Specific Recommendations from October 2000, WHCCAMP Meeting

Session I: Research Priorities and Public Input

Panel 1:

- Encourage CAM practitioners work within the current research system ad aspire to the rigorous, blinded, randomized studies that are the gold standard, while recognizing the other ways by which health and medicine information are obtained. **(Leon Rosenberg, Institute of Medicine, IOM)**

- Expand the pot of money available for CAM research at federal institutions and distribute it more evenly among the CDC, the Agency for Health Care Research and Quality, and other named entities in the federal establishment. **(Leon Rosenberg, IOM)**

- Encourage the NIH to expand its portfolio of clinical research with efforts that answer questions concerning modalities that are not going to be patentable and that will not have their research paid for by biotech or pharmaceutical or drug device industries. **(Leon Rosenberg, IOM)**

Panel 2: Federally Funded CAM Research

- Develop strategies to increase CAM cancer research needed to address the range of challenges—e.g., difficulty in establishing uniformity, complexity of individual regimens, difficulty replicating treatments in clinical settings—posed by the nature of the field. **(Jeffrey White, National Cancer Institute, NCI)**

- More fully examine the potential of CAM's whole-patient approach to improve the quality and perhaps quantity of remaining life for cancer patients. **(Jeffrey White, NCI)**

- Expand CAM research in ways that access the resources of the larger and more research-savvy conventional community. **(Jeffrey White, NCI)**

- Provide resources to bridge the "two culture problem." Opportunities and resources are needed to foster communication and collaboration between CAM and conventional practitioners and researchers. Inherent problems in CAM clinical research, difficulty in standardizing interventions, culture problems between practitioner and research communities, general awareness about CAM, can be resolved by building appropriate interdisciplinary collaborations **(Jeffrey White, NCI)**

- Use existing mechanisms of federal research support to train CAM practitioners areas in conventional research methodologies. (**Steven Hausman, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIAMS**)

- Look at low back pain as a vast potential opportunity for the integration of conventional and CAM modalities. (**Steven Hausman, NIAMS**)

- Study the placebo effect more rigorously. (**Steven Hausman, NIAMS**)

- Discourage rules barring Medicare payments for things Medicare does not normally cover, including many complementary and alternative modalities, which pose a significant obstacle for getting elderly people on Medicare to participate in CAM trials. (**Steven Hausman, NIAMS**)

- Invite the public to give their views in setting CAM research priorities. (**Steven Hausman, NIAMSD**)

- Encourage research into dietary supplements to be evidence-based and structured like other medical research. (**Paul Coates, Office of Dietary Supplements, ODS**)

- Support dietary supplement research activities that engage partnerships between research organizations, non-profits, and private industry with common interests in the field to help merge the sometimes conflicting impressions that (a) evidence supporting traditional CAM falls outside the American medical paradigm and should be ignored and that (b) traditional products don't need to be evaluated because of their long traditions of use. (**Paul Coates, ODS**)

- Increase the number of workshops and conferences that focus on interdisciplinary approaches to medical research as a way of increasing the share of the research pie that goes to CAM activities. (**Paul Coates, ODS**)

Panel 3: Academic Centers and Support for CAM Research

- Support clinical practice with a distributed virtual system for CAM practices and allow for practitioners to use employ those practices as is appropriate. (**Alfred Fishman, University of Pennsylvania, Penn**)

- Create a steering committee that understands CAM to advise IRB's on applications they may not fully appreciate. (**Alfred Fishman, Penn**)

- Integrate complementary and alternative therapists into the educational curriculum in places where it is appropriate to consider them. (**Alfred Fishman, Penn**)

- Sponsor a meeting with a critical mass of people at universities engaged in CAM research who want to exchange ideas. (**Alfred Fishman, Penn**)

- Address the issue of a fundamental lack of research orientation in CAM institutions by partnering with institutions that have a research focus. (**Alfred Fishman, Penn**)

- Encourage private philanthropy to fund CAM research to get things going to a point where federal funding, based on other criteria can be used. (**Daniel Federman, Harvard University**)

- When creating a new CAM division, engage people with real opposition to the idea in the planning panel. (**Daniel Federman, Harvard University**)

- Refrain from disparaging good, well-written anecdotes. Recognize that anecdotes are appropriately the precursor to rigorous scientific research. (**Daniel Federman, Harvard University**)

- Connect CAM with existing institutional strengths by granting programs cooperatively. (**Daniel Federman, Harvard University**)

