testimony and address barriers to delivery of CAM products and practices.

Consideration should be given to discussing:

1. Delivery of CAM products and practices as two separate issues
2. Overcoming barriers identified in previous testimony:
    - Integration of CAM vs. CAM separatism

      Please note that conventional medicine and CAM view integration differently. Conventional medicine is inclined to integrate therapies, modalities, and approaches with effectiveness supported by research, while CAM advocates for integration of whole systems of care (as opposed to selected components), "a level playing field," pleuralism of health care, and access to the same resources as conventional medicine.

    - Fragmentation of CAM "communities"

      Conventional medicine tends to see fragmentation among and even within various CAM disciplines, whereas CAM perceives a sense of "communities."

3. Models of delivery (which may be beyond the scope of the time-limited discussion)
4. Role of Community Health Centers (CHCs)
5. Balance of consumer choice and public health/safety

Any reimbursement-related topic or issue should be averted since this will be covered in a subsequent breakout session. Practice effective time management, since the session will be limited to 60 minutes.

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 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.

Recommendations Related to Conventional Medicine and Physician Resistance to CAM

- Direct education resources to training medical students and physicians in the effectiveness and cost benefits of CAM approaches as opposed to delivering the modalities themselves. **(Patricia Culliton, LAc)**

- Train all health professionals, not just medical doctors, but CAM professionals as well, in how to interrelate to each other. **(Patricia Culliton, LAc)**

- Improve teaching of nutritional information in medical schools. If implemented, the cost of care will undoubtedly come down by billions of dollars. **(Alan Gaby, M.D., nutritionist)**

- Encourage schools of medicine, complementary and mainstream, to foster relationship-centered care. **(Robert Duggan, TAI)**

- Establishment an emergency, "crash" education program on CAM for: 1) the approximately one-half million practicing physicians, 2) academic research scientists, and 3) the general attentive public. **(Rustrum Roy, University of Arizona Program for Integrative Medicine)**

- Promote initiatives to integrate nutrition into the core curricula at American medical schools.**(Neal Barnard, President the Physician's Commission for Responsible Medicine)**

- Promote programs to educate medical students and physicians about the use and effectiveness of all CAM modalities, especially medical acupuncture, and teach them that CAM is not a threat to their practice. **(Marshall Sager, President-elect of the American Academy of Medical Acupuncture)**

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.(**James Dillard, M.D., Oxford Health Plans**)

- Determine what are the most common guidelines for setting limits for access and apply them to CAM. Otherwise, carriers could be allowed to sell what is essentially an illusory benefit. (**Lori L. Bielinski, Washington State Office of the Insurance Commissioner**)

- Insert language for CAM in Federal entitlement acts, such as Medicare, Medicaid, Indian Health Service, and CHAMPUS for the military. (**Konrad Kail, Naturopathic Physician**)

- Support the passage of legislation currently in Congress, H.R. 1187 and S. 660, to provide outpatient medical care coverage for medical nutrition therapy for diabetes and kidney disease. (**Patsy Brannon, Registered Dietition, R.D.**)

- The expansion of Medicare and Medicaid coverage as recommended by the Institute of Medicine report for the treatment chronic diseases for which nutritional therapy has been documented to be effective. (**Patsy Brannon, R.D.**)

- Influence health plans to reimburse for evidence-based CAM interventions. (**Anna Silberman, High Mark**)

- Reimburse for Vedic medicine services that are shown to be effective and cost-effective in published, peer-reviewed scientific research, should be reimbursed, including by government payers, such as Medicare and Medicaid, and private reimbursers. (**Robert Schneider, M.D., Marharishi University**)

- Change the current reimbursement model, which favors the delivery of the modality over the healing art of the individual patient. (**Robert Duggan, President of the Traditional Acupuncture Institute, TAI**)

- Break down the barriers to reimbursement for CAM services. (**Milton Hammerly, M.D., of Catholic Health Initiatives, CHI**)

- Place a major focus on wellness and to recommend policies for reimbursing CAM providers for health promotion. **(Bruce Nordstrom, American Chiropractic Association)**

- Promote reimbursement of services rendered by Oriental Medicine physicians by all health insurance providers, both Federal and private. **(Doreen Chen, American Association of Oriental Medicine)**

- 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. **(Melinna Giannini, Director of Alternative Link)**

- Examine three major reports on the cost-effectiveness of chiropractic as part of the Commissions deliberations. **(William Meeker, chiropractor)**

- Provide greater funding for the NCCAM. **(Konrad Kail, naturopath)**

- Increase research expenditures on the clinical efficacy of acupuncture in conditions such as musculoskeletal pain and analgesia, breech aversion, nausea and vomiting, dysmenorrhea (menstrual pain), and bladder disorders. **(Patricia Culliton, Licenced Acupuncturist, LAc)**

- Funding for large clinical effectiveness study and cost effectiveness studies of acupuncture for specific conditions as well as the development of CME courses and CEU courses for physicians in acupuncture and for CAM modalities and approaches in general. **(Patricia Culliton, LAc)**

- All CAM research should be conducted by neutral observers who are objective and impartial, neither strong negative skeptics, nor strong proponents, but people who are committed to scientific research. **(Paul Kurtz, Ph.D., The Committee for the Scientific Investigation of Claims of the Paranormal)**

- The Federal government should use the investigation of CAM as an opportunity to solve its most pressing health problem: controlling spiraling health care costs. **(Robert Atkins, M.D., private practice physician)**

- Promote the kind of research that will allow conventional and CAM to be compared side by side with a matched group of subjects to determine which gets better results and at lower costs. **(Robert Atkins, M.D.,)**

- Continue to support scientific investigations into CAM treatments to help separate what is effective from what is not. (**Anna Silberman, High Mark Blue Cross/Blue Shield**)

- Pay more research attention to the interface of the issues of spirit and the neurophysiology of craving and compulsion and reward. (**Alan Trachtenberg, M.D., Office of Pharmacologic and Alternative Therapies at the Center for Substance Abuse Treatment, CSAT**)

- Encourage the Public Health Service issue grants for research on the effects of vegetarian and vegan diets for a number of chronic illnesses, and encourage the Department of Agriculture review of federal policies that conflict with healthy nutritional goals. (**Neal Barnard, President the Physician's Commission for Responsible Medicine**)

- Require the National Institutes of Health and the Department of Agriculture to conduct new research on the efficacy of diets that seek to reduce or treat many behavioral, learning, and health problems in children by eliminating synthetic dyes, artificial flavors, and certain preservatives from their diet. (**Jane Hersey, Director of the Feingold Association**)

- Support research on the role of toxic chemicals in syndromes, such as multiple chemical sensitivities, auto-immune diseases, fibromyalgia syndrome, and chronic fatigue syndrome. There also is the need for research to investigate the role of nutritional supplements in enhancing improved metabolic function in these syndromes. (**Lawrence A. Plumlee, M.D., National Coalition for the Chemically Injured**)

Recommendations Related to Balance of Consumer Choice and Public Safety

- Allow use of any medical treatment that has been in use in another country, where there is no evidence of it posing a danger to the patient. Because there are not good treatments for most degenerative diseases, people with such conditions should have the right to try potentially beneficial treatments developed in other countries with out fear of government interference. **(Berkeley Bedell, NFAM)**

- Encourage FDA to require nutritional supplement and herbal remedy manufacturers to put labels on their products warning against possible adverse effects or toxicity, and recommendations for proper usage. **(Dennis Awang, Ph.D., herbalist)**

- Promote proven CAM interventions to the public. **(Anna Silberman, High Mark)**

- Establish initiatives to foster CAM and wellness education from the first grade onward. **(Robert Duggan, TAI)**

- Institute a system, such as that proposed by the World Health Organization, to establish guidelines for the assessment of herbal medicines and to ensure proper identity and quality of both raw materials and finished products. **(Dennis Awang, Ph.D., herbalist)**

- Involve well-trained herbalists be in studying the safety and efficacy of herbs on a scientific basis because many scientists have the view that herbs do not work until it is proven that they do work, which is the antithesis of how an herbalist would view them. **(Christopher Hobbs, herbalist, licensed acupuncturist)**

- Recommend passage of The Access to Medical Treatment Act, which would make it possible for experimental "non-toxic" treatments to be tried under strictly controlled circumstances. **(Berkeley Bedell, president of the National Foundation for Alternative Medicine, NFAM)**

- Establish a separate agency, other than the FDA, to deal with the issue of the quality of herbs. **(Robert Duggan, TAI)**

Recommendation Related to Needs of Special Populations

- The development demonstration projects around the country that will allow hospice programs to provide care without a reimbursement cap and without a criteria or prognostic cap. **(J. Donald Schumacher, Center for Hospice and Palliative Care)**

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 use of an herb and to better educate consumers how to use them. Under such a system, manufacturers would be allowed to put the information on the known effects of nutritional supplements on the label so that it would greatly enhance both the effectiveness and the safety. **(Christopher Hobbs, herbalist)**

- The development of "peer" education programs to disseminate credible information on CAM to minority and ethnic communities. **(Denise Drayton, Exponents)**

Recommendations Related to Integration of CAM vs. CAM Separatism

- Any policies that the Commission recommends should not be biased in favor of full integration of CAM therapies into mainstream medicine. **(Mort Rosenthal, chairman and founder of Well Space, a for-profit CAM clinic)**

- Develop a 20-year plan to integrate conventional medicine into patient-centered, whole-person health care. **(Gary Sandman, founder of a community-based alternative medicine referral service)**

- Break down the barriers to collaboration with CAM practitioners. **(Milton Hammerly, M.D., of Catholic Health Initiatives, CHI)**

- Allow certified Vedic practitioners to practice, following the Minnesota model. States should adopt a licensure procedure for natural medicine practitioners, including Vedic medicine practitioners, and licensure would be dependent on certification and completion of other state licensing requirements, such as an exam or experience requirements. **(Robert Schneider, M.D., Marharishi University)**

Recommendations Related to Models of Service Delivery

- Embrace nutritional programs such as the Dean Ornish program by providing access to it for all populations. **(Richard Collins, cardiologist)**

- Use nurses as a resource in any effort to integrate CAM into conventional medicine. Nurses can serve as a bridge to help educate doctors. **(Charlotte Eliopoulos, American Holistic Nurses Association, AHNA)**

- Develop a system of integrative medicine in which a cadre of health care disciplines and practitioners, each with their own scope of practice, their own tools of their trade, but with a common understanding, common respect, and a shared commitment can coordinate care, cross-refer, and co-manage patients. **(Tori Hudson, N.D., National College of Naturopathic Medicine)**

- "Lifestyle behavior changes" should be listed as a prudent, first-choice medicine for people with heart disease. **(Richard Collins, cardiologist and Director of the Heart Disease Reversal and Prevention Program)**

- Federal grant should be made to educational institutions of higher learning for the training of Vedic medicine practitioners. **(Robert Schneider, M.D., Marharishi University)**

- Fund organized systematic reviews in a coordinated fashion on specific CAM methods and by clinical conditions. **(Harley Goldberg, D.O., Medical Director for CAM for Kaiser Permanente)**

- Increase research on the clinical implementation of specific CAM treatments for specific conditions. This research should involve CAM practitioners and experienced clinical researchers. **(Harley Goldberg, D.O., Kaiser Permanente)**

- Provide major medical schools and research centers throughout the United States with funding to set up models to study various CAM therapies, such as herbal medicine, homeopathy, and acupuncture. **(Nancy Dolores Kolenda, Director of the Center for Frontier Sciences at Temple University)**

Recommendations Related to CAM Service Delivery to Uninsured and Underinsured

- Support a bill currently before Congress that would forgive student loans to induce CAM practitioners who work in impoverished areas. (**Robert Duggan, TAI**)

- Develop a school loan forgiveness program for those people going to acupuncture schools, if they commit themselves to work in public health agencies after graduation. (**Patricia Culliton, LAc**)

Topic: Access and Delivery
December 4-5, 2000
Washington, DC: Commission Meeting
MEETING SUMMARY

The following is an overview of the presentations and major issues discussed during the recent meeting of the White House Commission on Complementary and Alternative Medicine Policy, held at the Hubert H. Humphrey Building in Washington D.C., December 4-5, 2000.

Session I: Overview

Commission chairman, Jim Gordon, M.D., began the meeting by saying that recent surveys (Eisenberg, 1998, Paramore, 1997) have established that approximately 40 percent of Americans are using some form of complementary and alternative medicine (CAM). He said, however, that this overall percentage of usage is based on phone surveys of English-speaking people. For many non-English-speaking populations, therefore, CAM may be, in fact, their source of primary care. Dr Gordon said, "one of the charges of the Commission is to address the needs of those people and to understand the importance of the contributions that those people make to our health care system, as well as the needs that they have from our health care system." He also noted that comparisons between recent surveys and earlier surveys (Eisenberg, 1993; Eisenberg, 1998) have shown a dramatic rise in the use of certain forms of CAM, particularly megavitamin, herbal treatments, and homeopathic remedies. Furthermore, recent studies show that although most people do not turn their back on CAM (Astin, 1998) but tend to use CAM to supplement their conventional treatments. He added that studies show CAM useage to be high among those facing chronic and life-threatening conditions (Eisenberg et al, 1998), that interest in and referrals to CAM by conventional physicians is relatively high (Astin et al, 1998; Bermen et al, 1995, 1998), and that the majority of medical schools in the U.S. are now offering at least elective courses in CAM therapies.

Dr. Gordon then went on to briefly summarize the problems that the commission was going to be addressing at this meeting, including the need for more data on effectiveness and cost effectiveness and the need for more research on the issue of integration. He said one of the "central purposes" of the meeting is for the Commissioners to hear testimony about some models of integration.

Panel Discussion:

Following Dr. Gordon's overview, Commissioners discussed whether the rise in use of certain CAM therapies was related to increase marketing of those therapies. Commissioner Jonas suggested that Commissioners may want to examine a book on the social dynamics of CAM use, which had just been released. Commissioners also discussed whether increased utilization of CAM therapies was linked with decreased access to health insurance. The consensus was that decreased access to health insurance did lead to increased use of CAM but was not the only explanation. Chairman Gordon said that in the homeless population, even though there was access to medical services through emergency rooms, CAM was appealing because homeless people do not feel particularly "cared for" when they go to hospitals.

Session II: Clinical and Cost Effectiveness of Selected CAM Services

Chiropractic:
William Meeker, D.C., MPH, testified that numerous studies have demonstrated the effectiveness of chiropractic manipulation, and it has been rated as an effective treatment for back pain by the United States Government, by the UK, Denmark, New Zealand, Australia, and Sweden, and others. In terms of cost effectiveness, he said studies suggest that the cost of chiropractic and conventional medical care is similar, although chiropractic patients tend to be much more satisfied with their care compared to patients receiving conventional care. He urged the Commission to examine three major reports on the cost-effectiveness of chiropractic as part of their deliberations.

Naturopathic Medicine:
Konrad Kail, N.D., P.A., testified that there are a number of studies demonstrating the effectivness of individual naturaopathic modalities. However, naturopathic medicine tends to combine many modalities in the treatment of a single condition. There have been few, if any, studies that have look at outcomes in naturopathic medicine in general. There is also only a short history of limited third-party reimbursement to look at utilization and cost effectiveness of naturopathic approaches. However, potential cost savings of naturopathic medicine include better education of patients about how to stay healthy and the greater knowledge and the home use of nutritional, botanical, and homeopathic medicines, both of which reduce costly visits to the physician. Dr. Kail urged the Commission to recommend greater funding for the NCCAM, and said it is extremely important for the Commission to recommend inclusionary language for CAM in entitlement acts, such as Medicare, Medicaid, Indian Health Service, and CHAMPUS for the military.

Acupuncture:
Patricia Culliton, LAc, testified that despite acupuncture's 4,000-year history, to date there have not been a great deal of studies done on the effectiveness of acupuncture for specific conditions. Therefore, she said, the acupuncture data, like the naturopathic data, is still in its infancy. She noted that in a recent NIH Consensus Conference on acupuncture, which was held in 1997, only two areas of utilization for acupuncture were considered to have definitive data, while several other areas had positive trends. Therefore, she "strongly" recommend further research expenditures on the clinical efficacy of acupuncture in conditions such as musculoskeletal pain and analgesia, breech aversion, nausea and vomiting, dysmenorrhea (menstrual pain), and bladder disorders. There have been no major cost effectiveness studies on acupuncture. However, several clinical studies have made cost-analysis and discovered that people in the experimental group that received acupuncture had significant financial savings compared to the control group. She urged the Commission to recommend large clinical effectiveness study and cost effectiveness studies of acupuncture for specific conditions as well as the development of CME courses and CEU courses for physicians in acupuncture and for CAM modalities and approaches in general. She also urged the Commission to consider a school loan forgiveness program for those people going to acupuncture schools, if they commit themselves to work in public health agencies after graduation.
Homeopathy:
Joyce Frye, DO, MBA, FACOG, said there are an estimated 2,500 medical practitioners using

homeopathy in the U.S.. Research on both clinical efficacy and cost effectiveness of homeopathy has suffered from limitations that are common to all of the CAM practices. The most useful summary of clinical efficacy, she said, is provided by the meta-analysis of 89 placebo-controlled trials published by Linde (Linde et al, 1997), which indicated that patients using homeopathy were 2.5 times more likely to have a therapeutic effect compared to placebo in a variety of conditions. The most complete data on cost effectiveness, she said, comes from the French Government Social Security statistics, which demonstrated significantly reduced costs using homeopathic versus conventional medical care. She said that these data are particularly compelling in view of France's ranking as the "number one" health care system in the world in terms of performance, in comparison to the United States, which is ranked 37th. She added that France also ranks third in life expectancy compared to 24th for the U.S.

