

White House Commission Testimony

Alternative Therapies in Health and Medicine

David Riley, MD — Editor-in-Chief

My name is David Riley and I am a physician board certified in Internal Medicine and the Editor-in-Chief of *Alternative Therapies in Health and Medicine*. We are a peer-reviewed medical journal and were the first to be indexed in the National Library of Medicine in 1996. We have the largest circulation among the peer-reviewed, indexed medical journals in the field of complementary and alternative medicine. I have included a copy of the May 2001 issue for your review.

Alternative Therapies in Health and Medicine is a forum for the development of information concerning the practical use of alternative therapies in preventing and treating disease, healing illness, and promoting health. *Alternative Therapies* does not endorse any particular methodology, but promotes the evaluation and appropriate use of all effective therapeutic approaches. The journal publishes a variety of disciplined inquiry methods, focusing on high-quality scientific research from randomized controlled trials to outcome studies to case reports. The journal encourages the

integration of alternative therapies with conventional medicine in a way that provides for a rational, individualized, comprehensive approach to healthcare.

Our journal is by paid subscription only. The readership consists of conventional healthcare providers, mainly physicians who are interested in CAM and who want to know more about the evidence for and against these therapies and other conventionally licensed healthcare providers such as nurses and psychologists. We do have some CAM practitioners who subscribe but historically, CAM providers have had their own journals. This is changing as the process of integration moves forward. We are not subscribed to by the general public.

We invite authors to submit original research papers for consideration. Papers most likely to be published are those that pass peer-review and present authoritative information on the integration of complementary and alternative therapies with conventional medical practices in preventing and treating disease, healing illness, and promoting health. We make available to authors and suggest they follow the *Uniform Requirement for Manuscript Submission* and the *Consort Guidelines* in manuscript preparation and submission.

For purposes of this publication, "alternative therapies" are defined as medical therapies not widely taught in medical school or widely available in hospitals. These include, but are not necessarily limited to, the following, which in some cases overlap significantly with conventional medical therapies:

▪ Anthroposophy ▪ Behavioral medicine ▪ Biofeedback ▪ Chinese medicine ▪ Chiropractic medicine ▪ Diet ▪ Environmental medicine ▪ Health promotion & Prevention ▪ Herbal medicine ▪ Homeopathy ▪ Imagery ▪ Indigenous medical practices	▪ Massage ▪ Meditation ▪ Mind-body therapies ▪ Naturopathy ▪ Nutrition (including dietary supplements) ▪ Osteopathic medicine ▪ Psychoneuroimmunology ▪ Psychotherapy ▪ Relaxation ▪ Spirituality ▪ Therapeutic Touch ▪ Tibetan medicine
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Our editorial and advisory board, and outside experts are chosen from the broad medical community with expertise in the therapies being investigated, the disease conditions being treated, and the research methodology being used. These groups form the primary reviewers for the journal. Article review can be challenging and finding experts with experience in reviewing manuscripts in some areas of CAM is difficult. Review of articles also requires an awareness that there may be different licensure, philosophies, and styles of practicing some CAM therapies (e.g. medical acupuncture versus 5 element, versus TCM). We maintain an updated record of our reviewers and all reviewers are rated collectively by the editors following the disposition of a manuscript.

In addition to myself, our professional editorial staff includes:

Executive Editor – Larry Dossey, MD
Senior Editor – Jeanne Achterberg, PhD
Assoc. Editors – Ben Kligler, MD, William Fair, MD, and Betsy Singh, PhD
Contributing Editor – Victor Sierpina, MD
Contributing Editor – Roberta Lee, MD
Contributing Editor – Michael Balick, PhD

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There have been a variety of calls for one standard of accountability for all of medicine. During the last 40 years, conventional medicine has relied on the data from a variety of research methods, increasingly randomized controlled clinical trials with support from case reports, outcome studies, and other research methods to develop an evidence profile for safety and effectiveness. CAM therapies vary widely, some are new and some are ancient, some use doses of medications that follow conventional pharmaco-kinetic models and others use no pharmacological interventions. Some are based on empirical evidence and n=1 trials which predate the current standards for conventional clinical research and focus on an individual patient's response rather than group characteristics. Others have a

limited body of relatively sophisticated clinical trials. These are steadily increasing due to the efforts of the NCCAM and pressure from Congress and the public.

Article statistics

87% of original research articles are rejected

79% of brief reports are rejected

73% of hypothesis articles are rejected

64% of review articles are rejected

Of those rejected the most common reason is a failure to follow the instruction for authors. Authors submitting articles on CAM have historically been less “seasoned” medical researchers and writers and are sometimes unfamiliar with biomedical research guidelines. The second most common reason is the conclusions are not support by the results and the research methods utilized were not appropriate for the hypothesis being tested.