- Develop an interdisciplinary, multi-disciplinary, interprofessional research agenda that employs social, clinical, and basic sciences, to integrate CAM and conventional medicine. (**William Meeker, Palmer College of Chiropractic, PCC**)

- Train CAM scientists. Provide programs, incentives, pre and post-doc positions and career tracks for capable and interested young people. (**William Meeker, PCC**)

- Create ways to encourage interdisciplinary, multidisciplinary and inter-professional collaborations between CAM institutions and tax-supported universities. (**William Meeker, PCC**)

- Apply the entire universe of research project and program funding mechanisms to initiate, encourage and support chiropractic and CAM research, including bricks and mortar. (**William Meeker, PCC**)

- Call for interdisciplinary conferences to explore scientific states-of-the-art on CAM topics and establish rigorous research agendas. Support the agendas with targeted research funding program announcements. (**William Meeker, PCC**)

- Encourage the National Library of Medicine to include CAM topics and references in its indexing systems. (**William Meeker, PCC**)

- Establish academic CAM clinical centers. (**William Meeker, PCC**)

- Support CAM training institutions in the broadest possible sense, like all other health professions, in order to eliminate the dependence on tuition and provide the resources to develop a more effective and consistent research culture. (**William Meeker, PCC**)

- Ensure that chiropractors and other CAM professionals are routinely appointed and otherwise included in research policy making efforts. (**William Meeker, PCC**)

- Consider something similar to the Centers of Excellence program in HRSA's Bureau of Health Professions to help jumpstart the research efforts of CAM professions and their institutions. (**William Meeker, PCC**)

- Develop training programs and career tracks, so that people that have a natural inclination in this direction see that they can have a job and a career doing it. That has not existed in the CAM profession so far. (**William Meeker, Palmer College of Chiropractic**)

Panel 4: CAM Research Support and Collaborations

- Promote preclinical studies that look at mechanism behind a CAM intervention at the same time as studies on safety and efficacy and not merely pursue whim and anecdote. (**Stephen Straus, National Center for Complementary and Alternative Medicine, NCCAM**)

- Reinforce the fact that science is a process not a philosophy. Support basic science and clinical science and to encourage advocacy organizations, industry, and the broad sweep of the American public to get behind asking questions critically and credibly will serve us well. (**Stephen Straus, NCCAM**)

Panel 5: Facilitating CAM Research and Regulatory Challenges

- Submit comments related to new guidelines, Botanical Drug Products, designed to open the door for the study of traditional botanicals without the barriers that currently exist, which are designed for synthetic drugs. (**Janet Woodcock, FDA, Center for Drug Evaluation and Research**)

- Provide input on proposed changes in combination product regulations, which were originally written for purified drugs and are being revised to help botanicals move through the approval stage more quickly. (**Janet Woodcock, CDER**)

- Provide additional resources to assist small companies to get through the FDA drug review. (**Janet Woodcock, CDER**).

- Encourage the FDA to promulgate additional chemistry and manufacturing standards to accommodate the reproducibility and stability and constant dose issues raised by plants.(**Janet Woodcock, CDER**)

- Create a place in FDA with sufficient staffing that could work with groups at various levels to assess the appropriate classification of botanicals as treatments. (**Janet Woodcock, CDER**)

- Define the safety standard for dietary supplements. As yet, the law is silent on the question of their benefits, and only speaks to their safety, though what degree of safety and confidence is still being determined. (**Joe Levitt, Food Center at FDA**)

Panel 6:Research in the Regulatory Framework

- Include in the guidelines for fraudulent and deceptive practices those guidelines standards for assessing the work of a non-institution based physician who is engaged in research. (**James Winn, Federation of State Medical Boards, FSMB**)

- Include on medical boards CAM consultants to assist in their evaluation of cases and any kind of complaint that comes forward. (**James Winn, FSMB**)

- Invite patent lawyers to address the issue of exclusive rights to botanical extracts. . (**Floyd Leaders, Botanical Enterprises, Inc.**)

- Rather than bring foreign plants to the US for research, work in a partnership within that country. (**Floyd Leaders, Botanical Enterprises, Inc.**)

- Allow the elimination of the disclaimer on a DSHEA regulated label if a certain threshold of evidence is achieved, or give it over-the-counter drug status. (**Robert McCaleb, Herb Research Foundation**)

- Increase the focus on traditional medicine, recognizing that DSHEA leaves that out. (**Robert McCaleb, Herb Research Foundation**)