Massage:

Tiffany Field, Ph.D., of the Touch Research Institute (TRI), testified that massage therapy, along with acupuncture, is one of the oldest therapies, dating back to Hippocrates in 400 B.C. She said that most of the research on the effectiveness of massage has been conducted at TRI during the last decade. TRI studies have demonstrated that massage can reduce prematurity and low birth rates associated with pregnancy, stress, and anxiety; can enhance the growth of preterm babies; can affect the outcomes of a number of psychiatric disorders; and can impact on immune problems, including asthma, diabetes, dermatitis, HIV, and cancer. The only study on the cost effectiveness of massage was in pre-term infants and was able to demonstrate a hospital cost savings of $10,000 per premature baby (Field et al, 1986). Multiplied by the 470,000 pre-term babies born in the U.S. each year, it equals a cost-savings of $4.7 billion per year, according to Dr. Field.

Panel Discussion:

Commissioners asked the panel to comment on: 1) their profession's attempts to teach self-management techniques patients, 2) where they thought cost-effectiveness studies should be directed, 3) what are the barriers to delivery of their therapies, 4) how their approaches to disease prevention might be broken down into reimbursable segments of time and services, and 5) what are the education priorities. Although all said teaching patients self-care is integral to their approaches. Dr. Meeker said he was not in favor of teaching self-manipulation to patients, however, because of the degree of skill needed to avoid self-injury. In regard to cost-effectiveness studies, Dr. Kail said that naturopathic studies must look at the whole system of care, because naturopathic physicians rarely deliver a single modality for condition. In regard to barriers, Dr. Fields said that in the field of massage, the traditional training of doctors not to touch patients is a major barrier. She said underlying mechanism studies to persuade the physicians that massage approaches work are necessary. In regard to reuimbursement, Dr. Kail said there are new reimbursement codes for time spent in discussion and patient education that are being underutilized by the insurance industry. He said that inclusionary language in Medicare and Medicaid is the fastest way to get those codes better utilized. In terms of education, Ms. Culliton said that education resources should be directed to training medical students and physicians in the effectiveness and cost benefits of CAM approaches as opposed to delivering the modalities themselves. Dr. Meeker said he agreed with Ms. Culliton. He added that there is an even greater need to train all health professionals, not just medical doctors, but CAM professionals as well, in how to interrelate to each other.

(Session II Continued)

Herbal Medicine:
Dennis Awang, Ph.D., SCIC, said herbal medicine's potential contribution to health care appears to be fundamentally related to the ability of the consumer to have access to safe and efficacious products. However, knowledge of the nature of active principles and the mechanisms of action of herbals remedies is severely limited. He recommended the institution of a system, such as that proposed by the World Health Organization (1978), to establish guidelines for the assessment of herbal medicines and to ensure proper identity and quality of both raw materials and finished products. Since most of the adverse reactions attributed to herbal remedies have been due to substitution, adulteration, misidentification, or linguistic confusion, he said it is not wise to leave the establishment of the identity and quality of these materials to manufacturers.

Christopher Hobbs, an herbalist and a licensed acupuncturist, said that he has received funding from a pharmaceutical company to sift through the literature on a hundred herbs in great detail. He and his colleagues have researched 26 international electronic databases and accessed a great deal of foreign material. Unfortunately, very few herb studies to date that have met high scientific standards. He recommended that well-trained herbalists be involved in studying the safety and efficacy of herbs on a scientific basis because many scientists have the view that herbs do not work until it is proven that they do work, which is the antithesis of how an herbalist would view them. He added, that although herbs can have side effects, generally speaking, herbs are far safer than drugs.

Nutritional Supplements:
Alan Gaby, M.D., provided examples of the superior cost effectiveness of nutritional supplementation versus conventional therapy for 10 common, but costly ailments. He added that he has seen many patients spend thousands of dollars on care that didn't work, when, in fact, all they were suffering from was a food allergy. Therefore, he recommended the better teaching of nutritional information in medical schools. If implemented, he said, the cost of care will undoubtedly come down by billions of dollars.

Patsy Brannon, Ph.D., R.D., a registered dietition, testified that the recent Institute of Medicine report on the role of nutrition and malnutrition in maintaining health in the nation's elderly (Institute of Medicine, 1999) defines two tiers of nutritional services that impact the consideration of CAM. The first is basic or general nutrition education or advice that can be provided by a variety of health care professionals. The second tier is medical nutrition therapy, which involves nutritional assessment, evaluation of nutritional needs, intervention, counseling, enteral and parenteral nutrition, and other modalities, as well as follow-up care. This type of therapy is generally provided by registered dietitians in a health care team of physicians, nurses, pharmacists, physical therapists, and psychologists. Beyond these two tiers, however, the vast majority of consumers get their nutritional information through the mass media. She said that nutrition therapy is "strongly supported" by observational studies, consensus documents, systematic reviews, and extensive clinical trials for a number of condtions. Furthermore, several

recent reports have examined the cost effectiveness of nutritional therapy and have found potential savings ranging from the millions to billions of dollars for the health care system. She said there are a number of barriers to nutrition therapy, including the lack of recognition of nutritional therapy by Medicare and Medicaid and private practice health plans. She recommended the passage of legislation currently in Congress, H.R. 1187 and S. 660, to provide outpatient medical care coverage for medical nutrition therapy for diabetes and kidney disease. She also recommended the consideration of expanded Medicare and Medicaid coverage as recommended by the Institute of Medicine report for the other chronic diseases for which nutritional therapy has been documented effective.

Integration Overview:

Harley Goldberg, D.O., Medical Director for CAM for Kaiser Permanente in Northern California, said his job is provide information on CAM practices to Kaiser's physicians, members, and health care providers, to coordinate a research program, and to evaluate education and training needs for providers. It is also his responsibility to identify the appropriate access and delivery systems. He said that a recent Kaiser-funded survey (Gordon et al, 1998), which found a very strong interest about CAM amongst Kaiser's members, patients, and physicians and clinicians, formed the basis of Kaiser's CAM strategy. Based on the survey, areas of modalities and conditions were identified in which to conduct systematic reviews. The systematic reviews, in turn, drive the activities of Kaiser's Education Committee, informs Kaiser's research agenda, and the consideration which CAM services to deliver. To be considered an appropriate for a specific condition, there must be reasonable evidence of safety and effectiveness. He, therefore, asked the Commission to recommend funding of organized systematic reviews in a coordinated fashion on specific CAM methods and by clinical conditions. He further suggested the need to increase research on clinical implementation of specific CAM treatments for specific conditions involving CAM practitioners and experienced researchers.

Panel Discussion

Commissioners asked Dr. Goldberg: 1) which CAM services Kaiser is currently providing, 2) who fills the role of the gatekeeper for these services, 3) what the process is for generating consensus, and 4) to explain Kaiser's system for CAM education. Dr. Goldberg replied that Kaiser is integrating acupuncture as one component of its chronic pain delivery system and provides manual therapies through Kaiser's Physical Therapy Departments. He said that the role of gatekeeper depends on whether a service requires physician referral and whether a service is available on self or patient referral. Treatments for a specific clinical condition require a primary care physician referral, although referrals can come from any specialist or any provider in the system. He said consensus was generated by the survey he mentioned, but members were not involved in reviewing the evidence. He added that Kaiser uses many different formats for imparting information on CAM, including in written summaries of the research, full practice guideline including the bibliographies and evidence tables, summaries of clinical information, and video conference presentations.

The Commissioners also asked panel members to make recommendations for improvements in

labeling regulations for herbal and dietary supplements, and on licensing and credentialling. Mr. Hobbs recommended a "traditional medicines" category that would take into account the historical and traditional use of an herb and to better educate consumers how to use them. Dr. Gaby suggested that manufacturers be allowed to put the information on the known effects of nutritional supplements on the label so that it would greatly enhance both the effectiveness and the safety. Dr. Awang noted, however, that much of the information currently put on labels is unreliable. He said that the most useful information that can be put on labels is warnings against possible adverse effects or toxicity, and recommendations as to use. On the other hand, he agreed with Dr. Gaby that limiting claims about efficacy is problematic because many people are buying herbs and nutritional supplements for treating specific conditions and they need accurate information on efficacy. For example, he noted that Saw Palmetto is often labeled as promoting prostate health rather than as a treatment for symptoms of benign prostatic hyperplasia, which is what most people buy it for. Dr. Brannon agreed with Dr. Awang that there needs to be added focus on potential adverse effects and not focus on those that do not have adverse effects. Finally, Dr. Goldberg said because it is such a long process to conduct randomized clinical trials on herbs for specific condition, to get relatively good answer questions more quickly, one can use epidemiologic data and other types of studies in the meantime.

Session III: Use of CAM for Selected Health Conditions

Substance Abuse/HIV-AIDS

Howard Josepher, Executive Director of Exponents, Inc., a not-for-profit drug treatment program in New York City, testified that because of AIDS, Exponents created an alternative approach to engaging and working with drug addicts, called ARRIVE. ARRIVE does not require abstinence for participation, but instead focuses on risk reduction for sex, drug use, and opportunistic infections and promotes proper nutrition through counseling and vitamin supplementation. ARRIVE also promotes stress reduction through a variety of CAM approaches including acupuncture, aromatherapy, music therapy, and meditation.

Denise Drayton, a graduate of the ARRIVE training program, and currently a staff member at Exponents, testified that she was first introduced to CAM during detoxification for heroin addiction. Her treatment including conventional treatment methods along with acupuncture for stress and pain management, which she continued using on an outpatient basis. She said the ARRIVE program also taught her visualization and deep breathing meditation and she has been drug-free for 10 years as a result. She said that in her community, however, CAM therapies are not readily available and even when it is, there a natural distrust of anything that is not traditional (i.e., conventional).

Cancer

Barrie Cassileth, Ph.D., Chief of Integrative Medical Services at Memorial Sloan Kettering Cancer Center in New York City, did not testify by submitted written testimony to the Commission, in which she described Sloan Kettering's CAM integration program and preliminary data on how its CAM services compare with conventional services. She said the CAM integration is extremely important to the treatment of cancer patients, because cancer is "a massive biological event and its treatments are often extremely difficult." She said that it is absolutely essential the CAM therapist work along side of oncologists at every stage of treatment and rehabilitation to ensure that therapies and their administration are consistent with patients' physiologic status and that patients receive only care that benefits them.

Jeanne Andrews, a cancer patient, testified that 21 months ago she was diagnosed with Stage IV colon cancer, after which she underwent colon resection and six months of chemotherapy. She was first introduced to CAM when a friend recommended that she see massage therapist. After her oncologist gave her the book, Comprehensive Health Care, she read it and contacted its author, Dr. Jim Gordon [Commission Chairman] and began attending programs at Dr. Gordon's center. There, she learned deep meditation, visualization, and a number of other forms of relaxation and also began undergoing acupuncture and intensive medical Qigong at another center. She said she is currently cancer-free and that she believes CAM treatments played a major role in her recovery. She said, however, there were a number of obstacles to her gaining access to CAM, including lack of insurance coverage and no central location for gaining credible information on CAM.

Heart Disease

Richard Collins, M.D., a cardiologist and Director of the Heart Disease Reversal and Prevention Program in Omaha, Nebraska, testified that traditional approach to cardiovascular disease management in this country is not cost-effective because there is a 30 to 50 percent restenosis rate after angioplasty or stent placement, and after typically bypass operations only last 7 years before costly recurrent admissions for heart failure occur. On the other hand, he said, the Dr. Dean Ornish program for heart disease reversal and prevention strikes at the very root cause of the disease process, by stabilizing plaques, reducing angina and costly readmissions to the hospital, and improving quality of life and well-being. He said several studies have documented and reconfirmed the programs effectiveness with multi-year follow-ups (Ornish et al, 1983; 1998). He said the Mutual of Omaha demonstration project has documented a cost savings $29,000 per patient. Similar finding also have recently been found by Highmark, Blue Cross/Blue Shield of Pennsylvania, which has embraced the Ornish program. For the insurees in Pittsburgh, a cost savings has been noted of more than $17,000 per person, improvement in SF well-being scores, outcomes, and reduction of angina. He, therefore, recommended that lifestyle behavior should be listed as a prudent, first-choice medicine for people with heart disease and said that the Commission also should "embrace" the Ornish program by providing access to it for all populations.

Walter Czapliewicz, a 45-year-old participant in Dean Ornish's program for reversing heart disease, testified that he came to the program after having had three heart attacks and bypass surgery. The bypass worked for about two years, but then he started having chest pains again.

However, within 10 days of starting the program, he said, he said his chest pain had diminished greatly and was completely gone after six weeks. He hasn't had any chest pain since then and has lost 64 pounds. In addition, his resting blood pressure has dropped from 160/80 to 128/72, his cholesterol is down from 196 to 114, and his triglycerides are down from 311 to 116. He said he truly believes this program saved his life.

Hospice Care

J. Donald Schumacher, Psy.D., of the Center for Hospice and Palliative Care, testified that in many ways hospice care is the epitome of high-quality CAM. Many of the nurses in his program are trained in therapeutic touch, and oftentimes engage in stress reduction using guided meditation and visualization. His program also employs homeopathy, chiropractic care, and acupuncture, the latter of which helps patients significantly reduce their dependence on narcotics and other debilitating medications. Unfortunately, one-third of the patients that receive hospice care die within seven days. As a result, most hospice care today is brink-of-death care, rather than true hospice care. He said that patients facing end-of-life problems need to be able to get access to hospice care sooner in order to be able to experience its full benefit.

Panel Discussion

The Commissioners asked Dr. Schumacher: 1) why referrals to hospice care have declined so dramatically in recent years, 2) what the hospice movement is doing increase access to hospice care for hospitalized patients, and 3) if hospice care could be delivered at home to save costs. Dr. Schumacher answered that cost is the major reason referrals to hospice have declined dramatically in recent years. "Our median length of stay has gone from about 29 days down to 14 days, and that is absolutely wrong for patients who need this care," he explained. He said that the hospice movement, with funds from the Robert Woods Johnson Foundation, has begun an innovative pilot project, called the Center to Advance Palliative Care, to help increase hopitalized patients' access to hospice are. He said that 80% of hospice care is provided at home. He emphasized, however, that there is a major distinction between hospice care and home health, particularly in regard to prescription benefits. For hospice patients, prescription drugs are paid for, for home health care patients, they are not. He said the largest obstacle to providing hospice in this country is the six-month criteria for Medicare coverage (i.e., the person has to have six months or less to live). He said he believes the Federal Government needs to develop demonstration projects around the country that will allow hospice programs to provide care without a reimbursement cap and without a criteria or prognostic cap.

The Commissioners asked Mr. Czapliewicz and Dr. Collins to make recommendations on how best to educate people of the benefit of lifestyle changes on the prevention and treatment of heart disease. Mr. Czapliewicz said that developing effective programs to educate people about what they are doing to their bodies through their diet is key. Dr. Collins added that it is extremely difficult to get people to listen to lifestyle advice until they are faced with the reality of increased risk. He said, however, that the new emerging technology, such electron beam CT scanner that can detect plaque in peoples' arteries and veins and determine total plaque load may change that. He cautioned, however, that lifestyle changes can only affect heart disease if an artery has not

been touched. "There is evidence that once an artery is touched, either through a stent or angioplasty, lifestyle cannot control it," he explained

Commissioners asked Mr. Josepher to elaborate on the ARRIVE program's efforts to reach out into the jails and prisons, and how such efforts may help prevent recidivism as well as prevent increasing illness from HIV, and if good studies existed that indicate there is a positive value of using CAM approached to help manage individuals in drug withdrawal. Mr. Josepher answered that ARRIVE does a substantial amount of outreach in the institutions in New York, primarily by engaging prisoners before they are released. Therefore, a whole new area that is being developed in addiction work with the criminal justice population is transitional planning, where the idea is to engage people in the institution and inform them of the various kinds of services that are available out in the communities. He added that most of the innovation and inroads that are currently occurring in addiction treatment are because of HIV and AIDS. In regard to research, Mr. Josepher said a Dr. Mike Smith from New York City, who developed auricular acupuncture has a substantial documentation on its effectiveness for managing drug withdrawal. However, he noted, that in the substance abuse field evidence of effectiveness often does not mean very much because it is a field that still prefers to treat drug use primarily through incarceration.