There are researchers, scientists, and clinicians who have begun to establish a scientifically based evidence profile for a wide variety of CAM therapies, separating those that are useful from those that are not. Evaluation of CAM using all of the research methods available to modern science is of critical importance in developing the tools necessary to assess the outcomes of research in an area of medicine where placebo controls are sometimes problematic and the individual response (rather than the group response) is critical. These are still issues in some areas of conventional medicine such as surgery where it is often virtually impossible—not to mention unethical—to conduct placebo controlled clinical trials.

Pilot studies, case reports, literature reviews, and prospective outcome studies—to name just a few of the research methods—will be important in the emergence of an evidence profile for CAM. Such data will guide the design of the next generation of clinical trials. Conventional medical research using established scientific research methods has more than a fifty-year head start. Clinical trials in CAM cannot be expected to be state of the art without proper footwork and funding, and reviews of the principles and theoretical underpinning of CAM are a critical part of the process of evaluation. The research foundation of this process is still in its early stages, requiring an exploration of a wide range of therapeutic possibilities and research methodologies. A negative clinical trial may not reflect on the therapy but an inadequate knowledge base to properly design or power a controlled clinical trial.

Obtaining financial support for research from the CAM industry which functions without the tremendous resources and advantages the conventional pharmaceutical industry has through patent protection—the economic engine that drives clinical research—is difficult. And yet, despite the historically low levels of funding for CAM research from a variety of sources, there are researchers and clinicians who are working to evaluate the scientific basis for a wide variety of therapies.

When one realizes that CAM has virtually no patent protection, that research funding is scarce, and that there is a constant struggles against publication bias it becomes easier to understand why it may be hard to find scientific evidence for CAM therapies in the Countway Library of Medicine

(a dearth bemoaned by the *New England Journal of Medicine* editors). Fortunately, the National Library of Medicine, the NIH, and the Cochrane collaboration have broadened their horizons and are beginning to help document the evidence profile for CAM.

We need a wide range of clinical trials—from case reports to systematic literature reviews to outcome studies to randomized controlled clinical trials—to begin to level the playing field so that non-scientific issues do not muddy the research, publication, and funding waters. It should be humbling to realize that in the global medical world, with an estimated 75% of the world’s population relying on “alternative” therapies, the conventional medical establishment is in the minority. It is not helpful in the process of evaluating CAM to make the sweeping generalization that “alternative medicine distinguishes itself by an ideology that largely ignores biological mechanisms, disparages modern science, and relies on what are purported to be ancient practices and natural remedies.” This is simply not the case much of the time. The scientific evaluations and testing requires a respect and understanding for the historical tradition and empirical evaluations associated with the use of these therapies. For the most part, the scientific researchers evaluating CAM recognize that many CAM therapies, like their conventional counterparts, have not been rigorously tested. They also understand that the scientific method is applicable to CAM therapies and should be used whenever possible.

Areas where conventional medicine has been scientifically demonstrated to be safe and effective and affordable need not be a priority for research funding in CAM. Further scientific exploration of CAM and its

effectiveness should be evaluated in relation to many of the challenging issues facing health care today. These include safety, efficacy, toxicity, prevention, cost-benefit, and quality of care. We need to continue to expand the treatment options available to patients without delaying access to proven treatments.

Thank you for your interest in *Alternative Therapies in Health and Medicine*.

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Christine Laine, MD, MPH is Senior Deputy Editor of *Annals of Internal Medicine*. Dr. Laine received her medical degree from State University of New York at Stony Brook and completed training in Internal Medicine at The New York Hospital-Cornell University Medical College. After residency, she completed a fellowship in General Internal Medicine and Clinical Epidemiology at the Beth Israel Hospital in Boston and has an MPH degree with a concentration in quantitative methods from Harvard University. Dr. Laine's current academic affiliation is with Jefferson Medical College, Thomas Jefferson University in Philadelphia where she is Associate Professor of Medicine in the Division of Internal Medicine and Research Associate in the Center for Research in Medical Education and Health Care. She has been on *Annals'* editorial team since 1995. Her research interests include health care delivery for persons with chronic illnesses, quality of care, and doctor-patient communication. She was a 1995 Picker-Commonwealth Scholar.

Annals of Internal Medicine

Responses to Questions for the Panel on Peer-Reviewed Journals

What criteria are used by your journal for accepting articles on CAM research?

Annals of Internal Medicine applies the same criteria to judge the suitability for acceptance of research reports concerning CAM as it does for research on traditional medical therapies. These criteria include: clinical relevance, importance of the question, originality, scientific validity, clarity and quality of the written presentation, and appropriateness for our readership. The criteria are somewhat different for papers that offer reviews, perspectives, or commentaries rather than report original research findings: relevance to our readership, accuracy of content, completeness, appeal to our readership, and educational value.