- Develop ways to look at historical information on herbs and using this information in the evaluation of their efficacy and safety. (**Robert McCaleb, Herb Research Foundation**)

- Facilitate international outreach in terms of accessing the information from European and Asian clinical practice. (**Robert McCaleb, Herb Research Foundation**)

- Cut through that maze of information and try to get information, especially for consumers and practitioners that is quality evaluated, so people can trust the

information and utilize in their decision-making process. (**Robert McCaleb, Herb Research Foundation**)

- More funding for libraries and collaboration to utilize the resources that are currently untapped. (**Robert McCaleb, Herb Research Foundation**)

- Appoint a panel of experts, who are really specifically focused in this area of natural product health care, to look at the evidence on herbs and make decisions. (**Robert McCaleb, Herb Research Foundation**)

- Adequately fund alternative medicine research centers so that they can collaborate with orthodox medicine. (**Anthony Rosner, Foundation for Chiropractic Education and Research, FCER**)

- Address anti-chiropractic sentiments in the composition and proceedings of institutional review panels and boards. (**Anthony Rosner, FCER**)

- Require an equitable number of individuals within each study section of a grant proposal, who are familiar with and sensitive to the conduct of CAM therapeutic regimes to be tested. (**Anthony Rosner, FCER**)

- Place far greater emphasis on cohort studies and case series in reaching its research goals rather than to assume categorically that they provide inferior guidance to the clinical decision-making than RCTs. (**Anthony Rosner, FCER**)

Panel 7: Outcomes Research Part I: Interface Between CAM

- Develop a forum for alternative practitioners or scientists who believe they are being harassed unfairly.(**Nicholas Gonzalez, Private Practice**)

- Use the threat of cuts in Medicare or Medicaid funding to force the states to protect new ideas.(**Nicholas Gonzalez, Private Practice**)

- Use health departments to identify the top 35 public health problems in the United States and aim therapies at them, also see what is working in clinical settings and use that evidence as a starting point for understanding why. (**Ann McCombs, Private Practice**)

- Explore how regulation could help the Best Case Series program become more productive being that some CAM practitioners are not willing to come forward because they feel they need to practice in secret. (**Jeffrey White, National Cancer Institute, NCI**)

- Learn more about problems with getting INDs for certain herbal products and the effect that is having on inhibiting some cancer research. (**Jeffrey White, NCI**)

Panel 8: Not-for-Profit Sector Support for CAM Research

- Improve funding access for CAM by improving the methodical rigor of proposed studies. **(John Templeton, Jr., John Templeton Foundation, JTF)**

- Encourage new researchers in CAM therapies with mentors trained in scientific research. **(John Templeton, Jr., JTF)**

- Develop better coordination between non-profit and federally supported CAM research by convening a jointly funded consensus conference to review in depth the strengths and weaknesses of existing research and propose new studies to build the science behind CAM. **(John Templeton, Jr., JTF)**

- Because the scientific study of spirituality is in its infancy, and as spirituality is hard to define, I think it is important to try and pick some aspect of spirituality that a group that practices a certain type of spirituality embraces and then study their intervention. **(John Templeton, Jr., JTF)**

- Promote a consensus conference to suggest ways of studying spirituality. **(John Templeton, Jr., JTF)**

- Train medical students and residents to understand that it is appropriate to take a spiritual or religious history. **(John Templeton, Jr., JTF)**

- Host introductory, face-to-face meetings and site visits among foundation people with representatives of existing CAM research centers currently funded by the NIH. **(Dyanne Hayes, Conrad N. Hilton Foundation)**

- Be more aggressive in seeking opportunities for foundation representatives to participate on panels such as this to discuss their experiences and perceptions regarding CAM and CAM research. **(Dyanne Hayes, Hilton Foundation)**

- Include foundations on mailing lists and publicize the those grants that do or have had public/private funding support. **(Dyanne Hayes, Hilton Foundation)**

- Encourage oundations be more willing to fund small pilot projects. **(Dyanne Hayes, Hilton Foundation)**

- Encourage foundations interested in CAM research to create a pooled fund of monies and announce the competition for projects up to so many dollars. The collaborative would set up a scientific advisory board of reputable scientists knowledgeable in the area in which the proposals are being submitted. **(Dyanne Hayes, Hilton Foundation)**

- Address the sense of separation between Eastern and Western cultures that pervades relations between the two communities. **(Dyanne Hayes, Hilton Foundation)**