Commissioners asked Ms. Drayton if there was a single, key ingredient that helped her the most and to suggest ways that the Public Health Service and other agencies can get the message out to the African-American community that CAM is not necessarily second-rate medicine
Ms. Drayton answered her first contact with ARRIVE gave her a newfound sense of self-worth and spirituality, which then led her to the use of acupuncture. She said that the most influential way to deliver health messages in her community is through peer education. "If it is coming from someone who has experienced it and has a working knowledge of it through first-hand experience, they tend to believe it," she explained. Mr. Josepher added that although race is sometimes a barrier, if teachers had information and have conviction, they can transcend those barriers.

Commisssioners asked Ms. Andrews to describe all of the CAM treatments that were not paid for by her insurance in her effort to try to create integrative cancer care for herself. Ms. Andrews replied that she has done Reiki, massage therapy, support groups, Chinese herbs, various vitamin supplements, acupuncture, and art therapy. The only one that was covered by insurance has been acupuncture when it is administered by a medical doctor. She added that prayer has been a very important part of her healing. She said that if one does not have hope or faith, it is extremely hard to beat something like cancer.

Session IV: Issues in Integrating CAM in Service Delivery

Richard B. Miles of Health Frontiers testified that 30 years ago he began organizing and managing major conferences on CAM, including the first national symposium on acupuncture at Stanford in 1972. He said the prevailing attitude of our conventional medical system has been that when an individual presents with a disease, they are essentially ill and need to be made well

with interventions. There is an emerging perspective, however, that people are essentially well and need to be made ill. If one can get the factors that are contributing to this illness out of the way, the system will heal itself. He said that he is currently working with organizations and programs that are trying to develop this particular kind of concept. Mr. Miles said that doctors should be better listeners and to help people reestablish connections with nature and allow the diseases of this culture to heal themselves rather than try to fix them.

Berkeley Bedell, former congressman from Iowa and current president of the National Foundation for Alternative Medicine, testified that he believes the Commission has a genuine opportunity to make a difference. He said that 3 years ago, he and his wife formed the National Foundation for Alternative Medicine to conduct CAM field trials that NIH was unwilling to conduct itself. He said the Foundation currently is focused on cancer treatments and is sending teams led by a medical doctor to visit alternative cancer clinics and go over their patient records. He said the foundation is finding clinics in Europe administering low-cost, non-toxic cancer treatments with success that would not be expected at major cancer clinics here in the United States. He, therfore, pleaded with the Commission to recommend passage of The Access to Medical Treatment Act, which would make it possible for these non-toxic treatments to be tried under strictly controlled circumstances. He also said the Commission should recommend that any medical treatment that has been in use in another country, where there is no evidence of it posing a danger to the patient, to be allowed here in the United States.

Paul Kurtz, Ph.D., a representative of The Committee for the Scientific Investigation of Claims of the Paranormal, said he was troubled by the lack of skepticism in the Commission's deliberations. He said that he and his colleagues are committed to scientific medicine because it has been the most effective way of curing disease and promoting human health. He said he was also troubled by the Commission's having categorized too many things as alternative, when some clearly are not. For example, he said that lifestyle management in cardiology should not be labeled as alternative medicine. As commissioners on a Presidential Commission, he said there is obligation to see that CAM methods are carefully judged by double-blind tests, that they are backed up by coherent theories, that there are studies of mechanisms to explain why they work. He emphasized that CAM research needs to be conducted by neutral observers who are objective and impartial, neither strong negative skeptics, nor strong proponents, but people who are committed to scientific research.

Panel Discussion:

Several Commissioners disagreed with Dr. Kurtz's assessment that most conventional medicine treatments have been scientifically proven to be effective while most CAM therapies have not. It was pointed out that most prescription drugs have not been shown to be more effective than placebos. Dr. Kurtz replied that even conventional medicine should be continually questioned. He said he is not defending conventional medicine, per se, but the system of scientific inquiry used to test it.

Commissioners asked Mr. Miles whether he viewed CAM as being able to co-exist with western

medicine or something that should be integrated into it. Mr. Miles answered that the groups he has worked with achieved their best results when there was collaboration between conventional and CAM practitioners. He said, however, that one of the main determinants of collaboration is the reimbursement system. The movement toward medical savings accounts appears to be a step in that direction, particularly, for separating routine preventive care from more catastrophic "insurance" care. He cautioned, however, that unless we change the mindset that people can do whatever they want to their bodies and the insurance system will bail them out, we will be facing an uphill battle.

Commissiors then asked Mr. Bedell to elaborate on his proposal to allow acceptance of use of therapies that have been shown to be relatively safe in other countries. He replied that because there are not good treatments for most degenerative diseases, people with such conditions should have the right to try potentially beneficial treatments developed in other countries with out fear of government interference. He said there is a need to "open up" the present regulatory system so that these new treatments can be at least tried. He said, however, that it would be a very different situation if there is any evidence that a treatment is toxic. Mr. Kurtz argued that "determining toxicity" is a difficult problem. There was not agreement among panel members regarding who should be responsible for determining toxicity--with Mr. Bedell saying that he didn't trust the FDA to do it because it is too closely alligned with the pharmaceticial companies—however, there was general agreement that the Federal Government should play some role in the process.

Session V: Meeting Public Needs/Systems of Delivery

Private Practice Integration:

Robert Atkins, M.D., a private practice physician, said he began practicing a "different kind" of medicine in the early 1960s in order to get better outcomes as well as to disprove prevailing medical notions about diet and illness. After many years of practicing medicine differently, he said he and his colleagues believed they had succeeded in achieving better outcomes in many areas than when they were practicing strictly conventional medicine. In the early 1970s, he wrote a book about his experiences. He said the term "complementary medicine" aptly applies to practicing physicians and, in fact, should be the future of mainstream medicine. He said complementary medicine should not be viewed as adding complementary therapies to mainstream medicine, but an entire system of patient care, a different system, a system which is based on a "working knowledge" of all of the healing arts. He said that complementary medicine offers the Federal government an opportunity to solve its most pressing health problem: controlling spiraling health care costs.

Nursing Integration of CAM:

Charlotte Eliopoulos, a representative of the American Holistic Nurses Association (HNA), said the nursing profession has a long history of providing holistic care. For a number of reasons--including their large relative numbers, the diverse clinical setting in which they practice, and their multi-disciplinary education--she said nurses must have a significant role in this integration of CAM into the health care system at large. She said there is a need for nurses to increase their knowledge about CAM through continuing education for the existing work force, as well as the integration of this within the undergraduate nursing programs.

Stand-Alone CAM Center:
Mort Rosenthal, chairman and founder of Well Space, a for-profit CAM clinic, said that Well Space has been open in Cambridge Massachusettes for 27 months. It has 21 treatment rooms, 70 practitioners, and offers massage, acupuncture, Chinese herbs, chiropractic, naturopathic medicine, and nutritional classes. To date, the clinic has served approximately 10,000 patients and will take in approximately $2 million year, a very small amount of which is profit. He said 45 percent of the Well Space visits are related to stress or the need for relaxation. The rest of the condition range form headaches, back and neck pain, sleep disorders to fibromyalgia, fatigue, and cancer. He emphasized that Well Space is complementary, not integrated, and that Well Space's patients, for the most part, are not interested in integrative care. He said that in more than 40,000 visits, no patient has asked to have information sent back to their conventional physician. He added, however, that Well Space has an excellent relationship with local physicians, whom often give them informal referrals, as opposed to a traditional referral. He said that in a recent six-month pilot study, among 2,000 people who essentially offered free CAM care without referral, 70 people took advantage of the program and 50 of those, or 71%, continued their care even though they now had to pay out of pocket. From a policy perspective, he said he believes that the delivery system for CAM will continue to be largely stand-alone. He suggested that any policies that are made should not be biased in favor of full integration.

Panel Discussion:
Commissioners asked Dr. Atkins to describe some of the obstacles he faced in setting up and implementing his practice. He answered that there were many areas that they believed their methods were getting good results, but that the insurance companies would not reimburse for them. For example, he said, he and his colleagues often use a high resolution microscope for diagnosing the presence of various bacteria, yeasts, and parasites, but that they could not get reimbursed for the use of this expensive equipment because there was not an insurance code for it. He added that very few of the cancer treatments he and his colleagues use as alternatives to chemotherapy and radiation are eligible for insurance reimbursement. Furthemore, he said that he and his colleagues us a number of treatments that have been approved in Europe but that have not been approved here in the U.S. for various conditions that are not being reimbursed. The solution to all of these obstacles is to fund the kind of research that will allow everyone to see the two systems of medicine—conventional and CAM--compared side by side with a matched group of subjects to determine which gets better results and at lower costs.

The Commissioners asked Mr. Rosenthal: 1) what Well Space was doing to increase access for low-income people; 2) if it has an approach for improving the dissemination prevention materials; 3) why more people didn't take advantage of its pilot program; 4) why Well Space chose to be complementary rather than integrative; and 4) to make recommendations for research. Mr. Rosenthal said Well Space does provide discounts to needy patients but that its prices are fairly inexpensive already. In terms of prevention information, he said that there are great deal of preventive CAM and non-CAM treatments that are not reimbursed, so reimbursement of these approaches certainly would enhance their access and delivery. Although the pilot program was not a great success, it was still worth trying. He said that education is key

because the people who know about CAM seem willing to pay for it and those who don't know much about it are not willing to pay for it. In terms of Well Space's model, he said there were three basic reasons that Well Space chose to be complementary rather than integrative: 1) concerns that physicians would be reluctant to treat CAM practitioners as equals; 2) there are several other clinics who have physicians in their models and they have not done too well; and 3) in order to be profitable, Well Space did not want to spend too many resources dealing with issues of reimbursement and the other problems inherent in a traditional health care system. In terms of research, he said that Well Space has more than 40,000 computerized records that should be useful for research purposes.

The Commissioners asked Dr. Eliopoulos to elaborate on the role nurses could play in helping to integrate complementary alternatives into mainstream. Dr. Eliopoulos answered that nurses can play a crucial role in educating physicians about complementary medicine. She added that perhaps one of the reasons that patient seen in a complementary medicine clinic did not want their records sent back to their physicians was because they did not want to be admonished by their doctors. She said that this is where nurses can play a vital role, because nurses are in private practices doctors as well as in hospitals and can help educated doctors about which CAM treatments may be effective and which have not been shown to be effective.

(Session V Continued)

Community Based Center:
Tom Trompeter, M.P.A., Executive Director of Community Health Centers (CHC) of King County, Washington, said that his organization is a private non-profit, tax-exempt organization, with six medical and four dental clinics in suburban Seattle. Each year, the CHC provide about 90,000 visits for people who are mostly poor and uninsured. Those patients who do have insurance are generally insured either by Medicaid or by the Washington Basic Health Plan, which is a sliding-scale, managed-care product designed for people with incomes significantly below poverty level. In 1995, CHC competed for and won a grant to establish an integrative medicine clinic. During that process, CHC developed a partnership with Bastyr University. The grant required the CHC to provide conventional primary care, along some elements of CAM. An evaluation component also was required. He said the process for determining which products and practices to make available for which conditions is based on soliciting input from the clinical and administrative leadership from both Bastyr and CHC. Through this process, four CAM disciplines were identified, including naturopathic medicine, acupuncture, chiropractic, and therapeutic massage. The decision was made to offer naturopathy and acupuncture on site, and to offer chiropractic and massage via referral. Just recently, however, he said that CHC hired a licensed massage practitioner to provide on-site therapeutic massage.

Hospital-Based Center:
Sylver Quevedo, M.D., Director of the Center for Integrative Medicine at the O'Connor Hospital in San Jose, California, testified that he believes integrative medicine is THE MEDICINE of the future. Any hospital not considering an integrative approach will be seen as obsolete within 10 years from now, he asserted. On the other hand, programs that take a proactive and serious look

at integration will have a competitive advantage. Indeed, integrative medicine offers advantages over the narrow biomedical model of care because it takes seriously the notion that culturally appropriate care in our increasingly pluralistic society is a necessity rather than an afterthought. He said that although there was initially resistance from the hospital medical staff, which was due primarily to unfamiliarity with CAM, once the dialogue began, such resistance largely disappeared. Now, the hospital medical staff are asking the Center to organize a department of integrative medicine to bring these therapies into the in-patient setting.

Integrated Academic Centers:
Woodson Merrell, M.D., Executive Director of the Beth Israel Medical Center's Continuing Center for Health and Healing in New York City, said that his Center, which just opened in June 2000, comprises 16 clinicians, nine physicians, and seven allied health and CAM providers covering most aspects of integrative medicine in a hospital-based practice. He said several years ago Beth Isreal Hospital quickly understood that integration is the future of medicine and put together a team of people to set up an integrative medical center that would be academically based and combine the best of the traditional healing practices with the best of conventional western bioscience. The Center includes all aspects of research, education, and clinical care and provides patients access to most CAM treatment modalities and approaches. Because Beth Israel Medical Center is a teaching hospital, it is very focused on integrating CAM into all aspects of training and has the nation's first required residency rotation in integrative medicine. It has just received funding to set up a two-year fellowship in integrative medicine. The Clinic is primarily fee-for-service, but there are a number of programs for uninsured and underinsured patients, including a program called Helping Hands Fund, which has raised approximately $50,000 to date to provide free care for the uninsured. He said it is "critically important" that most licensed fields of CAM be incorporated in these integrated centers and be allowed to be primary care providers, and, by doing so, it actually allows for many of these patients to come back into the traditional medical care model.

Panel Discussion:
The Commissioners asked Dr. Quevedo to elaborate on the "culturally appropriate" medical care offered in his clinic and how CAM practitioners are interacting with conventional physicians in the hospital setting. He answered that one of the most important issues to address with patients is language and belief systems. He said that all of us operate in a given belief system, and that belief matters, particularly in mind-body connections. In terms of CAM practitioner interactions with hospital staff, he said that the Center's agreement with the medical executive body is to limit the scope of CAM practice and credentialling to the out-patient setting until enough experience was gained. To date, therefore, the Center has declined the opportunity to provide CAM in the in-patient setting, a decision that has been greated with disappointment among the staff in the hospital who would like to give their patients access to these treatments. However, he said the Center staff is just beginning the process of helping the hospital to develop a CAM integration and credentialing strategy.

The Commissioners asked the panel about funding strategies that would facilitate integration and whether they believed they were at an economic disadvantage compared to other CAM stand-

alone models. Dr. Merrell said he thinks it is very difficult for these types of centers to exist without private funding and government grants, because it is very difficult to make money for the first three years of operation. He added that his Center is lucky because Beth Israel made the development of integrative medicine an integral part of it mission statement. By doing this, the Center gained access to the hospitals donor lists and the development office resources. Dr. Quevedo said that being associated with a hospital increases the value of what his Center is doing because it increases their visibility but is also adds additional burdens because of the heavy overhead and administrative costs inherent to being part of a hospital system. He said that for many reasons, however, his group decided against developing a proprietary model for its center. Mr. Trumpeter said having both conventional and CAM modalities under one roof has been a big boost for his program. He added that his group developed a rather elaborate protocol for informing patients of their options and their choices and ways of making sure that people knew what they wanted. However, he said they gave it up because people absolutely knew what they wanted to choose. Dr. Merrell added that the quality of the practitioners is key to success.

(Session V Continued-Reimbursement)

Oxford Health Plan:

James Dillard, M.D., said that in the mid-1990s, he was asked by Oxford Health Plans to help build a comprehensive CAM program inside the insurance company. To date the program has credentialed almost 3000 CAM providers in six areas. Although the program has, in many ways, been successful, the company had some financial challenges at the end of 1997, which has led to an incomplete experiment in building a CAM program. Oxford has had very remarkable financial turnaround recently. However, the widespread financial problems that have occurred throughout the managed care industry, making it a challenge to build these kinds of programs within a managed care environment. In terms of integration, he said there are a number of barriers, including resistance on the part of the physicians, resistance on the part of the CAM practitioners, and resistance on the part of patients. He said that many patients simply do not want their primary care physician to know that they are seeing a CAM practitioner and, thus, often are resistant to having their records shared by both their conventional and CAM physicians. Overall, he said, it is appropriate to create access to the therapies that are considered to be safe. However, reimbursement should only be embraced those therapies that have strong evidence supporting their effectiveness.