How do you choose your reviewers? What qualifications must they have? Are there standards for judging reviewer expertise?

Annals has an electronic database that includes over 9,000 reviewers. This file contains contact information and areas of interest and expertise for more than 9,000 potential reviewers. Most of the individuals who are in this database are experienced clinicians, researchers, and/or medical educators. Our Associate Editors grade each review and each reviewer's grades are recorded in this database. This enables us to target reviewers who have provided high quality reviews for *Annals* in the past when seeking reviewers for newly submitted manuscripts. The criteria that we use to judge the quality of reviews are:

- Adherence to instructions/guidelines
- Specificity and accuracy
- Completeness
- Does the reviewer pick up on subtle but important aspects that might otherwise be missed (e.g., ethical issues, redundant publication)?
- Does the review contribute unusual depth, insight, and expertise into the discussion of the manuscript?
- Useful recommendations
- Appropriate tone
- Internal consistency

Are the criteria used by conventional journals in accepting CAM studies similar to or different from criteria used for acceptance of conventional studies?

Yes, see response to #1 above.

Is there any outreach by conventional journals to include studies on CAM interventions?

Aware of the prevalent and increasing use of CAM by persons who also seek care from internists, *Annals* believes that high quality research and discourse concerning the effectiveness and safety of commonly used CAM therapies is of

great importance to our readership. Thus, we have developed a series of invited papers on CAM in close collaboration with two guest editors who are expert in the area. This series of approximately 15-20 papers will include a combination of original health services research, critical reviews of the literature, and commentary on a variety of CAM-related issues. Unfortunately, the series will not include original research addressing the effectiveness of specific CAM therapies, but this was not the purpose of the series. We do anticipate that publication of this series will be evidence of *Annals'* interest in the topic and may stimulate investigators who study CAM therapies them to send their original research reports to *Annals* for consideration.

What are the unique challenges facing CAM acceptance in conventional peer-reviewed journals?

Over recent decades, journals, like the larger medical community, have become increasingly aware of the importance of evidence-based medicine. The growth of large clinical trials, advances in statistical and analytic approaches, consensus guidelines such as the Consolidated Standards of Reporting Trials (CONSORT), and consortia such as the Cochrane Collaboration are among the many factors contributing to greater general awareness of the importance of methodological rigor in studies of health care interventions. In previous times, the medical community gave more weight to anecdotal evidence from case reports, case series, and uncontrolled trials. In current times, these forms of investigation are considered hypothesis generating at best. Unfortunately, much of the CAM-related literature relies on methods that lack the rigor conventional medical journals expect. This may be in part because CAM practitioners generally do not have the training and education in the scientific process that has become part of conventional medical education. Many of the studies of CAM that authors submit to our journal for consideration have important weaknesses such as being under-powered, uncontrolled, conducted in non-representative or biased populations, or having inadequate adjustment for potential confounders.

Are the criteria used by CAM journals in accepting research studies comparable to the standards used by conventional journals?

No comment, *Annals* is not a CAM journal.

What are the unique challenges facing CAM peer-reviewed journals?

No comment. *Annals* is not a CAM journal.

What are the most common reasons articles are rejected by your journal?

Issues of priority and insufficient methodological rigor are the most common reasons for the rejection of manuscripts submitted to *Annals*.

Are you able to calculate the rate of rejected submissions in general? For CAM in particular?

Annals of Internal Medicine publishes about 12% of the manuscripts submitted for consideration. We have the ability to determine the acceptance rate for

submissions relating to CAM and will try to obtain these data before the May 16th meeting.

On average, how many revisions are made before publication?

In a preliminary study, we found that original research papers we published in *Annals* underwent an average of over 50 substantive changes (that is, meaningful changes to content, over and above changes in grammar and style) between submission and publication, in response to the comments of peer-reviewers, editors, and statisticians (1).

1. Purcell GP, Donovan SL, Davidoff F. Changes to manuscripts during the editorial process: Characterizing the evolution of a clinical paper. *JAMA* 1998;280:227-8.

Does your audience include both CAM practitioners; conventional practitioners? What percentage of your readership do you believe falls into either category?

Conventional practitioners comprise the overwhelming majority of our readership. Some of these conventional providers may integrate CAM into their practices, but we suspect that this is the exception rather than the rule. However, many of our clinician readers encounter patients who use CAM.

What policy recommendations can you offer regarding the publication of CAM practices and products in peer-reviewed journals for the Commission's consideration as it develops its report to the President and Congress?