- Encourage NIH to do a quicker jog of digesting data and making it available for public consumption. **(Dyanne Hayes, Hilton Foundation)**

- Help the foundation community keep better informed on relevant symposia as well as what has been funded. **(Dyanne Hayes, Hilton Foundation)**

- Conduct research on why people are drawn to CAM, what people who are drawn to it, what do they mean by what we say works, and what do they find satisfying about it that they don't find satisfying in the rest of medicine? **(Daniel Callahan, Hastings Center)**

- Keep the discussion of Medicine as art or science alive. **(Daniel Callahan, Hastings Center)**

- Utilize CAM as a lens to help us envision the future of medicine when an aging population with chronic ills will share the national stage with a younger population that will need to learn how to take better care of itself. **(Daniel Callahan, Hastings Center)**

- Find some better ways of formalizing means of investigation other than randomized clinical trials in which one can have confidence. **(Daniel Callahan, Hastings Center)**

- Develop a think tank that brings together research methodologists, not just people interested in CAM, to discuss the methodological problems of investigating CAM. **(Daniel Callahan, Hastings Center)**

- Develop a generally accepted definition of CAM to ensure the everyone is talking about the same thing. **(Teri Ades, American Cancer Society)**

- Protect patient access to CAM, but provide more oversight and accountability by governmental, public, and private entities are needed to protect the public. **(Teri Ades, ACS)**

- Support NCCAM and its stress on the importance of systematic and scientific approaches to studying various medicines, as well as the NCI's Best Case Studies program.**(Teri Ades, ACS)**

- Support additional funding for mentoring programs that help those with promising therapies do the necessary research. **(Teri Ades, ACS)**

- Invest more efforts in understanding the limits of randomized clinical trials in CAM and in finding other research approaches that work better. **(Teri Ades, ACS)**

- Rather than consider incentives, consider setting the expectation that all therapies must be proved to be safe and effective so the public does not have to question their therapy. (**Teri Ades, ACS**)

- Have NCCAM serve as coordinator for a group of public, private, and governmental agencies convened to discuss how to better coordinate federal support for CAM research. (**Teri Ades, ACS**)

Panel 9: Private Sector Support for CAM Research

- Involve companies up front in developing a system of appropriate regulation. (**Randy Burkholder, Advanced Medical Technology Association, AMTA**)

- Provide incentives for developing CAM related medical devices with private or public reimbursement mechanisms. (**Randy Burkholder, AMTA**)

- Facilitate research collaborations with the private sector through a number of mechanisms including Small Business Innovation Research grants and in Technology Transfer, Cooperative Research Now. (**Raymond Ruddon, Johnson & Johnson, J&J**)

- Provide incentives for private industry's involvement in CAM research by resolving intellectual property issues through something akin to legislative exclusivity remedies like the Ortho-Drug program. (**Raymond Ruddon, J&J**)

- Provide proprietary protection around the process, extraction, production, and use of unique mixtures or combinations of agents for single herbs. (**Raymond Ruddon, J&J**)

- Expand communication between traditional and conventional medical experts. (**Raymond Ruddon, J&J**)

- Increase the availability of private and federal funding for CAM research. (**Raymond Ruddon, J&J**)

- Develop a rigorous review process involving both academic and industry scientists to evaluate scientific-merited CAM research proposals. (**Raymond Ruddon, J&J**)

- Develop discovery research in CAM using such things as gene expression arrays, or proteolytics to identify new bioactive substances in natural products and pharmacogenomics to individualize therapies. (**Raymond Ruddon, J&J**)

- Address the anti-CAM bias in subsequent editions of Goodman and Gelman's, Textbook of Pharmacology. (**Raymond Ruddon, J&J**)

- Create incentives for the private sector to invest more substantially in research and development of natural medicines like a Waxman-Hatch type data or marketing exclusivity period that would allow the investor to fully develop the medical and commercial potential of natural medicines. (**Frank Sciavolino, Pfizer**)

- Allowing early access to Phase II trials to help lower attrition rates for new neutraeuticals and to reduce overall development costs. (**Frank Sciavolino, Pfizer**)

- Explore the CDSL recommendation that label disclaimers mandated by DSHEA could be modified or removed if a botanical product met certain requirements for research. (**Mark Blumenthal, American Botanical Council**).