Highmark Blue-Cross/Blue-Shield:

Anna Silberman, a representative of High Mark Blue Cross/Blue Shield in Pittsburgh, Pennsylvania, said that in 1997, Highmark became the first insurance company in the country to both provide and pay for the Dean Ornish program. Highmark did this because if heart disease is managed with only surgery without also addressing the root causes, bypasses need to be redone in 7 to 10 years and angioplasties within six months. The Ornish program, which has four components and is delivered by a team of physicians, exercise physiologists, registered dieticians, yoga instructors, behavioral health clinicians, and other professionals, both alternative and conventional. She said Highmark's senior management supported the Ornish program because of the science behind it, and, to date, patients have experienced 57% less angina; 50% less depression; improved cholesterol (an average of 22 points); and a 10% reduction in body.

Most importantly, there has not been a single heart attack or death since 1997, when the program was implemented. There has been only one bypass surgery, one stroke, and four angioplasties among these 400-plus very high risk patients. Moreover, there has been a cost saving of $17,000 per patient, which translates into a little over $8 million in savings for the entire group of patients. As a result, Highmark has started a new company, called Lifestyle Advantage, to significantly influence the way heart disease is managed and financed in this country. She asked the Commission to: 1) continue to support scientific investigations into CAM treatments to help separate what is effective from what is not; 2) promote proven CAM interventions to the public; and 3) influence health plans to reimburse for evidence-based CAM interventions.

Washington State Office of Insurance:
Lori L. Bielinski, Senior health policy analyst for the Washington State Office of the Insurance Commissioner, gave the Commission background about how the Washington State law is being implemented. It allows consumers a choice of the provider who will treat the condition in which they are seeking care. There are currently several different coverage models of CAM services used in Washington State, including: 1) a dollar-cap model, 2) a condition-based model, 3) a gatekeeper model, 4) an open-access model, 5) a self-referral and preventive care model, and 6) a discount networks model. She explained the advantages of disadvantages of each of these models.

Panel Discussion:

The Commissioners asked Dr. Dilliard to explain: 1) the method of access to Oxford's CAM benefits program, 2) whether there has been a difference between when services that are covered as a benefit versus those that are discounted, and 3) how Oxford sets limits on access. Dr. Dilliard said that Oxford began by paying for chiropractic with referral from a primary care physician and mandated that patients could make up to eight visits before the chiropractors had to file a care plan. To date, three states have a standard benefit for chiropractic, which is managed the same as any other benefit. In Connecticut there is also a mandated naturopathic service, which Oxford treats exactly the same way as it does chiropractors. Finally, acupuncture was put into a rider, which was sold to about 60 large groups and was delivered in the same way and managed the same way as the chiropractic was in terms of an eight-visit limit. He said that recent surveys have shown that the most popular parts of the program have been chiropractic, nutrition, massage, and acupuncture, in that order. He added that there is discounted network program for chiropractic, in which patients can go to a chiropractor without a physician referral and simply pay the Oxford rate. The vast majority of utilization has been through the benefit with the primary care physician referral. He added that the direct access riders have been very popular products as well. He said, however, that Oxford has not had the resources to capture all of the data on CAM utilization rates that is available. In regard to limiting access, he said Oxford adopted mandated benefits that were fully in compliance with the Insurance Equality Act in New York State. If patients feel they have been wrongfully denied access, he said there is a peer-based appeals process. He added that Oxford is generally considered to be the most generous payer in the Mid-Atlantic, so consequently there hasn't been much of a problem in terms of limiting access.

Commissioners asked Ms. Silberman how Highmark chose to offer the Dean Ornish program and if it is planning to offer other CAM modalities in a similar way. She answered that choosing Dr. Ornish's program was simply a matter or her hearing Dr. Ornish speak at a conference, and presenting what she heard to Highmark's board of directors. They were very receptive to it, she said. In terms of expanding CAM offerings, she said that Highmark has a delivery system, called Health Place, with 17 centers delivering various CAM programs on a daily basis to about 40,000 people a month.

Commissioners asked Ms. Bielinski to help the Commission understand how the Department of Insurance in Washington looks at access. She answered that the State does not have a formula, statute, or a rule. However, there have been significant number of complaints filed by consumers about lack of access. In Washington State, CAM is not really differentiated with conventional medicine any more. The part where it gets to be confusing, she said, is when plans set an arbitrary limit. She, therefore, recommended that the Commission try to find out what are the most common guidelines for setting limits and apply them to CAM. Otherwise, she warned that the carriers could be allowed to sell what is essentially an illusory benefit.

(Session V Continued—CAM Systems of Medicine)

Ayurvedic Medicine:
Robert Schneider, M.D., of the Marharishi University in Fairfield, Iowa, submitted evidence on the effectiveness of Vedic medicine, which include meditation, herbal approaches, diet, purification therapies, behavioral approaches, and even the influences of architecture on the environment. He said the clinical syndromes that have shown to be most responsive to various approaches of Vedic medicine include cardiovascular disease and its risk factors, psychological disorders, cancer prevention and treatment in terms of quality of life improvements, chronic pain, age-related disorders, and many disorders commonly seen in primary care. In terms of cost effectiveness, several studies have reported 50 to 80 percent reductions in health care utilization and related health care costs, with meditation and other Vedic medicine approaches. This has been true for both in-patient and out-patient utilization. Patient satisfaction with Vedic medicine also is almost twice as high as is patient satisfaction with conventional medicine, he said. Based on these data, he asked that the Commission recommend that Vedic medicine services that are shown to be effective and cost-effective in published, peer-reviewed scientific research, be reimbursed by third-party payers, including government payers, such as Medicare and Medicaid, and private reimbursers. He also asked that certified practitioners be allowed to practice in their areas, following the Minnesota model. He said that over time, states should adopt a licensure procedure for natural medicine practitioners, including Vedic medicine practitioners, and licensure would be dependent on certification and completion of other state licensing requirements, such as an exam or experience requirements. He also asked the Commission to recommend Federal grant to educational institutions of higher learning for the training of Vedic medicine practitioners.

Naturopathic Medicine:

Tori Hudson, N.D., of the National College of Naturopathic Medicine in Portland, Oregon,said that naturopathic doctors, or NDs, essentially are licensed primary care family physicians with a specialty in natural medicine. NDs utilize nutrition and lifestyle counseling prescribe nutritional supplements, plant extracts, and other natural therapeutic substances and techniques, as well as selected pharmaceuticals. She noted that womens' health is an area in which an integrative medical framework could bring about a more reliable understanding of and treatments for a number of poorly understood and treated conditions, such as interstitial cystitis, vulvodinia, fibromyalgia, PMS, fibrocystic breasts, pelvic infections, menopause, endometriosis, and uterine fibroids. Her experience in Portland, Oregon, she said, is one of having a women's integrative clinic with ND, MD, DC, acupuncturists, massage therapists and counselor working together, referring back and forth, discussing the co-management of shared patients. Thus, she said her vision of integrative medicine is basically a cadre of health care disciplines and practitioners, each with their own scope of practice, each with their own tools of their trade, but also each with a common understanding, a common respect, and a shared commitment to coordinate care, cross-refer, and co-manage patients. The Federal government could go a long way towards providing a framework in which all of this can take place, she explained.

Traditional Chinese Medicine:

Robert Duggan, M.A., MAc, President of the Traditional Acupuncture Institute (TAI) in Columbia, Maryland, said that his school currently has 700 graduates across the country, many of whom are earning higher than average salaries. He emphasized that TAI students are trained not only in the modality of acupuncture but also in the art of healing, which is completely different than the reductionistic model of conventional medicine. In TAI's model, he said, the patient is the primary care provider. Only when the American health care system understands that by making the patient the primary health care provider, will it be able move the majority of the visits out of the sick care system into a wellness culture, he explained. Traditional acupuncturists who see themselves as educators of the empowerment of the patient, therefore, do better than those that are simply delivering a modality. He asked that the Commission consider changing a reimbursement model that favors the delivery of the modality over the healing art of the individual patient. He also suggested that all schools of medicine, complementary and mainstream, foster relationship-centered care. He suggested that a separate agency be established to deal with the issue of the quality of herbs and that a bill currently before congress that would forgive student loans to induce CAM practitioners work in impoverished areas should be fostered. Finally, he said there should be an initiative to foster CAM and wellness education from the first grade onward.

Panel Discussion:

The Commissioners asked Mr. Duggan to elaborate on his comments about the regulation of herbal therapies as well as his proposal about educating people about wellness and lifestyle choices. Mr. Duggan replied that he believed it was wrong to turn plants into products. He said the policy issue for the Commission would to look at ways restore an awareness of plants as healing and then begin to define where is that line between what is food and what is medicine and must be professionalized. That is why he believes there needs to be a separate agency from the FDA to address the questions about herbs differently that it is currently being dong. Mr.

Duggan said that education about wellness and healing needs to start from the first grade, by teaching children an awareness of breathing, of drinking, of sleeping, of eating. He added that there need to be incentives for people to learn how to take care of themselves.
The Commissioners then asked the panel members to tell what their institutions are doing to reach out to the less advantaged in their communities. Dr. Hudson said that her clinic has three tiers of pricing to give people different cost options as well as some free clinics. In addition, she said that she practices one month a day at a rural clinic. Mr. Duggan said that TAI commits aproximately $200,000 a year to an inner-city clinic and that a several TAI graduates have established similar clinics. Dr. Shneider said that his institution is part of a federally funded center that has conducted a number of randomized trials of mind-body approaches in high risk African-Americans for the treatment and prevention of cardiovascular disease. Also, it has been very involved with the nation's historically black medical institutions in rolling out CAM approaches in lower socioeconomic and ethnic communities, particularly African-American communities. It also is planning initiatives in Native American and Hispanic communities and other ethnic communities.

Session VI: CAM Integration in Existing Delivery Systems

Alan Trachtenberg, M.D., medical director for the Office of Pharmacologic and Alternative Therapies at the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA), said that a vital part of SAMHSA's mission is the full integration of CAM services with the rest of the public health and medical care system. He said the bulk of his activities at CSAT are currently involved with taking over from FDA in the regulation of opiate addiction treatment providers. For example, the kind of CAM clinic CSAT is now dealing with includes a group of Yale who recently published the results of randomized trial of ear acupuncture for cocaine addiction that achieved highly significant results. He said CSAT supports a variety of alternative practices that maybe included as elements of comprehensive treatment programs, including acupuncture, meditation, and culturally-specific healing practices, such as sweat lodge and traditional Hawaiian medicine. He said alternative therapies and traditional healing practices have been included in CSAT's programs, primarily as culturally relevant elements of a comprehensive treatment and outreach program. If an alternative therapy brings patients into the treatment setting and keeps them coming longer, then it has utility over and above whatever specific efficacy it may have. He said CSAT is presently requesting funds to assemble a consensus panel to make recommendations about how acupuncture should be incorporated into more existing drug treatment programs.

Milton Hammerly, M.D., of Catholic Health Initiatives (CHI), said that the system he represents encompasses more than 100 facilities in 22 states, employing more than 75,000 people. He said the incorporation of CAM services into this system has been an evolutionary process, beginning with a steering committee consisting of CAM proponents Early on, there was a steering committee, but now there is a more heterogeneous cross-section of the organization involved, including skeptics. He said CHI now has unanimous organizational buy-in and support of the philosophy of integration. He said the essence of CHI's philosophy, which is to provide comprehensive mind-body spirit care which personalizes care and which has to be, of necessity,

collaborative. He said, however, CHI faces a number of barriers in integration. The first is research. CHI has not been successful in accessing research funding, which seems to be mostly finding its way to academic centers, he said. In an effort to remedy this, CHI have approached pharmaceutical companies with synergistic combinations of supplements and pharmaceuticals which are, in fact, patentable, providing an incentive for them to want to pay for the research. Another barrier is the issue of reimbursement. He said, however, that reimbursement is only a barrier because the system is still trying to put the new clinical model of integrative health care in the old reimbursement model. He said clinicians can have far greater impact by working together as an orchestra than they can by practicing as individuals. He said that the Commission, by helping to break down the barriers to collaboration as well as the barriers to reimbursement in clinical areas, can actually help lead that orchestra.

Panel Discussion:
The Commissioners asked Dr. Trachtenberg if there was research looking at the effects of CAM on compulsive behaviors as well as to elaborate on his organizations efforts to reach the untreated populations and Native Americian populations. Dr. Trachtenberg said unfortunately there has been too much attention on withdrawal and not enough attention paid to compulsion to date. He added, however, that addiction treatment in this country, even in fairly conventional circles, has traditionally had a spiritual dimension. He said that the Commisson could perhaps urge that more attention be given to the interface of the issues of spirit and the neurophysiology of craving and compulsion and reward. In terms of reaching out to those who currently want treatment but are not receiving it, Dr. Trachtenberg said that our society is often too willing to blame people for their problem and put such a moralistic judgment on this particular category of illnesses [sustance abuse], that there is a significant barrier to treatment even when it is available. He said, therefore, that stigma, in addition to resources and the lack thereof, has much to do with that treatment gap. In terms of programs for Native Americans, Dr. Trachtenberg said those programs are part of community-based treatment programs that are serving specific Native American communities. The leaders from the communities themselves being served usually provide the culturally resonant aspects of the overall treatment program, such as sweat lodge or vision quest. He noted that such programs typically begin as grants to local groups and are used a method for the Federal Government to gain access to these groups.

Commissioners asked Dr. Hammerly if CHI has any ongoing data monitoring program related to CAM interventions and to comment further on the environmental aspects and obstacles encountered in CHI's CAM program. He answered that CHI has a comprehensive care assessment tool, which has the SF-36 embedded in it. Unfortunately, with the lack of research funding, CHI has not actually started collecting data. In terms of addressing the hospital environment, he said that program looks at a number of factors in the hospital environment that can impact on patients' heath, including the lighting, the food, the presence of plants. He said there is no organized initiative, but that several hospitals have Healing Environment Committees and are looking at models that are changing the environment to more holistic, and not as sterile a setting. In terms of obstacles, he said that to make integration work, there is a need to address the underlying philosophy of patient care. If the philosophy it is not coherent, there is organizational dissonance and nothing works. He added that the integration program needs to be very much

tailored to the specific location and environment. The approach needs to be sensitive to consumer interests and readiness, the availability of services, physician readiness, and to politics.

Public Comments:

Francine Butler, Executive Director of the Association for Applied Psychophysiology and Biofeedback, said that biofeedback is one of the most well-established of the CAM therapies, and here is a large body of scientific work demonstrating its treatment efficacy without adverse side effects. She said largest problem with access and delivery of biofeedback is denial by third-party payers because biofeedback is still branded as experimental. Nancy Dolores Kolenda, Director of the Center for Frontier Sciences at Temple University, said that it is important that the major medical schools and research centers throughout the United States have access to funding to set up models to study various CAM therapies, such as herbal medicine and homeopathy and acupuncture. Because our nation's major medical schools are facing critical financial crises, they are now more open now than ever to incentives to advance the research in CAM. Diana Chambers, of Friends of Health, said "whole person healing" as best describe most CAM practices, which primarily focus on prevention, wellness, and health. She said that Friends of Health wants the Commission to focus carefully on issues of language and philosophy of CAM as well as access and delivery issues for the poor, both urban and rural. Rustrum Roy, a representative of the University of Arizona Program for Integrative Medicine, said there are three primary communities that need to have better access to knowldege about CAM: 1) the approxmately one-half million practicing physicians, 2) academic research scientists, and 3) the general attentive public. He said there is a need for an emergency, crash education program for these groups. Bruce Nordstrom, on behalf of the American Chiropractic Association, encouraged the Commission to focus on wellness and to recommend policies for reimbursing CAM providers for health promotion. He said a good example of how prevention is cost effective can be found in an HMO in Illinois called Alternative Medicine, Inc., (AMI), which utilizes doctors of chiropractic as traditional gatekeepers and has reduced the rate of hospitalization for its members by about 75 percent. Neal Barnard, President the Physician's Commission for Responsible Medicine, said that nutrition is the most fundamental medical treatment, and esearch proves that when patients change their diets, in combination with other lifestyle changes, they can reduce cholesterol levels, reverse heart disease, improve and sometimes even cure Type II diabetes, and hypertension. He recommended that the Commission promote initiatives to integrate nutrition into the core curricula at American medical schools, encourage the Public Health Service issue grants for research on the effects of vegetarian and vegan diets for a number of chronic illnesses, and encourage the Department of Agriculture review of federal policies that conflict with healthy nutritional goals. Doreen Chen, chair of the Chinese Medicine Advisory Council of the American Association of Oriental Medicine, said that integrative medicine is the future of medicine and asked that the services rendered by an Oriental Medicine physician be covered by any health insurance, both Federal or private. Gary Sandman, founder of a