Given that CAM therapies have the potential to both benefit and harm patients, the scientific and medical community should subject them to the same careful study as conventional therapies. It is *Annals'* opinion that studies of CAM therapies should also be subject to the same peer review process as studies of conventional therapies. Of course, the ethical principles that apply to the study of conventional therapies should apply to studies of CAM therapies. In this vein, funding agencies and institutional review boards should consider the likelihood that a particular study will arrive at a reasonably definitive answer to the research question addressed before approving a particular study. It is unethical to enroll patients in a study that is unlikely to produce conclusive results.

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Divider Title: _____

BIOGRAPHICAL SKETCH

Arnold S. Relman, M.D.

Arnold S. Relman was born in New York City in 1923. He graduated from Cornell University in 1943 with Distinction in Philosophy and received his M.D. degree from Columbia University in 1946. After his internship and residency at the Yale-New Haven Hospital, he became a National Research Council Fellow in the Medical Sciences at Boston University School of Medicine. He was appointed Assistant Professor of Medicine at Boston University in 1951 and remained on the BU faculty until 1968, achieving the rank of Professor of Medicine in 1961. From 1962 to 1967 he was Editor of the *Journal of Clinical Investigation*. In 1967 he became the Conrad Wesselhoft Professor of Medicine and Director of the V and VI Medical Services at the Boston City Hospital. From 1968 to 1977 Dr. Relman was the Frank Wister Thomas Professor of Medicine and Chairman of the Department of Medicine at the University of Pennsylvania School of Medicine. In 1977 he was appointed Editor of the *New England Journal of Medicine*, Professor of Medicine at the Harvard Medical School and Senior Physician at the Brigham and Women's Hospital in Boston. In 1991 he became Editor-in-Chief *Emeritus* of the *Journal*, and Professor of Medicine and of Social Medicine at the Harvard Medical School. In 1993 he became Professor *emeritus* of Medicine and of Social Medicine at the Harvard Medical School.

Dr. Relman began his research career in nephrology and electrolyte and acid-base balance while at Yale, and over a period of nearly 30 years he published numerous original research and clinical studies as well as textbook chapters and monographs on these subjects. His major research interests were in potassium metabolism, renal acidosis and the regulation of acid-base balance. He was the co-editor, with F. J. Ingelfinger and M. Finland, of two volumes of *Controversy in Internal Medicine*. In recent years he has written widely on the economic, ethical, legal and social aspects of health care.

Dr. Relman is a Fellow of the American Academy of Arts and Sciences, a member (and former member of the Council) of the Institute of Medicine of the National Academy of Sciences, a former President of the American Federation for Clinical Research, the American Society of Clinical Investigation, and the Association of American Physicians. He has been a member of the American Board of Internal Medicine (twice certified by the Board), as well as of the Board of Directors of the Hastings Center for Bioethics. He is also a Master of the American College of Physicians and a Fellow of the Royal College of Physicians of London. He is a Trustee of Columbia University *emeritus*, continues to serve on the Columbia University Trustee Committee on the Health Sciences, and is a former trustee of the Boston University and University of Pennsylvania Medical Centers.

Dr. Relman holds honorary degrees from the University of Pennsylvania, the Medical College of Wisconsin, Brown University, Union University, the State University of New York, the Medical College of Ohio, Temple University and the Mt. Sinai Medical School of the City University of New York. In 1975-76 he was a Macy Foundation Faculty Scholar at Oxford University and a Visiting Scientist in Biochemistry at Merton College, Oxford. In 1981 he was awarded the Alumni Gold Medal of the College of Physicians and Surgeons of Columbia University and, in 1985, the John Phillips Medal of the American College of Physicians. In March, 1987, Dr. Relman was given the Distinguished Service Award of the American College of Cardiology. In 1990 he was the Phi Beta Kappa Orator at the Harvard University Commencement. In 1991 he was elected to the Senate of Phi Beta Kappa and received the McGovern Award of the Cosmos Club Foundation of Washington, D.C. In the fall of 1992, Dr. Relman was given the Peters Award of the American Society of Nephrology. In May of 1993, he was also awarded the Kober Medal of the American Association of Physicians. In 1993 he was asked to serve with the Health Professionals Review Group by The White House. In 1995 Dr. Relman was appointed to the Board of Registration in Medicine of the Commonwealth of Massachusetts by Governor Weld. In 1997 he received the Lectureship Award of the American Association of Clinical Chemists.

Relman

PUBLISHING CAM CLINICAL RESEARCH IN PEER-REVIEWED JOURNALS

By Arnold S. Relman, M. D.

I cannot speak for the current policies of the *New England Journal of Medicine* because I retired from the post of Editor-in-Chief nearly ten years ago, after serving in that capacity for 14 years. However, I was familiar with the *NEJM*'s policies under its next two editors until the present editor assumed his post a little less than a year ago.