- Allow centers for manufacturers to publish clinical studies that deal with their specific product and get that information into current medical journals and in the news, especially when that publicity is tied to the brand that is studied. (**Mark Blumenthal, ABC**)

- Find a viable balance among free market and competitive issues, science, regulation, and the need to respect cultural heritage, and traditional use. (**Mark Blumenthal, ABC**)

- Help promote research by making structure/function claims approvable by FDA, modifying the dietary supplements disclaimer following some clinical study review, allowing process and use patents for botanicals, providing tax credits for research funding. (**Mark Blumenthal, ABC**)

- Establish an expert review panel similar to Commission E to evaluate the safety and appropriateness for claims for herbal products, both the structure/function claims under DSHEA and as OTC drugs. (**Mark Blumenthal, ABC**)

- Encourage the CAM industry to submit its studies to peer review journals for publication and provide data from its unpublished studies to assist in selection of therapies for further study and to contribute to study design. (**Annette Dickenson, Council for Responsible Nutrition, CRN**)

- Encourage the supplement industry to cosponsor symposia or conferences to provide networking opportunities between researchers and clinicians. (**Annette Dickenson, CRN**)

- Convene meetings with journal editorial boards to solicit recommendations which would increase the acceptance of papers submitted by the supplement industry. (**Annette Dickenson, CRN**)

- Encourage the supplement industry to generate a clinical trials guidance document outlining the standard components and proper design of study protocols. (**Annette Dickenson, CRN**)

- Encourage the supplement industry to form partnerships with clinicians or academia, depending on the type of study. (**Annette Dickenson, CRN**)

- Establish a special web site to facilitate communications regarding ongoing research needs and opportunities. (**Annette Dickenson, CRN**)

- Develop a primer on funding mechanisms for research and conferences within government agencies that apply to industry should also be compiled to explain, for example, cooperative research and development agreements, small business grants, investor-initiated grants, and contracts. (**Annette Dickenson, CRN**)

- Develop a document for industry use, explaining, how each research agency determines its research agenda. (**Annette Dickenson, CRN**)

- Develop a government-industry partnership to conduct testing to confirm the safety of the product not simply in terms of lack of any knowledge of un-safety, but in terms of proactive, positive demonstration of lack of teratogenicity and for safety during pregnancy. (**Annette Dickenson, CRN**)

- Give the FDA more enforcement authority to assure that products are what they are supposed to be. (**Annette Dickenson, CRN**)

Panel 10: Outcomes Research Part II - CAM Research and Experimental Study Design

- Provide funding and trust-building for the Best Case Series Program. NCCAM funded centers could play a very important role in the Best Case Series Program by providing methodological support to clinicians (**Leanna Standish, Bastyr University**)

- Create partnerships between CAM academic centers and CAM practitioners for developing Best Case studies, especially in the cancer area, and have that collaborative work be funded by the NCI. (**Leanna Standish, Bastyr University**)

- Encourage institutional review boards to be flexible in assessing joint CAM/conventional medicine research efforts. (**Leanna Standish, Bastyr University**)

- Have practitioners develop algorithms to describe the "if then" nature of CAM treatments and formalize them, to facilitate doing individualized therapy inside of a clinical study. (**Leanna Standish, Bastyr University**)

- In assessing CAM, analyze a therapeutic approach that is not too refined and examine the entire system and include elements like lifestyle, exercise, plus the addition of dietary modification or we will miss the forest for the trees. (**Elaine Cramer, Center for Disease Control and Prevention, CDCP**)

- Put together an integrated team of researchers from both the CAM and conventional communities who are open-minded practitioners, who are really willing to collaborate and randomize patients to CAM treatment arms as well. **(Elaine Cramer, CDCP)**

- Use integrative research to study integrative medicine. The way to properly evaluate any outcomes is through a team-based approach using existing methods. **(Elaine Cramer, CDCP)**

- To implement these strategies in a community setting, solicit proposals from integrated research teams which are comprised of both CAM and conventional practitioners who demonstrate the ability to collaborate on, not just the study design, but case definitions, the selection of exposures, and the designation of CAM and conventional treatment sites. **(Elaine Cramer, CDCP)**

- Assign a research mentor not only to CAM practitioners who are interested in evaluating CAM therapies, but whoever needs research and who really needs some assistance with both protocol and study design development. **(Elaine Cramer, CDCP)**

- Establish experienced research teams that are comprised of scientists, subject matter experts and send them out en masse to selected research sites to really expedite development and implementation of the protocols for CAM evaluation. **(Elaine Cramer, CDCP)**