community-based alternative medicine referral service in the Washington, D.C., area, said CAM tends to teach empowerment, and individuals that are empowered tend to heal. He said there needs to be a 20-year plan to integrate conventional medicine into patient-centered, whole-person health care. Danny Freund, a cancer survivor, said he has tried many CAM therapies in the course of his recovery and now teaches a course on CAM. He said there is a great deal of information on CAM but there is no central source on information to help people decide how to find and interpret it. Melinna Giannini, Director of Alternative Link, said that her company has developed about 4,000 codes that describe what is said, done, ordered, prescribed, or distributed by alternative care practitioners, and each one of these codes has a relative value unit attached to it so that a rate can be developed for each procedure. She asked that the Commission promote the incorporatation of this code 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. Jane Hersey, Director of the Feingold Association, said that a the Feingold Association show families how to reduce or eliminate many behavior, learning, and health problems in their children by eliminating synthetic dyes, artificial flavors, and certain preservatives from their diet. Despite the potential of this healthy option to help medical and social problems, and despite all of the supporting evidence, it is opposed, ignored, or misrepresented by Government agencies and professional organizations that should embrace it. She asked that the Commission urge the National Institutes of Health and the Department of Agriculture to conduct new research on the efficacy of the elimination diet. Boyd Landry, Executive Director of the Coalition for Natural Health, said the Commission needs to seize the opportunity "to look outside the box," rather than looking at ways to fit CAM inside the box. He said the Commission should focus on what consumers want, not what practitioners want. He, therefore, urged the Commission to seek out consumer input. Lawrence A. Plumlee, M.D., President of the National Coalition for the Chemically Injured, said there is a great need to conduct research on the role of toxic chemicals in syndromes, such as multiple chemical sensitivities, auto-immune diseases, fibromyalgia syndrome, and chronic fatigue syndrome. Currently, he said, patients with these conditions are subjected to dangerous and ineffective psychiatric drugs which prolong the illnesses, because the causes are not recognized and eliminated. There also is the need for research to investigate the role of nutritional supplements in enhancing improved metabolic function in these syndromes. Another area requiring scientific research and better medical education is the induction of mild immunodeficiency by some toxic chemicals with resultant super infections by viruses, bacteria, parasites, and fungi. Appropriate diagnosis and treatment of these infections will enable substantial gains in health. Michael John Rohrbacher, Director of music therapy at Shenandoah University in Winchester, Virginia, said that music therapy is the use of music in the accomplishment of therapeutic gains, the restoration, maintenance, and improvement of mental and physical health. He said there are over 3,700 individuals currently hold American Music Therapy Association membership, and mationwide, there are 69 undergraduate music therapy programs, 25 graduate programs, and 159 internship sites approved by AMTA. Andrew Rubman, of the American Association of Naturopathic Physicians, said the present needs of our citizens and the enormous body of emerging medical information leaves us no choice but to produce a better model of health where no one approach to medical care is forced to stand in judgement of others. He said that incorporating naturopathic medicine as a guiding principle to help shape and implement the new

medicine will allow our citizens to become better, more objective consumers, limiting high-priced procedures and pharmacy by increasing their wellness and thereby avoiding disease. Marshall Sager, President-elect of the American Academy of Medical Acupuncture, said that medical acupuncture, which is the practice of acupuncture by fully trained and licensed physicians, falls within the scope of the practice of medicine. The fact that most health care plans do not reimburse for physician acupuncturists services has forced patients from their primary medical care providers and out of the health care system. Medical students and physicians must be educated about the use and effectiveness of all complimentary medical modalities, especially medical acupuncture and must understand that medical acupuncture is not a threat to their practice. Diana Miller, an attorney, said she is committed to research, education, and designing laws that take away the legal barriers for consumers for access to alternative health and other kinds of health care that they deem necessary for their healing. She said the current system is disempowers consumers, and anything that disempowers consumer makes healthcare more expensive and impedes wellness. She said the exception is the State of Minnesota, which believes consumers have the right to access any person or treatment they deem helpful to bringing them to full health. Courtney Banks, a former Hodgkin's Disease patient, said that CAM saved her life. After radiation therapy, she began exploring and using acupuncture, eating only organic fruits and vegetable and whole foods, and using homeopathy. She said she has never felt healthier, had more energy, and a more positive outlook. Richard Pavek, from the Biofield Research Institute, said that he was concerned that the movement toward integration would disenfranchise alternative practitioners who are not doctors. He said that every alternative practice, teaching, method, or philosophy was developed outside of conventional medicine. He recommend that alternative practitioners be enfranchised with as much legal right to practice as possible.

Session VII: Commissioners' Discussion:

Chairman Gordon began the discussion by saying it was very much an open discussion and he wanted to give everyone a chance to share their thoughts, observations, and concepts about the meeting and about future directions. Commissioner Chappell said he believed the Commission needed to affirm the equal importance of promoting wellness as well as healing and to see CAM as having two charges: equal rights and equal accountabilities. He said that if the Commission seeks to create equality, then integration can occur wherever it is natural.

Commissioner Bresler said that another recurring theme appears to be the need for early education the let people know two things: first, what are they doing that is deleterious to their health, and second, what they can do in order to enhance and improve their health. Commissioner Gutierrez said that it would be helpful for her to know what is the intent and purpose of each provider group. Commissioner Rolin emphasized that the Commission needs to focus on those that aren't being served, such as Indian tribes living on reservations, because she said those are areas where CAM can make vast improvements within the communities. Commissioner Kerr said that in the future she would like to hear from agencies and organizations that may be impacted by the Commission's recommendations, such as the Department of Agriculture or a Fortune 500 company or a pharmaceutical company or public health people. She

said such agencies and companies are willing to help and want to be called to service. Commissoner Chow said that the Commission is talking about more than health care but also about lifestyles. She agreed that the conversation needs to be expanded and more skeptics included. She added that new paradigms and spiritual issues also needed to be considered. Commissioner Fins endorsed Commissioner Kerr's comments and added that he there needs to be a broad articulation of principles that will set the agenda for the next 20 years, in addition to concrete recommendations. He also said that the Commission needs a better sense of the sociology of CAM and to consider the mechanisms and agencies and collaborations that will allow dialogue to continue when the Commission is no longer around. Commissioner Paz said that as culture here in the U.S. becomes more and more diverse it will be necessary to continually expand the list of potential CAM therapies. Commissioner Bernier said the time is ripe to take a major step in integrating CAM. Nevertheless, there remain a number of issues, including guaranteeing the safety and efficacy of treatments of all types. One of the problems, he said, is that the term "CAM" means so many different things, and many CAM disciplines are not necessarily eager to see themselves integratied with convetional medicine. Chairman Gordon suggested that the Commission should begin to dialogue more with the conventional medicine community, particularly the American Medical Association and the American Association of Medical Colleges. Commissioner Bernier agreed to help begin the dialogue with those groups. Commissi medicine for conditions affecting people who are not valued in the community. Commissioner DeVries encouraged the Commission to create recommendations tcan be applied to multiple tracks, regardless of which way our country moves forward with its health care policy.

Commissioner Low Dow said that there have to be social policies in place that allow for healthy communities and healthy families and healthy children. She said that as the Commission discusses various issues, she hoped it didn't lose track of the bigger issues. Commissioner Fair expressed concern that there was a great need for education but that the Commission had heard nothing concrete about how to increase education. He said the Commission should stress the develop of plan for universal health education. By educating people universally, the personal, family and community improvements will follow, he said. Chairman Gordon reminded the Commission that the next two meetings were going to focus primarily on professional education and on public information, which includes education in the schools and in other places. Commissioner Jonas added that the most effective use of resources may be health care advertising, maybe even more than education. He added that the two types of activities that can lead to more specific items that deal with wellness are the area of health support and health promotion. He added that a focus on accountability was also necessary, including accountability of care and services on the part of the CAM providers. Commissioner Low Dog agreed, saying that she hopes the Commission looks at access as givng people the freedom to seek the practitioners they want as long as there is some type of accountability. Commissioner Chappell added that he would like to see a focus on bringing health promotion and health support to the public in an affordable way. He said his concern about the discussion on reimbursement is that it is not in the control of the consumers' hands. So affordability is the language to use as a goal to try to get that. Commissioner Tian said the Committee has to make sure that it adequately defines the CAM modalities what it is considering. It also needs to answers three important questions: where we are; where we are going; and how to get there? He said that each professional group can help with these answers. He also suggested that the

Commission invite the FDA as well as consumers, because when the Commission dicusses herbal nutrition, for example, a lot of these are controlled by FDA policy. Commissioner DeVries said that one critical issue the Commission needs to remember is that the individual states, not the Federal government, regulates the individual licensures of providers. The Commission, therefore, can consider recommending licensing statutes for acupuncture, massage, and naturopathy. This would go along way toward helping this modalities gain access to reimbursement and create the ability to access benefits. Chairman Gordon then thanked everyone for coming and participating, whereupon the meeting was adjourned.

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Public Comments

Divider Title: _____

Public Comment Session

1. **James Sensenig**, American Academy of Naturopathic Physicians
2. **Candace Campbell,** American Preventive Medical Association
3. **Diane Davis**, University of Virginia Cancer Center
4. **Katherine Gorton**, American Dietetic Association
5. **Audrey Di Maria**, Secretary of Art Therapy Credential Board
6. **Judy Simpson,** American Music Therapy Association
7. **Richard Goldberg**, Private Practice
8. **Nancy Kristine Haller**, Feldenkrais Guild of North America
9. **Christine Herlihy**, National Certification Commission for Acupuncture and Oriental Medicine
10. **Alice McCormick**, National Certification Commission for Acupuncture and Oriental Medicine
11. **Su Liang Ku**, Florida Institute of Traditional Chinese Medicine
12. **Sharon Stevenson**, National Center for Homeopathy
13. **Barbara Moquin**, National Naval Medical Center
14. **Matt Ward Russell**, National Integrative Medicine Council
15. **Carolyn Jones Sabatini**, Pharmavite Corp.
16. **Christina Walker**, The Shenk Human Energetic Institute
17. **Alan Dumoff**, Private Practice

Sensenig # 47

AMERICAN ASSOCIATION OF NATUROPATHIC MEDICAL COLLEGES

AND

AMERICAN ASSOCIATION OF NATUROPATHIC PHYSICIANS

TESTIMONY TO WHITE HOUSE COMMISSION ON CAM POLICY

WASHINGTON, D.C.

MAY 16, 2001

Dear Commissioners and Staff:

Thank you for the opportunity to appear before you today. While we have provided information at previous WHCCAMP meetings, we would like to make the following points:

THE HEALTH OF THE AMERICAN PEOPLE IS AT RISK

- reimbursement for CAM services and products, and coordination of CAM research, is in the American public's interest
- access to CAM services is needed by the elderly, the poor, the uninsured, and in rural areas

PLURALISM IN AMERICAN MEDICINE

- diversity, with separate but equal systems of healing
- professions in parallel, collaborative integration
- maintain the "gene pool" of ideas
- enhance creativity, critical thinking, competition of ideas, economic competition, and market forces
- each system of healing has its strengths and weaknesses; combining systems results in losses for each

"To many observers, modern medical control over the terms and process of integration has resulted in the loss of important aspects of traditional theory and practice, issues seemingly unimportant to modern medicine. [For example] Fewer

acupuncture points are taught than in the classic system and aspects of the theory of traditional Chinese medicine have been de-emphasized. The effect of "modernization" resulting in a lesser system has also occurred with traditional medical education in India." (British Medical Journal, Vol. 322, 20 Jan 2000, p.165)

- assimilation impacts public safety

  Adverse events are far more common in less-trained medical acupuncturists (tends to be MDs with less than one year of training) than in better-trained acupuncturists (36 to 43.6 months training. The adverse event rate has been reported as 2:1. (Towards a Safer Choice: The Practice of Traditional Chinese Medicine by Bensoussan and Myers, 1996, Australia)

- the various CAM professions and traditions, their history, their standards, their bodies of knowledge, represent a national resource

  - naturopathic physicians represent a separate and distinct medical system

    - distinct standards, licensing, credentials, accreditation

    - distinct body of knowledge, scope of practice

    - recognized as physician providers in eleven states

      Naturopathic medical college prepare(s) NDs "with a biological and biomedical education of the same breadth and depth that prepares an MD to be a primary care physician. Naturopathic medicine...diverges from other forms of primary medical care at that point where professionals in common possession of scientific facts conscientiously disagree on how best to use their shared knowledge in treating patients." (Oregon Office of Educational Policy and Planning Administrator David Young, April 18, 1989)

  - CAM providers are sought by the public, not for certain modalities, but for the clinical philosophy or culture or paradigm in which they are applied

  - in a pluralistic system, there should be equal access to and equal regulatory and financial support for the various systems

REIMBURSEMENT FOR CAM PRACTICES AND PRODUCTS

- public choice requires equal access to physician providers of various schools of medicine

  - one example: Connecticut requires any insurance company which covers the services of a physician to not discriminate among MDs, DOs, or NDs

- however, Connecticut's policy does not apply to federal employees and Medicare beneficiaries

- such "illusionary access" should be prohibited by federal policy by eliminating conflicting policies, regulations and laws

- public safety for providers who diagnose and treat, and are primary care or primary contact, requires access to credentialed, licensable professionals with educational standards, clinical training, board examinations, and peer review

  - credentialing is required in order to receive reimbursement for CAM services

  - to be credentialed, one must be licensed, and trained in an accredited program to a recognized scope of practice

  - licensure, credentialing, and education are linked through the reimbursement system for public safety

  - the licensed CAM professionals must be integrated throughout the health care system for safe and effective access

  - Data on access, delivery, and reimbursement for naturopathic care are available from several states (Washington, Connecticut, Montana)

    Price-per-member per month for users of CAM services (acupuncture, massage and naturopathic medicine) has been found in one study to be approximately $0.20. A large majority perceived these services to be helpful. 61% reported that the CAM treatments had resulted in diminished use of their pain medication, and 55% reported a decrease in the use of their "conventional medical team." (Utilization, Patient Satisfaction and Cost Implications of Acupuncture, Massage and Naturopathic Medicine Offered as Covered Health Benefits. Darrell Stewart, MHA, John Weeks, Stephen Bent, MD)

COORDINATION OF CAM RESEARCH

- the coordination of CAM research has been addressed by our profession's representatives in previous Commission meetings (see testimony from Traub at San Francisco Town Hall Meeting, Standish and Pizzorno at Seattle Town Hall Meeting, Kail at Dec.4-5 meeting,)

- NCCAM is coordinating CAM basic science and clinical research, and facilitating the development of infrastructure at CAM research institutions

• the proposed Office of CAM at HHS should coordinate other types of research not included in the NCCAM mandate, such as research in health services, cost effectiveness, policy, education, and practice guidelines. This Office could also collaborate with NCCAM in holding a conference on the challenges of CAM research and CAM research methodologies

• appropriations are necessary for demonstrating efficacy and cost-effectiveness of CAM services and products. The burden of funding this research should be fair and equitable compared to that which is provided for conventional care pathways and interventions.

SPECIFIC POLICY RECOMMENDATIONS

1. **Commit to medical pluralism**

• embrace the fullness of diverse health care systems

Conventional, traditional, indigenous, complementary and alternative models of care, and their bodies of knowledge, have contributions to make to the healthcare which is culturally most appropriate and effective for individuals and communities. Best practices are discovered through exploring diverse structures for integration, including parallel, collaborative, and assimilative models.

• encourage licensing all CAM providers consistent with educational standards

• require inclusion of licensed CAM providers in CAM policy making and as researchers and advisors in all federally-funded CAM studies

• establish CAM offices at and appoint naturopathic physicians and other licensed CAM professionals to the staffs of federal health care agencies, including NCCAM, NIH, DHHS, CDCP, Agency for Health Care Policy and Research, Bureau of Indian Affairs, Public Health Service, National Health Service Corps, VA, and HRSA

•appropriate funds to layer a premium on any grant at NCCAM for including a CAM research institution instead of only a conventional one, and, for naturopathic institutions, it be a Council on Naturopathic Medical Education-approved naturopathic medical school that conducts research

• use the term "every category of provider" in federal law

•has withstood challenges through both Democratic and Republican legislature majorities, has generated the most controversy, and is the most popular, as well as having been upheld by the US Supreme Court

• specific criteria must be met: the CAM profession must be regulated by the state Department of Health with licensure or certification; the scope of practice must allow the provider to treat the condition that the patient presents; the provider must be contracted to be eligible for reimbursement; the patient must have benefits covering a condition that is within the scope of practice of the chosen provider

• this is not the same as "any willing provider", nor is it a mandated benefit; it allows consumers access to a choice of the provider who will treat the condition in which they are seeking care

• insurers have the right to credential providers as long as the standards are consistent with those established by the Department of Health

• fund residency programs for naturopathic physicians so that they may provide care and conduct research along side MD/DO residents at federally-funded health clinics and hospitals

• authorize HCFA and provide appropriations to reimburse for licensed CAM services to Medicare recipients, the poor, uninsured and underserved

2. Mandate a non-discrimination policy for reimbursement for licensed CAM providers in all federal health care programs and agencies

• remove exclusionary language from existing federal laws and regulations

• examples of agencies with exclusionary language or no mandates (for naturopathic physicians and other licensed CAM providers):

Indian Health Service policy-restrictive

National Health Service Corps - exclusionary

Field and Public Health Research - Centers for Disease Control - no mandate or appropriation for funding

Outcomes Assessment and Cost Effectiveness - Health Care Financing Authority/Medicare-exclusionary

NIH Institutes for Cancer, Heart, Lung, Blood research need mandates for CAM "offices" for research.