Given these limitations, I can state confidently that from July, 1977, until July, 2000, the *NEJM* treated manuscripts dealing with CAM in exactly the same manner it treated those concerned with more conventional therapies -- and that is the way it should be.

I do not know how many CAM manuscripts we received during those years. We kept no special file on this, but there were certainly only a handful of such submissions. In any case, they were handled just like all other submissions and judged purely on their scientific merits and their suitability for our kind of journal and our readership. Given the mounting interest in CAM, and the growing discussions about its credibility, we would have been inclined to choose a CAM manuscript over a more conventional submission of equal scientific merit -- provided, of course, that it passed peer review.

The fact that the *NEJM* has published only a few CAM papers during the past 23 years primarily reflects, I believe, the paucity of such submissions, but unfortunately I do not have statistical data on the relative success rates of CAM papers in passing review.

In any case, I think the issues are straightforward. If CAM research is to have any credibility, it will have to be submitted to the same peer-reviewed journals as the more conventional manuscripts dealing with similar illnesses, and it will have to pass the same kind of peer-review. There cannot be two

Relman

standards of science or two standards of peer-review. Unless CAM clinical investigators want to stay outside the mainstream of modern medical science, they must play by the same scientific rules of evidence and publish in the same journals as other clinical investigators.

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Ellwood

Divider Title: _____



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

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April 10, 2001

Kathleen C. Ellwood, Ph.D.

National Program Leader, Human Nutrition

USDA/ARS/NPS

5601 Sunnyside Avenue

Beltsville, MD 20705

Dear Dr. Ellwood:

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?

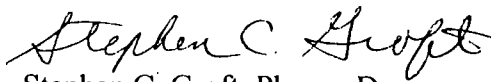
What policy recommendations can your agency offer regarding research on CAM for the Commission's consideration as it develops its report to the President and Congress?

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, Pharm. D.
Executive Director

Attachment

Common CAM Therapies

Acupuncture
Acupressure
Alexander Technique
Applied Kinesiology
Anthroposophic Medicine
Aromatherapy
Autogenic 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

Pollen, Geraldine (NCCAM)

From: Kathleen Ellwood [KCE@ars.usda.gov]
Sent: Thursday, April 19, 2001 10:04 AM
To: Pollen, Geraldine (NCCAM)
Cc: CER@ars.usda.gov; JSC@ars.usda.gov; LFF@ars.usda.gov
Subject: CAM

Dear Ms. Pollen,

This e-mail is in response to the letter from Stephen Groft, Pharm. D., dated April 10, 2001 regarding research the USDA's Agricultural Research Service is doing related to complementary and alternative medicine (CAM). ARS' mission is to conduct research to develop and transfer solutions to agricultural problems of high national priority and provide information access and dissemination to ensure high-quality, safe food and other agricultural products, assess the nutritional needs of Americans, sustain a competitive agricultural economy, enhance the natural resource base and the environment, and provide economic opportunities for rural citizens, communities, and society as a whole. ARS' Human Nutrition Program research is with healthy people. Research within ARS' plant science programs are not for the purposes stated in the letter. To conduct research in the area of complimentary and alternative medicine would be out of our mission and is within the purview of other agencies, such as NIH.

I suggest that you contact other agencies within USDA such as the Cooperative State Research, Education and Extension Service (CSREES), the Food and Nutrition Service (FNS) and the Economic Research Service (ERS) if you have not done so already. I can not answer for the type of work that these agencies may be involved with in regard to complimentary and alternative medicine.

If you have any further questions, please contact me.

Dr. Kathleen C. Ellwood
National Program Leader, Human Nutrition
USDA/ARS/NPS
5601 Sunnyside Ave.
Beltsville, MD 20705-5138
Phone: (301)504-4675; Fax: (301)504-5467
e-mail: kce@ars.usda.gov

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White House Commission on Complementary and Alternative Medicine Policy

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April 10, 2001

William H. Dietz, M.D., Ph.D.

Director

Nutrition and Physical Activity Division, CDC

4770 Buford Highway, NE, MSC K24

Atlanta, GA 30341-3717

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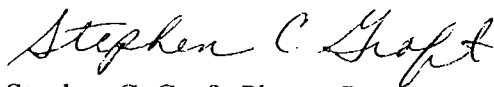
What policy recommendations can your agency offer regarding research on CAM for the Commission's consideration as it develops its report to the President and Congress?