- Conduct clinical outcomes research on CAM to determine what is efficacious, what is effective, what is safe, and to give the patient a wider choice of treatment modalities. **(Lydia Segal, Kaiser Permanente)**

- Develop research training programs for clinicians that allow them to stay in their practice, be it a mentoring program or a partnership with academic or government institutions, while bringing researchers into the clinical environment. **(Lydia Segal, Kaiser Permanente)**

- Develop research designs to accommodate the patient specific nature of CAM treatments to make different treatments statistically comparable. **(Lydia Segal, Kaiser Permanente)**

- Encourage collaborative research efforts between conventional and CAM academic institutions. **(Douglas Lloyd, Association of Schools of Public Health,ASPH)**

<u>Panel 11: Federal Agency Support for CAM Research (Cont'd)</u>

- Work with tribal governments to establish research priorities for investigating traditional practices utilized by American Indians and Alaska Natives. Priorities and policy should set by Native Americans, not by researchers. (**Craig Vanderwagen, Indian Health Service, IHS**)

- Examine how CAM might reach out to tribal communities and offer them tools and techniques for examining internally the effectiveness of their providers. (**Craig Vanderwagen, IHS**)

Public Comment

- Develop a comprehensive plan for the development of a healthy conditioning for our youth and for the citizens of the United States that uses CAM as an alternative to steroids. (**Phillip Shinnick, Research Institute of Global Physiology**)

- Invite Gene Upshaw to come and talk about professional education from the athlete's side. (**Phillip Shinnick, RIGP**)

- Provide athletes with better information concerning the connections of "natural supplements" and steroids and about the value of meditation. (**Phillip Shinnick, RIGP**)

- Unify the efforts of practitioners of sports medicine alternative and engage the NIH in national conferences on the subject. (**Phillip Shinnick, RIGP**)

- Consider employing the tools of alternative dispute resolution to deal with the high emotions, complexity and conflicting positions grounds in science that charaterize the current discussion on acceptance of CAM. While peer review is not a mechanism for resolution, aspects of it partake of the mechanism.(**Linda Lazarus, mediator**)

- Expose medical students to alternative therapies to change the practice of medicine. (**Sandra McLanahan, physician**)

- Redo the Chantilly Report, which made practitioners of alternative medicine aware of the possibility of using the Western paradigm in research to help facilitate better choices at the NIH for research funding. (**Sandra McLanahan, physician**)
- Change how medicine approaches end-of-life care in this country. (**Sandra McLanahan, physician**)

- Increase funding for the FDA's Center for Food Safety and Applied Nutrition, which is responsible for enforcing the governing most CAM products (DSHEA). (**Tony Martinez, attorney**)

- Focus specifically on mind-body-spirit practices like energy healing, oracle meditation, regression, psychotherapy, relaxation procedures, a wide range of alternative hypnotic procedures, plus traditional hypnosis, behavior modification, cognitive therapy, reprogramming techniques, and psychodynamic psychotherapy used to impact on catastrophic illness such as cancer, and not simply to assist in patient adjustment to coping with such illness whose effects are being vastly underestimated. (**Rick Levy, clinical psychologist**)

- Contact the relevant professional societies to begin ongoing formal dialogue to develop recommendations on how to operationalize the entrance of CAM interventions into the traditional health care communities. (**Rick Levy, clinical psychologist**)

- Encourage Congress to continue and increase funding for the National Institutes of Health Center for Complementary and Alternative Medicine. (**Ingrid Lucis, American Chiropractic Association**)

- Contact professional organizations representing complementary and alternative providers that can direct the Commission to research organizations that are actively engaged in researching CAM practices. (**Ingrid Lucis, ACA**)

- Change regulatory guidelines that restrict and deny reimbursement for complementary and alternative health care in all federally funded programs. (**Ingrid Lucis, ACA**)

- Have Congress direct the Health Care Financing Agency tp provide reimbursement for CAM practices in these clinical trials. (**Ingrid Lucis, ACA**)

- Make available short courses on CAM data and paradigms, such as those from the University of Arizona and other sources, to all potential collaborators in conventional medicine. (**Diana Chambers, Friends of Health**)

- Seek NEH funding to help develop a language that adequately represents the movement toward integrated medicine. (**Diana Chambers, Friends of Health**)

- Avoid forcing CAM therapies into the strict and reductionistic procedure which conventional medicine utilizes. (**Boyd Landry, Coalition for Natural Health**)

- Allow public to choose Cam or holistic therapies without regulation, as long as a the therapy doesn't involve things that are invasive, where the potential for harm is of a serious nature. (**Boyd Landry, Coalition for Natural Health**)

- Take note of Medical Outcomes Trust, a Boston-based organization that designs outcomes-based measurement instruments. (**Thomas Deboroski, entrepreneur**).