Graduate Medical Education - exclusionary

• as a first step, fund residency programs for naturopathic physicians in rural health settings, and include student loan forgiveness programs and Medicare reimbursement

• improve reimbursement for both conventional and licensed CAM providers under federal programs for behavioral change (affects greater than 50% of major diseases and their costs)

• fund a HRSA or DHHS National Credentialing Roundtable

• investigate and integrate licensed CAM systems and modalities and training standards as credentialing requirements for provision of CAM services by all health care providers

• endorse inclusion of naturopathic physicians and other licensed CAM providers at HCFA's CPT "table"

• prohibit any "separate but equal" costly, segregational, and disintegrational CPT scheme for any physician level provider, especially naturopathic physicians, as it does not result from any profession-wide consensus

• use the model of the Washington State Insurance Commissioner's Work Group on a federal level

3. Fund research on utilization of naturopathic medicine and CAM providers

• harvest existing information

• evaluate beyond clinical outcomes to global measures

• include patient satisfaction, lost time/productivity, functionality, quality of life, use of conventional services and medications, emergency department visits, hospitalization

• mandate a GAO report on the cost savings possible through the incorporation of licensed CAM services and CAM products

We once again appreciate the opportunity to bring our concerns before you. Please contact us if you would like any further information or clarification.

Sincerely,

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I will speak on the need for pluralism in American medicine. Give examples of reimbursement systems for naturopathic medicine that work, and give recommendations to the commission for reimbursement of naturopathic services for inclusion of naturopathic physicians in federal programs.

Candace Lee Campbell, B.A.
American Preventive Medical Association

I would like to tell the Commission about the Access to Medical Treatment Act, which would give Americans the right to use therapies that have not been approved by the FDA.

Pearson-Cmtl

Agencies -

Allow Health Claim

Testimony Before the
White House Commission on Complementary and Alternative Medicine Policy
Washington, D.C.
May 16, 2001
By Candace Campbell
Executive Director, American Preventive Medical Association

The American Preventive Medical Association was founded by physicians to be an advocate for health care freedom. We now have as members consumers, companies and practitioners from many disciplines. The tie that binds us as an association is the belief that American consumers should have the right to access the entire tool kit of therapies, not just those that have been sanctioned by one particular branch of health care.

We work primarily at the federal level to increase consumers' access to complementary and alternative (CAM) therapies. We do not promote one type of practitioner over another, or one therapy over another. Our goal, instead, is to increase patients' awareness and access to the full range of health care options, and to protect the practitioners who want to offer CAM therapies without fear of censure or recrimination.

I am here today to ask the Commission to recommend passage of the Access to Medical Treatment Act which will be introduced in the House this week and the Senate soon thereafter. I understand that you will be sending specific policy recommendations to Congress later this year, and I ask that you make the Access Bill one of those. A copy of the bill and background materials is included with my testimony.

Why, you may ask, am I requesting passage of legislation like this when the topics this week are research and reimbursement? Because we believe that Americans should have the right

to access therapies as soon as possible, and not have to wait decades for all the research to be in, or for the FDA to approve a drug. We believe that many lives could be improved and saved in those interim years. Simply speeding up the FDA approval process would not solve this problem.

As you may know, APMA led the effort to pass the legislation that created the National Center for Complementary and Alternative Medicine at NIH. We did this for two reasons: first, because the Office of Alternative Medicine was severely hampered by its status as an Office, and second, because we believe there is a crying need for more and better research into CAM.

Part of that legislation also created this White House Commission. We felt the need for a White House Commission level of review because there is presently no easy way to identify or coordinate federal efforts to support an integrated health care system. The left hand doesn't know what the right hand is doing. Resources cannot be managed effectively, and goals cannot be shared. Nor has there been a nationwide analysis of the needs or barriers to integration. How can we fix the system if we don't know where it's broken and where it's working? Our assumption is that the Federal Government is not doing everything it can to ensure that consumers have access to a full range of treatment options, and that it is also getting in the way of access and education regarding CAM. We felt that a White House Commission could survey the health care landscape, identify areas of need as well as barriers to integration, make specific policy recommendations, and help ensure a coordinated approach that would maximize federal resources and optimize health care.

You are also devoting time in these hearings to the subject of insurance reimbursement. Our members are split on this issue. For some, insurance reimbursement for CAM represents the great equalizer. It would ensure that more Americans have greater access to valuable therapies.

It would end the unfortunate dilemma faced by many patients who would prefer to receive CAM therapies but must settle for conventional treatments because that is what their insurance covers. Paying out of pocket is not an option. Why continue a system in which only the "haves" can truly choose their treatment, while the "have-nots" settle for what their insurance company allows.

On the other hand, we have many members who view insurance as silk shackles. They prefer not to accept insurance at all because it limits their income, creates a tremendous paperwork burden and now, thanks to the Health Insurance Portability and Accountability Act, exposes them to charges of insurance fraud for miscoding. HIPAA not only made insurance fraud a federal crime, with huge financial penalties and serious jail time, it also extended the Federal Government's reach beyond federal insurance program fraud to private insurance fraud. Given the fact that many CAM therapies do not yet have insurance codes, CAM practitioners are often forced to make due, choosing codes that seem to fit, or using locally accepted codes that will no longer be valid when the electronic filing requirements go into effect. This is a dangerous practice when such patchwork solutions can be deemed insurance fraud.

Many of our members also oppose the violations of senior citizens' rights caused by the Health Care Financing Administration's prohibition against private contracting. Surprisingly, Americans who are old enough to participate in Medicare may not private contract with a physician. This means that if Medicare deems a service unnecessary, but the patient wants it anyway, and his doctor thinks it would be beneficial, the patient may not pay for that service (private contract) if his doctor participates in Medicare. This is a gross violation of seniors' health care rights and an unwarranted interference in the doctor-patient relationship. A significant number of our members have opted out of Medicare so that they do not need

participate in what they believe is an unfair, unconstitutional system. To opt out, they must agree not to accept Medicare for a period of two years for any patient, and they must renew that "opt out" by filing an affidavit with the Department of Health and Human Services biannually.

For these practitioners, and many of our other members who are either unwilling or unable to opt out of Medicare, insurance coverage for CAM therapies would be no bargain, only more of the same – increased paperwork, government interference, reduced fees, restrictions on the number of visits and type of therapies available, increased hassle and an expansion of the violation against seniors' rights.

While APMA has encouraged the creation of ABC codes for CAM therapies by the private company Alternative Link, we do so with one caveat: that the codes not be used to create a CAM ghetto. As I'm sure you have heard these past few days, more than one practitioner organization has voiced concerns that a separate system of codes may result in marginalizing and eventually destroying CAM practices by establishing unreasonably low fees to CAM providers. So, while many will argue today for increased insurance coverage of CAM, I trust that the Commission will remain cognizant of the potential pitfalls when making policy recommendations.

All this debate over insurance reimbursement, however, begs the questions. If it's illegal to access many therapies, isn't it premature to talk about reimbursement? While we wait for sufficient research to be done to completely convince the medical community, and while we wait for the insurance issues to be settled, patients still want and need access to CAM therapies. It is both cruel and pointless to deny Americans access to therapies that could be improving and saving their lives.

Many of these therapies are used in other countries but not available in the United States. Many are considered experimental because they have not been approved by the Food and Drug Administration (FDA). Others are in the drug-approval pipeline but not widely available, even though they would be helpful and even life saving to people outside the clinical trial. The range and number of such unapproved therapies is both heartening and depressing. Why can't Americans have access to them? Why do they need to wait until the FDA has approved them? What of the therapies that will never get FDA approval, either because the foreign companies choose not to seek it, or because the therapies are non patentable?

Today, Americans' health care choices are considerably restricted to those approved by the FDA, and sanctioned by the American Medical Association, the Federation of State Medical Boards, and other enforcement bodies deeply entrenched in the allopathic medical model. As my teenage daughter would say, "Who died and appointed them God?" Why should we be asked to believe that one system has all the answers? The individuals and organizations making this most personal of all decisions on behalf of patients, know little or nothing about CAM therapies used effectively in other countries, or by the wide array of practitioners outside the allopathic community.

Why the lack of knowledge? For some, it is due to time constraints; they simply don't have the time to study new approaches or disciplines. For others, it's more a refusal to accept different ideas than a lack of knowledge. New ideas can be frightening and besides, we are told, if it was any good, they would have learned it in medical school. Another category of practitioners opposes the use of CAM because it represents a direct threat to their bottom line. If a person dedicates his life to becoming the best cardiac surgeon in the state, isn't it asking too much to expect him to embrace non-invasive CAM therapies that help patients avoid surgery?

Fortunately, health care isn't plumbing. It is an art as much as a science, and it should be allowed to constantly evolve. When the lid is slammed down on advancement (which often means experimentation and observation), patients lose. Instead of a health care system that encourages practitioners to incorporate new ideas and the best practices from around the world, we have a system that in all its glorious arrogance assumes that it is best and must not be challenged. To challenge the system is to risk personal and financial ruin. Just ask the APMA members who have gone bankrupt defending their right to offer their patients alternatives.

Patients are discovering this sad lack of freedom for themselves. Typically, they don't realize their lack of freedom until they are sick and up against the system. More and more, they are not settling for the options laid out for them by conventional medicine. They are investigating and researching, talking about their experiences and pushing the envelope. It's not only the terminally ill who are trying new things; it's also the ones who are sensitive to drugs, who prefer a more holistic approach, or who prefer to try the simplest, safest, least invasive approach first before resorting to the big guns of Western medicine. You all know the numbers; millions of Americans are now using alternative therapies. American consumers are voting with their feet, and finally, the medical community is taking notice.

Increasing numbers of medical doctors are educating themselves about CAM and incorporating it into their practices. They are tired of pushing antibiotics and surgery; tired of failure; tired of the side effects. For their trouble, they are being called quacks and charged with practicing sub-standard medicine when, in reality, they are just not blindly restricting themselves to the so-called standard of care. It takes tremendous nerve to step outside the box in this environment. It often takes deep pockets as well.

In response, APMA is supporting the Access to Medical Treatment Act. It probably should have been called the Health Care Bill of Rights. Scheduled to be reintroduced this week in the House and very soon thereafter in the Senate, the Access Bill enjoys strong bipartisan support. It would create a federal statutory right for consumers to use any therapy they desire, so long as they and their authorized practitioner follow the many consumer safeguards in the bill. This means that Americans would no longer have to sneak across the border into Mexico or fly to the Bahamas to get medical care. It means that products used safely and effectively for decades in Europe would be available easily and safely to Americans. It means that patients would no longer be forced to seek out an underground market in alternative therapies, or break the law to save their lives. It means that doctors who offer these products to their patients would no longer be treated as criminals or forced to defend themselves before medical boards that value tradition more than patient care.

To discourage fraud, practitioners and manufacturers would be forbidden to advertise such "unapproved" products, and prevented from making a profit on their sale. Patients would have to be fully informed of the risks and benefits, and of the fact that the FDA has not approved the product. Practitioners would not be allowed to exceed their scope of practice or violate state laws. Unfortunately, this means that in California, it would still be illegal for a physician to treat cancer with anything except chemotherapy, radiation and surgery, but since states have the constitutional right to regulate the practice of medicine, we must leave it up to state legislators to remove their own restrictions on patient freedom. I should point out that all of the many and thorough consumer safeguards (malpractice, scope of practice, anti-fraud, etc.) remain in place and would serve, as now, to protect patients.

I have attached a copy of the bill that will be introduced in the 107th Congress. It reflects the concerns and issues we have heard over the past six years that this legislation has been floating around. Consumer protections have been strengthened; reporting requirements for both positive and negative results have been added; data collection has been mandated; and informed consent procedures have been expanded to mirror those used in clinical trials. It has been on the back burner for six years because issues such as FDA Reform and Medicare Reform and the Patients Bill of Rights have bumped it from the short list. We were asked by the leadership to take a back seat until those bills could be addressed. But the time has come for the Access Bill. We, APMA, practitioners and the American public, have waited long enough for rights we should have had all along.

We think the bill provides a balance between increased consumer freedom and consumer protection. It reasserts Americans' right to make their own health care decisions, free from the tyranny of the established (and government funded) medical monopoly and the well-intentioned paternalism of the federal government. If it passes, Americans will move closer to an ideal health care system than any other nation in the world.

Freedom to choose the therapies to treat, cure, prevent or mitigate one's disease should be the bedrock upon which all health care is based. The Access Bill would establish that freedom. I hope the Commission has the fortitude to make such a powerful recommendation.

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Why Is Passage Of The Access To Medical Treatment Act Necessary For All Americans?

Medical doctors using only conventional therapies probably won't change their way of practicing medicine if the Access to Medical Treatment Act (AMTA) becomes law. The small percentage of doctors using alternatives in medicine, naturopaths, dentists, nutritionists and others however, will finally be free to use the therapies they believe are best for their patients, and no longer have to worry about harassment, censure, or recrimination.

As things stand now, those who hold one view of health care expect to be allowed to decide what constitutes legal methods of healing. It is just this kind of despotism that our Founding Fathers intended to prevent. Benjamin Rush, MD, a signer of the Declaration of Independence and personal physician to George Washington said: "Unless we put medical freedom into the Constitution, the time will come when medicine will organize into an undercover dictatorship to restrict the art of healing to one class of men and deny equal privileges to others; the Constitution of the Republic should make a special privilege for medical freedoms as well as religious freedom."

Actually, access to the full range of therapies, products and medical devices is quite restricted in the United States today. Americans are prevented from using life enhancing and even life saving therapies that have been used in other countries for decades. In surveys done by the Competitive Enterprise Institute, emergency room physicians, oncologists, neurologists, neurosurgeons and cardiologists overwhelmingly favored access to unapproved drugs and devices, as long as the products carried a warning about their unapproved status. They also overwhelming agreed that the FDA's approval process has hurt their ability to treat their patients with the best possible care.

The FDA's present monopoly over approving new medical therapies is creating a two-tiered health care system. Those with more resources are able to access the best that the world has to offer. The rest of the population must make due with what the FDA has approved.

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Examples of therapies that would be available under the Access to Medical Treatment Act

Through conversations with various doctors, I have compiled the following examples. It is my understanding that none of these items are available legally in the United States at this time because they have not been approved by the FDA. They would be available if the Access to Medical Treatment Act.

1. Intravenous vitamins - delivering vitamins intravenously makes them a drug. They can be much more effective in treating diseases when delivered this way. They have been used to treat AIDs, cancer, and chronic fatigue, among other things. A witness at the House Government Reform and Oversight Committee testified that her breast cancer went into remission after beginning intravenous vitamin therapy, but the FDA won't allow her to import them anymore.

2. Full-body hypothermia - is an effective treatment for cancer. It should be done in a hospital setting, but hospitals will not provide it for cancer patients because it is considered experimental. In laymen's terms, the therapy heats the patients blood to levels that kill cancer cells, without damaging healthy cells.

3. Coley's toxin - this therapy has been used since 1890. It is still offered in Europe and Mexico, but not in the United States. Patients receive an injection of the toxin which results in the blood temperature increasing, which kills cancer cells. While it is effective, it is less so than full-body hypothermia.

4. Ukrain - this treatment for cancer has been called "elegant" by leading physicians. It is a nontoxic therapy that migrates only to cancer cells while supporting the immune system. It can also be used as a diagnostic tool, because it fluoresces cancer cells, making it easier to identify them throughout the body. For instance, a physician who suspects that a patient has bladder cancer could use Ukrain to find a malignant tumor.

Evidently NCI rejected proposals to study Ukrain because it didn't meet the parameters of their protocol. I was told that while it was effective and nontoxic, it did not reach the level of cell death required by the protocol. At present, the product is available in other countries, but the quality is inconsistent and it is very expensive because it is made in small quantities. It is patented, but the owner of the patent cannot afford to pursue FDA approval.