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, Pharm. D.
Executive Director

Attachment

Common CAM Therapies

Acupuncture
Acupressure
Alexander Technique
Applied Kinesiology
Anthroposophic Medicine
Aromatherapy
Autogenic 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



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

MAY 01 2001

Stephen C. Groft, Pharm.D.
Executive Director
White House Commission on Complementary
and Alternative Medicine Policy
6701 Rockledge Drive
Suite 1010, MS-7707
Bethesda, Maryland 20817-7707

Dear Dr. Groft:

Thank you for your letter to Dr. William Dietz requesting the Centers for Disease Control and Prevention (CDC) respond to questions regarding complementary and alternative medicine (CAM). Enclosed is CDC's response.

We appreciate the opportunity to discuss areas related to CAM. A copy of this letter and enclosure have been faxed to Ms. Geraldine Pollen.

Sincerely,

James S. Marks, M.D., M.P.H.
Assistant Surgeon General
Director
National Center for Chronic Disease
Prevention and Health Promotion

Enclosure

cc:
Ms. Geraldine Pollen
Dr. William Dietz

The Centers for Disease Control and Prevention's (CDC) Responses to Questions from the White House Commission on Complementary and Alternative Medicine (CAM) Policy

Question 1

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?

Response 1

In order for CAM activities to be established or strengthened among the various Federal agencies, there is a critical need to create an intragency committee to delineate and coordinate roles.

Working with not-for-profit and private sector organizations can not be enhanced and/or established until the various Federal agencies working on CAM have defined roles and a coordinated effort.

Question 2

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

Response 2

The growing prominence of CAM is widespread, therefore, it is critical to bring together standard medicine practitioners and CAM practitioners to recognize the shared standards of science for effectiveness, to establish regular dialogue, and to collaborate on research projects.

Question 3

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

Response 3

Yes, CDC does support CAM research activities. In 1999, CDC initiated research to better understand the use of CAM therapies. CDC is collaborating with CDC-funded Prevention Research Centers, a network of academic research centers committed to prevention research and the translation of that research into programs and policies. Activities include the development and application of standards necessary for a practiced-based assessment of potentially successful CAM therapies, exploration of methods to identify promising CAM therapies for debilitating and

potentially lethal illnesses, and better characterization of the use of complementary and alternative treatments among persons with various forms of arthritis. Arthritic conditions that receive the most attention include osteoarthritis, rheumatoid arthritis, and fibromyalgia - three of the most common rheumatic conditions that affect more than 27 million Americans. Initial steps have been taken toward the development of national surveillance of CAM utilization. CDC collaborates other federal agencies to assure that CAM activities supported by CDC complement other agencies' efforts and to coordinate government efforts for dietary supplements research, use, and safety.

Question 4

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?

Response 4

The most important policy recommendation is that CAM become part of the day-to-day mission of the various Federal agencies.

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Masten

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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

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Maureen Miller, MPH, RN

James Swyers, MA

April 13, 2001

Scott A. Masten, Ph.D.

NIEHS, MD B3-10

P.O. Box 12233

Research Triangle Park, NC 27709

Dear Dr. Masten:

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. This letter is a followup to a recent conversation between Dr. Ken Fisher and Dr. Skip Matthews.

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

We understand that the NIEHS National Toxicology Program has looked at several dietary supplements. The Commission would be interested in knowing about this activity and whether the Institute has any future plans in this area.

Are there other NIEHS programs involved in CAM-related activities? If so, who should we contact?

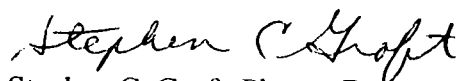
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We would appreciate your response **by May 1** either by email or fax so that the Commissioners will have time to review it before the May meeting. Please email your response to Ms. Geraldine Pollen at polleng2@mail.nih.gov, or send it by fax to Ms. 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,

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Stephen C. Groft, Pharm. D.
Executive Director

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Institute of
Environmental Health Science
P. O. Box 12233
Research Triangle Park, NC 27709

April 30, 2001

Stephen C. Graft, Pharm. D.
Executive Director
White House Commission on Complementary
and Alternative Medicine Policy
6701 Rockledge Drive, Suite 1010, MS-7707
Bethesda, MD 20817

Dear Dr. Graft:

I am writing in response to your request of April 13 for information regarding ongoing NIEHS and National Toxicology Program (NTP) activities relating to Complementary and Alternative Medicine (CAM).

NIEHS and NTP activities in this area focus mostly on examining the biological effects of herbal and non-herbal dietary supplements as well as the general role of nutrition and diet in health and disease. I am pleased to provide you with the following brief responses to the three questions posed in your letter.

We understand that the NIEHS National Toxicology Program has looked at several dietary supplements. The Commission would be interested in knowing about this activity and whether the Institute has any future plans in this area.