Summary of Major Themes and Recommendations from October 5-6, 2000 Research Meeting

The following themes and recommendations drawn form the October 5-6, 2000 meeting on research have been placed under the panels in which they were discussed.

However, you will find considerable overlap of the issues and recommendations from panel to panel. Multiple panels may include references to research, research training, integrative academic centers, regulatory agencies, foundations, the private sector, and so forth.

Please keep in mind this list of themes and recommendations and the presentations and discussions from the May 15-16 research meeting when you discuss key issues and recommendations during your breakout sessions on the afternoon of May 16.

Panel I: Research Priorities and Public Input

The IOM recommendation to increase the public's voice in the NIH priority setting process can serve as a model for public input into the process of developing recommendations for CAM policy setting.

Encourage CAM practitioners to work within the current research system and aspire to the rigorous, blinded, randomized studies that are the gold standard, recognizing the ways by which reliabel, objective data on health and medicine may are obtained, such as observational data, pilot studies, case studies. **(Leon Rosenberg, Institute of Medicine, IOM)**

Encourage the NIH to expand its portfolio of clinical research with efforts that answer questions concerning modalities that are not going to be patentable and that will not have their research paid for by biotech or pharmaceutical or drug device industries. **(Leon Rosenberg, IOM)**

In addition to full support for NIH, a remarkably successful Federal research agency that has served the public so well, fund related Federal agencies, such as CDC, FDA, HRSA and others, adequately so that they may carry out their public health mandates, and include CAM-related activities as part of their mandate.

Panel II: Federally Funded CAM Research

One of the biggest hurdles facing CAM is opening up dialogue and collaboration with conventional practice and conventional clinical research. CAM practitioners interested in research must make their voices heard more strongly. Sponsor interdisciplinary workshops and conferences. Invite CAM practitioners and researchers to serve on interdisciplinary advisory groups and sit on committees.

The RCT is the preferred method of clinical study and can be applied successfully to some CAM questions. However, traditional clinical trials may not be very informative about the efficacy of many CAM treatments. CAM research questions are hard to validate. Some CAM regimens are difficult to study because they are complex, individualized, lack uniformity, and are hard to generalize. It is difficult to acquire preclinical information on many CAM patients. Survival as the endpoint may not apply to CAM treatments. Many CAM modalities are not presently reimbursed by Medicare.

NIH Institutes interested in studying CAM modalities may face a lack of validated data and reluctance of established investigators to do the research. To encourage established scientists to address CAM questions, define a measurable research question and explore ways of obtaining pre-clinical data . In developing protocols, there are methodologies other than the gold standard to employ. If necessary, the challenge exists to develop new ways of pursuing the question.

Define the types of questions that are and that are not appropriate for RCTs. Identify the appropriate methodology for the type of (scientific) question being asked.

Develop alternative investigative methods for studies where there is concern about using a placebo as a standard part of the technique. Because of the risk of using uncertain measurement techniques to study untested CAM approaches, a grant should be announced to bring together experts with broad experience and interest in research methodology to explore, in a think tank effort, with CAM practitioners and trained researchers possible scientific approaches to various types of questions.

Many CAM practitioners are unfamiliar with research techniques and requirements. The lack of trained CAM investigators is a significant problem. Funds must be made available to train people interested in CAM. Fund and plan workshops to enhance communication and awareness in both communities, and to offer guidance on how to prepare grant applications and obtain grant funding. Promote research partnerships with CAM practitioners and researchers.

Increase funding for research, training, and infrastructure at CAM research institutions, and open doors to cross training and collaboration between conventional and CAM institutions.

Quality research leads to credibility and credibility leads to acceptance and integration of services. There needs to be a paradigm shift to respect the modality under study, and research training programs for clinicians, through academic partnerships, that allow them to stay in practice and become familiar with the clinical environment and clinical outcomes research.

Federal efforts in CAM are expanding. CAM research now has funding, better peer review, and credibility at NIH. There is still a need for research infrastructure and training at CAM centers. FDA policies and procedures also must address CAM issues.