5. Calcium AEP - is "the treatment of choice" for autoimmune diseases in other countries of the world. Eighty percent of multiple sclerosis patients show major improvement on the therapy. It can also be used to treat juvenile diabetes and lupus, which are also autoimmune diseases. Based on Hans Nieper's concept, the product is not sold in the United States and the FDA confiscates shipments at the border. It was discovered 31 years ago and is now made by several small companies in other countries.

6. Mistletoe - has shown promise as a cancer treatment. At least six companies are selling a

product based on it; Eurixor is the most well known and supposedly the most effective. It works by building up immune parameters. Mistletoe is widely used in other countries.

7. Bloodroot - is also an effective cancer treatment, eight times stronger than Ukrain, according to several physicians. As a natural product, it is not patentable.

8. Tryptophan - is now available only by prescription through compounding pharmacies. It now costs $75.00 for one hundred 500mg. capsules; about five times more than when it was sold as a dietary supplement. It is also still available in hospital settings, and in baby food produced and sold in the United States. It is also available through veterinary supply houses.

9. Radio-labeled immunoglobulin therapy - for Hodgkins Disease is no longer available in the United States because the clinical trials were shut down. According to a witness before the House Government Reform and Oversight Committee, the trial was ended because the FDA did not get the proper paperwork at some point in the study.

10. Ozone therapy - is widely used in Europe for a number of diseases, including cancer and AIDs. It is my understanding that it works by heavily oxygenating the blood. The equipment has not been approved by the FDA, and the manufacturers have no interest in spending the money and time it would take to achieve such approval.

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Access to Medical Treatment Act
Questions & Answers

Q. Will this bill cost the federal government any money?

A. No. In fact, it could save the federal government and individual consumers billions of dollars because it encourages true preventive medicine and the use of natural remedies, which are often many times cheaper than conventional treatments. It also gives Americans access to therapies that are being used safely and effectively in other countries, but which are not available here because they have not been approved by the FDA. This bill will encourage the use of less-expensive, less-dangerous approaches first. It will also foster true disease prevention, not simply early detection, which is what passes for prevention today. In this sense, the bill could save the federal government billions of dollars in Medicare costs alone. The true savings, however, will be in preventing human suffering and death because the bill will give Americans access to therapies that will improve their quality of life, and even save their lives. It's difficult to put a cost on that.

Q. How will this bill change the practice of medicine?

A. Very little, but at the same time, very much. Doctors using only conventional therapies probably won't change their way of practicing medicine. The small percentage of doctors using alternatives in medicine, nutritionists, naturopaths and others, however, will finally be free to use the therapies they believe are best for their patients, and no longer be harassed, censured or subject to recrimination.

As things stand now, those who hold one view of health care expect to be allowed to decide what constitutes legal methods of healing. It is just this kind of despotism that our Founding Fathers intended to prevent. Benjamin Rush, MD, a signer of the Declaration of Independence and personal physician to George Washington said: "Unless we put medical freedom into the Constitution, the time will come when medicine will organize into an undercover dictatorship to restrict the art of healing to one class of men and deny equal privileges to others; the Constitution of the Republic should make a special privilege for medical freedoms as well as religious freedom."

Q. Don't people already have access? Why is this bill necessary?

A. Actually, access to the full range of therapies, products and medical devices is quite restricted in the United States today. Americans are prevented from using life enhancing and even life saving therapies that have been used in other countries for decades. This bill is necessary because many states have chosen to be quite restrictive, and many medical boards,

hospital and HMO boards, and insurance companies make it difficult, if not impossible, for physicians to use unconventional therapies. For instance, in California, it is illegal for a doctor to treat cancer with anything except chemotherapy, radiation and surgery. Even if all of those measures have been tried without success, patients in California are not free to try something else. A doctor recommending another treatment could lose his license. In other states, doctors using safe and effective but unconventional therapies are threatened with censure or loss of license. The FDA has made it virtually impossible for practitioners to access therapies that are used safely and effectively in other countries, and has steadily increased its efforts to regulate the practice of medicine, even though that is not its responsibility. The agency is also slow to approve new devices, and clearly biased against natural remedies. Efforts to ease the FDA's death grip on access to drugs is met with strong resistance.

As a consequence, the federal government is creating a stratified health care system in which only the best educated and wealthiest Americans have access to the full range of care. If patients cannot depend on their practitioners to provide the best quality care available, the doctor-patient relationship will be completely undermined. The wealthiest patients will travel abroad to receive life saving treatment; the best educated will find, through dogged research, that they have other options and seek it out; and the rest of the population will have to make due with what the FDA has seen fit to approve.

Increasing numbers of US physicians see promise in alternative therapies but are afraid to use them for fear of being harassed, censured or worse. The AMTA would help eliminate much of that fear, and encourage the advancement of medical science by encouraging practitioners to use therapies that show promise. Perhaps the most important result of the bill will be the advancement of medicine, because it will free practitioners to use the full range of therapies and determine the most effective approaches to disease treatment and prevention.

Q. Does this bill circumvent the FDA?

A. The AMTA would not dismantle FDA or allow pharmaceutical companies to circumvent the agency, nor would the agency lose its responsibility for certifying treatments as safe and effective. The legislation merely attempts to open up a closed system to the utilization of alternative treatments. The strict claims restriction in the bill is designed to ensure that little incentive exists for marketing non-FDA approved treatments.

Q. Won't people forego conventional therapies and perhaps suffer or die as a result?

A. No. This red herring is always raised but both common sense and experience tell us that people don't avoid safe and effective therapies or gamble with their health, especially when their lives are at stake. In cases of non life-threatening, chronic disease, there is no harm in trying safe

alternatives. In cases of terminal illness, there is no harm in allowing patients to pursue other options when conventional therapies have nothing to offer them.

In many instances, people who use alternative therapies have already tried conventional methods to no avail. Others seek alternative therapies as an adjunct to their allopathic care. In some cases, patients prefer not to suffer the side effects of conventional therapies and look to alternatives because they are less toxic or allow them to maintain their quality of life. This bill lets the patient make this choice for himself.

Note, too, that the bill requires practitioners to fully inform their patients about all of their options, including conventional treatments. This will ensure, for instance, that patients of physicians using unconventional therapies will have the benefit of knowing about the full range of therapies available to them, plus the pros and cons of each. Patients of conventional physicians, on the other hand, may be unaware of their options because their practitioners are required only to inform them about treatments considered "standard of care." There is a lawsuit underway now in California against a hospital and tumor review board for their failure to inform a patient about an alternative therapy that has shown success in treating a form of brain cancer for which there is no conventional therapy, and of which the physicians were well aware.

Q. Doesn't this bill open the door to quackery?

A. No, the legislation provides that treatments will be administered by practitioners who are licensed or otherwise authorized to provide health care services. It does not permit them to provide services that are outside their normal scope of service; for instance, it won't permit acupuncturists to perform surgery. It does, however, help ensure that a practitioner would not be subject to disciplinary action solely because his treatment methods are considered unorthodox by the medical establishment.

We believe that individuals, not the federal government, the FDA or the American Medical Association, should be the final arbiters of individuals' health care regimens.

Most importantly, this bill covers only those therapies provided by an authorized practitioner who has personally seen and diagnosed the patient. It does not cover mail order or internet sales of unapproved products, or permit unauthorized practitioners to treat patients.

Q. Does this shield doctors from malpractice claims?

A. No. Doctors are still accountable for the welfare of their patients, and still held to the prevailing standards in providing care. Nothing in this legislation dilutes patients' abilities to sue a doctor for malpractice. In fact, the AMTA actually increases patients' rights by requiring full disclosure and informed consent before a practitioner can treat patients with an unconventional or non-FDA approved therapy.

Q. Does this bill guarantee insurance coverage for alternative therapies?

A. No. Such decisions will still be determined by the states and by individual insurance companies. The bill could make it more likely that insurance companies will be willing to cover alternatives, however, because they could do so knowing that the practitioners have the right to provide such therapies. By removing the fear of censure and FDA raids, the bill could free insurance companies to reimburse patients for a broader range of therapies. Several insurance companies have already begun providing coverage for acupuncture, massage, chiropractic and other therapies that were once considered unconventional. Consumers, of course, have already voted with their pocket books. According to an article in the *New England Journal of Medicine*, Americans spend over $10 billion dollars on alternative medicine, including nutritional supplements, even though only a fraction of that is covered by insurance.

Q. Why is there such resistance from the allopathic medical community to the use of alternatives if they are safe and effective?

A. Whenever the status quo is challenged, you can expect three stages of reaction. First, there is ridicule; second there is anger and recrimination; and third, there is acceptance. In 1848, Semmelweis proposed that child bed fever was caused by morbid matter carried from cadavers to the delivery room by his fellow physicians who refused to wash their hands. Of course, he was ridiculed at the time, but now the importance of hand washing would never be questioned. To achieve advancements in science and medicine, orthodoxy must be challenged. If we don't allow such challenges, the caliber of health care in this country will quickly fall behind.

It may be threatening to the U.S. pharmaceutical industry, but the decision to allow Americans access to drugs used safely and effectively in other countries should not be based on turf considerations or its effect on a company's bottom line. The determining factor should be whether or not that access will save or improve the quality of life of the patient in question.

Q. Don't we need the FDA to approve these substances and therapies to ensure that they are safe and effective?

A. "There is no greater frustration on the part of a treating physician than to know that the best and most up-to-date treatment cannot be made available or, more frequently, may lead to potential medicolegal action because of the inaction and delay on the part of the FDA," wrote the Center for Patient Advocacy. "This intrusion into the doctor-patient relationship must not be tolerated by a government agency whose primary job is the evaluation of safety, not clinical practice."

The FDA is not in the business of regulating the practice of medicine, yet it has tried to insert itself into the process through its hammerlock on the dissemination of scientific information, its attempts to classify natural substances as drugs, its delay in approving therapies that have been used successfully in other countries for decades, and its insistence that all drugs, whether approved elsewhere or not, go through the long and expensive FDA approval process. If Americans are to continue benefiting from the best health care in the world, the present system of regulation must be altered.

Q. Why don't companies simply get their therapies approved by the FDA?

A. The present system doesn't work for many unconventional therapies for several reasons.

♦ First, many of them involve natural substances which are not patentable. It costs over $300 million and takes a decade or more to achieve FDA approval of pharmaceuticals today. No company would undertake such an expenditure of time and resources to get FDA approval to make a health claim for injectable Vitamin C, for instance, because they could not recoup any of those costs.

♦ Second, the definition of a drug is problematic; it hasn't kept pace with the science. Many doctors use injectable vitamins to treat, cure, prevent and mitigate disease, which technically turns those supplements into unapproved drugs. Intended use and labeling determine whether the very same substance is a supplement or a drug.

♦ Foreign companies are under no obligation to undergo the FDA approval process for drugs that are already approved in other countries. The cost of the process ($300+ million) and time involved are weighed against the potential value of accessing the U.S. market.

♦ Small U.S. companies and individual clinicians don't have the resources to complete a new drug application and run clinical trials. The Investigational New Drug process is lengthy, expensive, and requires a tremendous amount of paperwork. It must be administered under an Institutional Review Board (IRB) that is responsible for monitoring compliance with the protocol during clinical trials. The FDA must approve the protocol and determine the number and type of patients who will participate.

Patients who do not exactly meet the criteria would be denied access to the therapy during the clinical trial, which can take years to complete. The process is designed for testing drugs that may eventually be patented, so the applicant has every expectation that the considerable expense may eventually be recouped. This means that INDs are feasible only for large manufacturers who can afford to provide the product free to hundreds of physicians (an FDA requirement) who must then strictly adhere to the protocol, report their results to the IRB, and provide the drug for free to patients. It is simply not feasible for an individual doctor, in most cases, to fulfill the requirements of an IND, because of the incredible expense, manpower and time required; nor are the substances necessarily patentable.

The present system is designed to accommodate drugs developed by large pharmaceutical companies; drugs designed to treat one symptom of one disease, and drugs for which a tight

protocol can be designed, (ie: a drug to treat breast cancer in women over the age of 30 who have had surgery but not radiation.) The system does not have the flexibility to address the many and unique sources and designs of other types of drugs.

Q. Does this bill pre-empt states' rights or state medical board authority?

A. No. Each state still has the right to regulate the practice of medicine within its own borders. Eleven states -- Alaska, Colorado, Georgia, Minnesota, New York, North Carolina, Ohio, Oklahoma, Oregon, South Carolina and Washington -- have already passed access-type bills to ensure that alternative therapies are available to consumers. Efforts are also underway in California, Delaware, Florida, Kentucky, New Jersey, Massachusetts, Missouri, Virginia and Wyoming to pass similar legislation.

Some states are openly hostile to unconventional therapies, and several have even passed legislation outlawing specific treatments. In California, for instance, it is illegal for a doctor to treat cancer with anything except chemotherapy, radiation or surgery. Even if a patient has tried all of those and has been told conventional medicine has nothing else to offer, he still cannot receive an alternative treatment. Doctors providing such treatment could lose their license to practice. As a consequence, states are unwittingly driving people to other countries and creating a black market in health care. We are trying to rectify that scenario with the AMTA.

Q. If this bill doesn't pre-empt states' rights to regulate the practice of medicine, how will it make a difference in states that are openly hostile to the use of alternative therapies?

A. If you live in a hostile state, you may still have problems accessing therapies that would be allowed under this bill. Texas, for instance, has its own FDA, and may regulate products differently than the federal government. Nevertheless, AMTA does help in these situations because it creates a federal statutory right for consumers to use unapproved products, which means they will have a position from which to challenge any state restrictions to that right. Without AMTA, they have no such leverage. The bill also gives practitioners some leverage if they choose to go to their medical board or state legislature seeking changes in state laws or regulations. Most states look to the FDA for guidance. If this bill removes the federal prohibition from access to unapproved drugs and devices, a state may be more likely to consider allowing such access as well.

Q. Isn't this really a state issue?

A. Not solely, because federal policies, laws and the FDA directly impact how the states regulate the practice of medicine. State regulatory bodies do not operate in a vacuum. Most medical boards look to the FDA for guidance. If the FDA has not approved a drug, for instance, a state board is unlikely to allow its use. This is not to say the FDA has refused to approve the drug,

only that it has not approved it, perhaps because the manufacturer hasn't submitted an application for consideration. As outlined above, many of the therapies that would be accessible under this legislation are simply not patentable, and therefore the manufacturers would never seek FDA approval.

In addition, by not permitting the interstate shipment of unapproved items, the FDA effectively regulates the practice of medicine. The Access bill would permit the interstate shipment of substances used under the specified parameters outlined in the consumer protection language of the legislation. Passage of this legislation would send an important message to state boards: unapproved does not automatically mean ineffective or dangerous.

Too often, state boards demand strict adherence to the limits of "standard of care", when in fact, those standards should remain fluid to reflect advancements in medicine. Today's unapproved therapies may be tomorrow's standard of care.

Q. What kinds of things, specifically, *will be* available if the bill passes, that are not available now?

A. There are three main categories of products that would be available under the Access Bill.

1. Therapies that have been used in other countries, sometimes for decades, would be available in the United States. Many of them are quite effective, but have simply not been approved by the FDA, so Americans cannot access them unless they have the time and money to go abroad. For instance:

- an experimental cancer therapy using 714x is being used in Canada with impressive results;
- in Germany, ozone therapy is used to treat a number of conditions, with great success, but it is not available in the United States;
- former Iowa Congressman Berkley Bedell successfully recovered from Lyme Disease after conventional methods failed, by using an unapproved therapy. Although the therapy was safe, inexpensive and effective, it has not been approved by the FDA. Tthe individual who assisted him in producing the substance was charged with practicing medicine without a license and had to endure a lengthy and expensive trial before being acquitted. Hundreds of people have called Mr. Bedell, desperate for access to this therapy, but he must tell them that it is illegal for them to cure their debilitating disease using this effective therapy. The therapy is not available anywhere else in the world;
- full-body hypothermia is being used to treat cancer elsewhere in the world. It should be done in a hospital setting, but U.S. hospitals will not provide it for cancer patients because it is considered experimental. In laymen's terms, the therapy heats the patient's blood to levels that kill cancer cells, without damaging healthy cells.

- Coley's Toxin has been used to treat cancer since 1890, and is still used in Europe but not the United States. Patients receive a injection of the toxin which results in the blood temperature increasing, which kills cancer cells. While it is effective, it is less so than full-body hypothermia.
- in California, it is illegal to treat cancer with anything except surgery, radiation and chemotherapy. Intravenous nutrition therapy is prohibited.

2. Drugs undergoing clinical trials could be made available to individuals who do not fit the protocol. Under the present regime, the FDA is unlikely to allow such access, even if there is a strong likelihood that the drug would be advantageous, because the agency does not want to skew the data by including "outlyers" whose results would affect the statistical results of the strict protocol. Manufacturers also understandably want to limit the number of patients participating in clinical trials because they are not permitted to make a profit by selling the experimental drug to participating patients; it must be provided at no charge. The Access Bill would not completely remedy this situation but physicians would at least be allowed to make the drug available at cost, which is a dramatic improvement over the complete lack of access under the present system.