The National Toxicology Program (NTP) was established in 1978 by the Secretary of Health and Human Services to coordinate toxicology research and testing activities within the Department, to provide information about potentially toxic chemicals to regulatory and research agencies and the public, and to strengthen the science base in toxicology. The NTP considers 30 or more substances each year for comprehensive toxicology testing though all are not necessarily selected for such studies. At this time there are approximately a dozen studies in the NTP testing program on substances that are either herbal products or single chemicals thought to be responsible for the toxicity of a herbal product. These herbal products include goldenseal, milk thistle, kava kava, echinacea, aloe vera gel, ginseng and *Ginkgo biloba*. There are also studies on three other substances which may be considered dietary supplements: chromium picolinate, androstendione and indole-3-carbinol. These studies focus on characterization of potential adverse health effects including metabolism and disposition, general toxicity, carcinogenicity, developmental and reproductive toxicity, neurotoxicity, and immunotoxicity, as well as those effects associated with short-term high dose exposure and chronic low dose exposure. In general, the study design is typical of NTP toxicity/carcinogenicity studies consisting of a 14-

day, 13-week and 2-year exposure to both sexes of rats and mice. Currently, most of these studies are in the literature evaluation and study design/planning stage. Studies of androstenedione, goldenseal, milk thistle extract, thujone (a component of wormwood and other herbs) and chromium picolinate are expected to begin later this year. We will continue to consider for testing other herbal products and dietary supplements as these substances are nominated to the NTP.

Our goal for the botanical products is to test materials that are typical of what is being marketed and we have the cooperation of one of the Trade Associations in finding source material. Since these products are somewhat variable from source to source, season to season, etc, the materials used in the toxicology studies are characterized chemically against known marker compounds or active ingredients when known.

NIEHS contacts: Dr. Tom Burka (919) 541-4667 (ongoing NTP studies); Dr. Scott Masten (919) 541-5710 (nominations for new NTP testing)

Are there other NIEHS programs involved in CAM-related activities? If so, who should we contact?

NIEHS continues to support intramural and extramural studies that validate the importance of nutrition in maintaining health and preventing disease. Whole grain foods, for example, have been identified in NIEHS rodent studies as being protective against breast cancer and have been shown in a NIH-supported longitudinal study of nurses to protect against stroke. Nutrition is a major environmental risk component of many diseases. For this reason the NIEHS partnered with the NIH Office of Dietary Supplements (ODS) to fund a Center for Phytochemical and Phytonutrient Studies. This Center was competitively awarded in year 2000 in response to the Trans-NIH RFA OD-99-007 that NIEHS co-sponsored. The NIEHS Center for Phytonutrient and Phytochemical Studies is located at the University of Missouri, Columbia and will identify and characterize a large number of botanical species, varieties, and cultivars used as source material for producing commercial herbal preparations. Their plan is to provide an authenticated reference manual for the herbal industry to use in verifying plant shipments prior to their use in over-the-counter formulations. This center is currently investigating the ability of phytochemicals to prevent or treat prostate cancer, the role of phytoestrogens in altering immune response and possibly predisposing some women to autoimmune diseases, and the capacity of bioflavonoids to protect brain tissue from oxidative damage.

The NIEHS and ODS sponsored a workshop on November 2-3, 2000 on ways to employ DNA technology to identify and quantitate botanicals in dietary supplements. Another Trans-NIH workshop co-organized by NIEHS on Prostate Growth and Aging was held September 13-15, 2000. It included a session on environmental factors that considered diet and dietary supplement exposures. The research areas identified in these workshops are under evaluation for initiative development by the sponsoring NIH institutes, including the NIEHS.

NIEHS scientists are also analyzing several existing databases to assess the role of vegetable intake in reducing breast cancer risk, the role of alcohol intake in increasing breast cancer risk, the relationship of eating frequency to risk of colorectal cancer, and the possible protective effects of antioxidants in modifying risk for amyotrophic lateral sclerosis (ALS).

NIEHS contact: Dr. Michael McClure (919) 541-5327

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

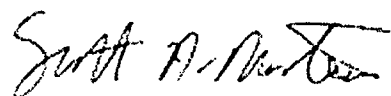
It would be desirable if dietary supplement manufacturers used what the NTP learns about the conduct of toxicity/carcinogenicity on these complex materials to conduct studies on some of the remaining untested dietary supplements in commerce. This is particularly important since this basic safety and toxicity information is urgently needed and the NTP has only a limited capacity for testing the many products in popular use.

More studies in humans and experimental animal models are needed to better understand the potential for herb/herb and herb/drug interaction and more severe adverse effects in sensitive populations (e.g. developing fetus, elderly, immunocompromised).

Further research is needed on DNA based methods to identify and quantitate the different botanical components of dietary supplements and on hormonally active botanical dietary supplements with potential for endocrine disruption effects in males and females.

We'd be happy to provide additional details if you wish on any of these activities. You may contact either myself or the specific individuals listed above.

Sincerely,



Scott A. Masten, Ph.D.
Head, Office of Chemical Nomination and Selection
Environmental Toxicology Program
Tel: (919) 541-5710; Email: masten@niehs.nih.gov

Cc: Dr. Tom Burka, NIEHS
Dr. Michael McClure, NIEHS
Dr. Sheila Newton, NIEHS
Dr. Kenneth Olden, NIEHS
Dr. Christopher Portier, NIEHS

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Maureen Miller, MPH, RN
James Swyers, MA

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.

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Sincerely,

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Stephen C. Groft, Pharm. D.
Executive Director

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National Aeronautics and
Space Administration
Headquarters
Washington, DC 20546-0001



MAY - 1 2001

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Reply to Attn of:

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,

A handwritten signature in black ink, appearing to read "Kathie L. Olsen", with a long, sweeping horizontal line extending to the right.

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

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James Swyers, MA

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.

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Questions

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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?

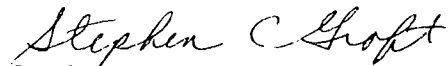
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Sincerely,



Stephen C. Groft, Pharm. D.
Executive Director

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Spiritual Healing
Therapeutic Touch
Yoga

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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>

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Linnea Larson, LCSW, LMFT
Tieraona Low Dog, MD, AHG
Charlotte Kerr, RSM
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Doris Kingsbury
Geraldine Pollen, MA

Consultant Staff

Kenneth Fisher, PhD
Maureen Miller, MPH, RN
James Swyers, MA

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.

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 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.

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, Pharm. D.
Executive Director

Attachment

Common CAM Therapies

Acupuncture
Acupressure
Alexander Technique
Applied Kinesiology
Anthroposophic Medicine
Aromatherapy
Autogenic 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

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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

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Effie Chow, PhD, RN, DiplAc

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Xiaoming Tian, MD, LAc

Donald Warren, DDS

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.

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James Swyers, MA

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,

A handwritten signature in cursive script that reads "Stephen C. Groft".

Stephen C. Groft, Pharm. D.
Executive Director

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Buford Rolin

Julia Scott

Xiaoming Tian, MD, LAc

Donald Warren, DDS

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.

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Executive Director

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Corinne Axelrod, MPH

Joseph Kaczmarczyk, DO, MPH

Doris Kingsbury

Geraldine Pollen, MA

Consultant Staff

Kenneth Fisher, PhD

Maureen Miller, MPH, RN

James Swyers, MA

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, Pharm. D.
Executive Director

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

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Kenneth Fisher, PhD
Maureen Miller, MPH, RN
James Swyers, MA

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
Coverage/Reimbursement

Geraldine Pollen 301-435-6233
Maureen Miller 301-435-7592

Thank you for your attention to this information request.

Sincerely,



Stephen C. Groft, Pharm. D.
Executive Director

Enclosure

Common CAM Therapies

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Massage Therapy
Meditation
Naturopathy
Nutritional Therapy (Nutrition)
Reflexology
Relaxation and Visualization
Shiatsu
Spiritual Healing
Therapeutic Touch
Traditional Chinese and Oriental Medicine
Yoga

Adapted from Zollman C, Vickers A. What is Complementary Medicine?
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Access and Delivery
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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 Dietitian, 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., Maharishi 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 effectiveness of individual naturopathic 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 looked 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" recommended 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 reimbursement, 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 dietitian, 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 conditions. 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 credentialing. 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 Czaplewicz, 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 Wood Johnson Foundation, has begun an innovative pilot project, called the Center to Advance Palliative Care, to help increase hospitalized patients' access to hospice care. 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 as electron beam CT scanner that can detect plaque in people's 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.

Commissioners 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, therefore, 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.

Commissioners 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 without 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 aligned with the pharmaceutical 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 Massachusetts 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 from 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. Furthermore, he said that he and his colleagues use 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 educate 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:

Sylvester 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 Israel 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 credentialing 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 greeted 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 its mission statement. By doing this, the Center gained access to the hospital's 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 it 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 for 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 dietitians, 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 of 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 Maharishi 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 women's 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, vulvodynia, 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 to 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 be to look at ways to 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 than it is currently being done. 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 approximately \$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 American 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 Commission 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' health, 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 knowledge about CAM: 1) the approximately 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 research 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 incorporation 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 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 nationwide, 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.

Commissioner 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 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 integrated with conventional 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. Commissioner DeVries encouraged the Commission to create recommendations that can 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 development of a 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 giving 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 answer 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 discusses 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 these 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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