3. Natural products and therapies designed by individuals who have neither the means nor the resources to get FDA approval would still be available to patients. The Lyme Disease treatment which cured Berkley Bedell, for instance, would be accessible to thousands of patients who have not been cured by conventional antibiotic treatment.

Q. Can't patients take advantage of the personal use importation system to access drugs used in other countries?

A. Technically they can, but in reality this is quite difficult to do. Individuals are only allowed to purchase such unapproved drugs if there is no approved drug available in the United States for their condition. This eliminates access to drugs the patient may prefer to take for a myriad of reasons. It also leaves up to the FDA the choice of treatment, eliminating the patient's right to make that decision for himself. Assuming the patient is able to meet this burden of proof to the satisfaction of the FDA, he must then find a doctor to write a prescription for the foreign drug, and locate a foreign source willing to sell and ship it to him. He patient may only purchase a 30-day supply. When the product enters the United States, the FDA inspects it and sends a frightening letter to the recipient notifying him of the restrictions on his ability to continue importing the drugs. Patients are easily intimidated by the letter, and often misunderstand the intent, believing that they are no longer allowed to purchase the drug. Because the FDA does not keep statistics on the amount or duration of personally imported drugs, we have no way of monitoring the amount of access this system allows. We can say with certainty, however, that it is a cumbersome and unnecessarily intrusive process that can be navigated by only the most determined patients.

Q. Would this bill legalize the use of marijuana for the treatment of medical conditions?

A. No. The bill will not allow access to illegal drugs or interfere with state statutes outlawing any use of marijuana. It says, specifically, that the practitioner may not violate the Controlled Substances Act.

Q. Would this bill legalize suicide?

A. No. The purpose of the bill is to increase consumers' access to the full range of therapies, within the confines of a safe, regulated health care environment. The goal is to strengthen the doctor-patient relationship by returning decisions about therapy choice to the individual, and to promote advancements in medicine by allowing new and alternative approaches to emerge and be considered without fear of censure or harassment. The bill would not pre-empt state laws regarding suicide or physician-assisted suicide.

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(Original Signature of Member)

107TH CONGRESS
1ST SESSION

H. R. _____

IN THE HOUSE OF REPRESENTATIVES

Mr. DEFAZIO introduced the following bill; which was referred to the Committee on _____

A BILL

To allow patients access to drugs and medical devices recommended and provided by health care practitioners under strict guidelines, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Access to Medical Treatment Act of 2001".

SEC. 2. DEFINITIONS.

In this Act:

(1) ADULTERATED.—The term "adulterated" means any unapproved drug or medical device that in whole or part consists of any filthy, putrid, or decomposed substance that has been prepared, packed, or held under unsanitary conditions where such drug or device may have been contaminated with such filthy, putrid, or decomposed substance and be injurious to health.

(2) ADVERTISING CLAIM.—The term "advertising claim" means any representation made or suggested by statement, word, device, sound, or any combination thereof with respect to medical treatment.

(3) COSTS.—The term "costs" means a charge to patients equal to the amount necessary to recover expenses for making or obtaining the unapproved drug or medical device and providing for its transport to the health care practitioner. Such term does not include the fees charged by a health care practitioner for his or her professional services in admin-

istering, providing, or counseling the patient concerning the unapproved drug or medical device.

(4) DANGER.—The term "danger" means an adverse reaction, to an unapproved drug or medical device, that used as directed—

(A) causes serious harm to the patient in a case in which such harm would not have otherwise occurred; or

(B) causes harm that is more serious than side effects for drugs or medical devices approved by the Federal Food and Drug Administration for the same disease or condition.

(5) DRUG.—The term "drug" has the same meaning given that term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(6) HEALTH CARE PRACTITIONER.—The term "health care practitioner" means a physician or other individual who is a provider of health care, who is authorized under the law of a State to prescribe drugs or devices.

(7) INTERSTATE COMMERCE.—The term "interstate commerce" means commerce between any State or Territory and any place outside thereof, and commerce within the District of Columbia or

within any other Territory not organized with a legislative body.

(8) LEGAL REPRESENTATIVE.—The term "legal representative" means a parent or other person who qualifies as a legal guardian under State law.

(9) MEDICAL DEVICE.—The term "medical device" has the same meaning given the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(10) PATIENT.—The term "patient" means any person who seeks medical treatment from a health care practitioner for a disease or health condition.

(11) SECRETARY.—The term "Secretary" means the Secretary of the Department of Health and Human Services.

(12) UNAPPROVED DRUG OR MEDICAL DEVICE.—The term "unapproved", with respect to a drug or medical device, means a drug or medical device that is not approved or authorized for manufacture, sale, and distribution in interstate commerce under section 505, 513, or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360c, and 360e) or under section 351 of the Public Health Service Act (42 U.S.C. 201).

SEC. 3. ACCESS TO MEDICAL TREATMENT.

(a) IN GENERAL.—Notwithstanding sections 501(a)(2)(B), 501(e) through 501(h), 502(f)(1), 505, 513, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B), 351(e) through 351(h), 352(f)(1), 355, 360c, and 360e) and section 351 of the Public Health Service Act (42 U.S.C. 201) or any other provision of Federal law, a patient may receive, and a health care practitioner may provide or administer, any unapproved drug or medical device that the patient desires or the legal representative of the patient authorizes if—

(1) such practitioner has personally examined such patient and agrees to treat such patient;

(2) the unapproved drug or medical device is recommended by a health care practitioner within that practitioner's scope of practice under State law;

(3) the provision or administration of the unapproved drug or medical device is not a violation of the laws of the State or States in which the activity is carried out; and

(4) the health care practitioner abides by all of the requirements in subsection (b).

(b) REQUIREMENTS.—A health care practitioner may recommend, provide or administer any unapproved drug or medical device for a patient, pursuant to subsection (a), if that practitioner—

(1) does not violate State law by providing or administering the unapproved drug or medical device;

(2) does not violate the Controlled Substances Act (21 U.S.C. 801 et seq.) by providing or administering the unapproved drugs;

(3) has concluded based on generally accepted principles and current information that the unapproved drug or medical device, when used as directed, will not cause a danger to the patient;

(4) provides the recommendation under circumstances that give the patient sufficient opportunity to consider whether or not to use such a drug or medical device and that minimize the possibility of coercion or undue influence by the health care practitioner;

(5) discloses to the patient any financial interest that such a practitioner may have in the drug or medical device;

(6) has informed the patient in writing, prior to recommending, providing, or administering the unapproved drug or medical device—

(A) that the unapproved drug or medical device is not approved by the Secretary as safe

and effective for the condition of the patient and is considered experimental;

(B) of the foreseeable risks and benefits of the unapproved drug or medical device, including any risk to an embryo or fetus, and expected possible side effects or discomforts that the patient may experience and any medical treatment available if side affects occur;

(C) of any appropriate alternative procedures or courses of treatment (including procedures or courses of treatment that may involve the use of a drug or medical device that has been approved by the Food and Drug Administration), if any, that may be advantageous for the patient's condition;

(D) of any interactions the unapproved drug or medical device may have with other drugs, if any;

(E) of the active and inactive ingredients of the unapproved drug and the mechanism of action of the medical device, if known;

(F) of the health condition for which the unapproved drug or medical device is provided, the method of administration that will be used, and the unit dose;

(G) of the procedures that will be employed by the health care practitioner in using such a drug or medical device;

(H) of the extent, if any, to which confidentiality of records identifying the patient will be maintained;

(I) for use of such a drug or medical device involving more than minimal risk, of the treatments available if injury occurs, what such treatments involve, and where additional information regarding such treatments may be obtained;

(J) of any anticipated circumstances under which the patient's use of such a drug or medical device may be terminated by the health care practitioner without regard to the patient's consent;

(K) that the use of an such a drug or medical device is voluntary and that the patient may suspend or terminate treatment at any time;

(L) of the consequences of a patient's decision to withdraw from the use of such a drug or medical device;

(M) if any information described in subparagraphs (A) through (L) cannot be provided by the health care practitioner because such information is not known at the time the practitioner provides or administers such drug or medical device, that such information cannot be provided by the practitioner; and

(N) of any other information or disclosures required by applicable State law for the administration of experimental drugs or medical devices to human subjects;

(7) has not made, except as provided in subsection (d), any advertising claims for the unapproved drug or medical device;

(8) does not impose a charge for the unapproved drug or medical device in excess of costs;

(9) complies with requirements for reporting a danger in section 4; and

(10) has received a signed affidavit from the patient or the patient's legal representative confirming that the patient or the legal representative—

(A) has received the written information required by this subsection and understands it; and

(B) desires treatment with the unapproved drug or medical device as recommended by the health care practitioner.

The provisions of paragraph (8) shall not be construed to apply to dietary supplements.

(c) MANDATORY DISCLOSURE.—Any manufacturer of an unapproved drug or medical device shall disclose, to any health care practitioner that has received such drug or medical device from such manufacturer, all information available to such manufacturer regarding such drug or medical device to enable such practitioner to comply with the requirements of subsection (b)(3) and make a determination regarding the danger posed by such drug or medical device. Compliance with this subsection shall not constitute a violation of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(d) ADVERTISING CLAIMS EXCEPTION.—Subsection (b)(7) shall not apply to a health care practitioner's dissemination of information on the results of the practitioner's administration of the unapproved drug or medical device in a peer-reviewed journal, through academic or professional forums, or through statements by a practitioner to a patient. Subsection (b)(7) shall not apply to any accurate and truthful statement made in person by

a health care practitioner to an individual or a prospective patient.

SEC. 4. CESSATION OF USE, AND REPORTING OF, DANGEROUS DRUGS AND MEDICAL DEVICES.

(a) DUTY TO PROTECT PATIENT.—If a health care practitioner discovers that an unapproved drug or medical device causes a danger to a patient, the practitioner shall immediately cease use and recommendation of the unapproved drug or medical device and provide to the manufacturer of the unapproved drug or medical device and the Director of the Centers for Disease Control and Prevention—

(1) a written evaluation of the patient's medical condition before and after administration of the unapproved drug or medical device;

(2) a written evaluation of the adverse reaction, including its physiological manifestations, duration, and the effect of cessation of treatment upon the patient's condition;

(3) any other information the health care practitioner deems pertinent to an evaluation of the adverse reaction;

(4) the name, occupation, business address, and business telephone number of the physician;

(5) the name of the unapproved drug or medical device and a description of the method of administration and operation, dosage, and duration of treatment;

(6) the lot number, if any, of the unapproved drug or medical device; and

(7) an affidavit pursuant to section 1746 of title 28, United States Code, confirming that all statements made to the manufacturer are accurate.

(b) MANUFACTURER'S DUTY TO REPORT.—Any manufacturer of an unapproved drug or medical device that receives information provided under subsection (a) shall immediately—

(1) cease sale and distribution of the unapproved drug or medical device pending completion of an investigation to determine the actual cause of the danger;

(2) notify all health care practitioners to whom the manufacturer has provided the unapproved drug or medical device of the information provided to the manufacturer under subsection (a); and

(3) report to the Secretary in writing that an unapproved drug or medical device (identified by name, known method of operation, unit dose, and intended use) that the manufacturer provided to a

health care practitioner for administration under this Act has been reported to be a danger to a patient and confirming that the manufacturer—

(A) has ceased sale and distribution of the unapproved drug or medical device pending completion of an investigation to determine the actual cause of the danger; and

(B) has notified health care practitioners to which the unapproved drug or medical device has been sent of the information it has received.

(c) INVESTIGATION.—

(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention, upon receipt of the information described in subsection (a), shall conduct an investigation of the unapproved drug or medical device that a health care practitioner has determined to cause a danger to a patient in order to make a determination of the actual cause of such danger.

(2) REPORT TO SECRETARY.—The Director of the Centers for Disease Control and Prevention shall prepare and submit a report to the Secretary regarding the determination made under paragraph (1), including a determination concerning whether the unapproved drug or medical device is or is not

the actual cause of danger or whether the actual cause of danger cannot be determined.

(3) DUTY OF SECRETARY.—Upon receipt of the report described in paragraph (2), the Secretary shall—

(A) if the Director of the Centers for Disease Control and Prevention determines that the cause of such danger is the unapproved drug or medical device, direct the manufacturer of such drug or medical device to—

(i) cease manufacture, sale, and distribution of such drug or medical device; and

(ii) notify all health care practitioners to whom the manufacturer has provided such drug or medical device to cease using or recommending such drug or medical device, and to return such drug or medical device to the manufacturer as part of a complete recall;

(B) if the Director of the Centers for Disease Control and Prevention determines that the cause of such danger is not such drug or medical device, direct the manufacturer of such drug or medical device to inform all health care

practitioners to whom the manufacturer has provided such drug or medical device of such a determination; and

(C) if the Director of the Centers of Disease Control and Prevention cannot determine the cause of the danger, direct the manufacturer of the drug or medical device to inform all health care practitioners to whom the manufacturer has provided such drug or medical device of such a determination.

(d) SECRETARY'S DUTY TO INFORM.—Upon receipt of the report described in subsection (b)(3), the Secretary shall promptly disseminate information concerning the danger to all health care practitioners in the United States, to the Director of the National Center for Complementary and Alternative Medicine, and to agencies of the States that have responsibility for regulating unsafe or adulterated drugs and medical devices.

SEC. 5. REPORTING OF RESULTS OF UNAPPROVED DRUGS AND MEDICAL DEVICES.

(a) REPORTING OF RESULTS.—If a health care practitioner provides or administers an unapproved drug or medical device, that in the opinion of the health care practitioner, produces results that are more beneficial than results produced from any drug or medical device approved

by the Food and Drug Administration, or produces other results regarding the effectiveness of the treatment relative to treatments approved by the Food and Drug Administration for the same condition, the practitioner shall provide to the manufacturer—

(1) the results of the administration of the drug or device;

(2) a written evaluation of the patient's medical condition before and after administration of the unapproved drug or medical device;

(3) the name, occupation, business address, and business telephone number of the physician;

(4) the name of the unapproved drug or medical device and a description of the method of operation and administration, dosing, and duration of treatment; and

(5) an affidavit pursuant to section 1746 of title 28, United States Code, confirming that all statements made to the manufacturer are accurate.

(b) MANUFACTURER'S DUTY TO REPORT.—Any manufacturer of an unapproved drug or medical device that receives information under subsection (a) shall provide to the Director of the National Center for Complementary and Alternative Medicine—

(1) a complete copy of the information;

(2) the name, business address, and business telephone number of the manufacturer;

(3) the name, business address, and business telephone number of the health care practitioner who supplied information to the manufacturer;

(4) the name of the unapproved drug or medical device;

(5) the known method of operation and administration of the unapproved drug or medical device;

(6) the per unit dose; and

(7) the intended use of the unapproved drug or medical device.

(c) DIRECTOR'S DUTY TO MAKE PUBLIC.—The Director of the National Center for Complementary and Alternative Medicine shall review and analyze information received pursuant to subsection (b) about an unapproved drug or medical device and make available, on an Internet website and in writing upon request by any individual, an annual review and analysis of such information, and include a statement that such drug or medical device is not approved by the Food and Drug Administration.

SEC. 6. OTHER LAWS NOT AFFECTED BY THIS ACT.

This Act—

(1) shall not be construed—

(A) to have any effect on section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a); or

(B) to supersede any law of a State or political subdivision of a State, including laws governing rights and duties among health care practitioners and patients;

(2) shall not apply to statements or claims permitted or authorized under sections 403 and 403B of such Act (21 U.S.C. 343, 343–2); and

(3) shall not in any way adversely affect the distribution or sale of dietary supplements (as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)).

SEC. 7. AUTHORIZED ACTIVITIES OF HEALTH CARE PRACTITIONERS.

(a) INTRODUCTION IN INTERSTATE COMMERCE.—To the extent necessary to comply with this Act, a health care practitioner may—

(1) introduce an unapproved drug or medical device into interstate commerce;

(2) deliver an unapproved drug or medical device for introduction into such commerce;

(3) transport an unapproved drug or medical device in such commerce;

(4) receive an unapproved drug or medical device in such commerce and deliver the unapproved drug or medical device; and

(5) hold an unapproved drug or medical device for sale after shipment of the unapproved drug or medical device in such commerce.

(b) RULE OF CONSTRUCTION.—This Act shall not be construed to limit or interfere with the authority of a health care practitioner to prescribe, recommend, provide or administer to a patient for any condition or disease any unapproved drug or medical device lawful under the law of the State or States in which the health care practitioner practices.

SEC. 8. PENALTY.

A health care practitioner or manufacturer found to have knowingly violated this Act shall be denied coverage under this Act.