The social sciences and behavioral sciences are receiving more recognition, and more attention is being paid to promoting health and preventing disease. CAM approaches contribute to general health and wellness. Opportunities to study these approaches to improve quality of life should be encouraged. CAM helps to envision what the future in medicine will be, especially given an aging society suffering with chronic illnesses, and a need to strengthen health maintenance in younger people.

There is overlap between CAM and conventional medicine in areas such as nutrition, analysis of plant and animal products, mind-body medicine, pain control and palliative care. Nutrition and prevention were once disregarded by conventional medicine; now they are becoming standard. Patients who suffer from chronic diseases like low back pain and arthritis often turn to CAM.

Encourage strengthened support for NCAAM and its collaborations with other NIH Institutes, the NCI best case series program, and the ODS, which is supporting such studies as the synergistic properties of blended compounds. Also support Federal funding for clinical research on nonpatentable modalities.

An important challenge is finding a way for the CAM community to work with the medical establishment. CAM needs to strengthen its reputation and reach out to people in conventional medicine who can make a contribution.

The absence of common and consistent definitions of CAM contributes to problems in communication.

Develop strategies to increase CAM cancer research needed to address the range of challenges—e.g., difficulty in establishing uniformity, complexity of individual regimens, difficulty replicating treatments in clinical settings—posed by the nature of the field. **(Jeffrey White, National Cancer Institute, NCI)**

More fully examine the potential of CAM's whole-patient approach to improve the quality and perhaps quantity of remaining life for cancer patients. **(Jeffrey White, NCI)**

Expand CAM research in ways that access the resources of the larger and more research-savvy conventional community. **(Jeffrey White, NCI)**

Provide resources to bridge the "two culture problem." Opportunities and resources are needed to foster communication and collaboration between CAM and conventional practitioners and researchers. Inherent problems in CAM clinical research, difficulty in standardizing interventions, culture problems between practitioner and research communities, general awareness about CAM, can be resolved by building appropriate interdisciplinary collaborations **(Jeffrey White, NCI)**

Use existing mechanisms of federal research support to train CAM practitioners areas in conventional research methodologies. **(Steven Hausman, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIAMS)**

Look at low back pain as a vast potential opportunity for the integration of conventional and CAM modalities. **(Steven Hausman, NIAMS)**

Study the placebo effect more rigorously. **(Steven Hausman, NIAMS)**

Discourage rules barring Medicare payments for things Medicare does not normally cover, including many complementary and alternative modalities, which pose a significant obstacle for getting elderly people on Medicare to participate in CAM trials. **(Steven Hausman, NIAMS)**

Invite the public to give their views in setting CAM research priorities. **(Steven Hausman, NIAMS)**

Encourage research into dietary supplements to be evidence-based and structured like other medical research. (**Paul Coates, Office of Dietary Supplements, ODS**)

Support dietary supplement research activities that engage partnerships between research organizations, non-profits, and private industry with common interests in the field to help merge the sometimes conflicting impressions that (a) evidence supporting traditional CAM falls outside the American medical paradigm and should be ignored and that (b) traditional products don't need to be evaluated because of their long traditions of use. (**Paul Coates, ODS**)

Increase the number of workshops and conferences that focus on interdisciplinary approaches to medical research as a way of increasing the share of the research pie that goes to CAM activities. (**Paul Coates, ODS**)

Panel III: Academic Centers and Support for CAM Research

Encourage Federally-funded universities to develop programs that bring CAM clinical research into the academic health centers working with CAM practitioners/researchers. Create interdisciplinary collaborations with CAM institutions to develop research capability.

Increase the publication of valid CAM research findings in major medical journals and increase the readership of quality CAM journals. Lack of coverage limits further study

Increase awareness of physicians regarding CAM therapies their patients are using to avoid adverse reactions.

Create a steering committee that understands CAM to advise IRB's on applications they may not fully appreciate. (**Alfred Fishman, Penn**)

Integrate complementary and alternative therapists into the educational curriculum in places where it is appropriate to consider them. (**Alfred Fishman, Penn**)

Sponsor a meeting with a critical mass of people at institutions engaged in CAM research who want to exchange ideas. (**Alfred Fishman, Penn**)

Address the issue of a fundamental lack of research orientation in CAM institutions by partnering with institutions that have a research focus. (**Alfred Fishman, Penn**)

When creating a new CAM division, engage people with real opposition to the idea in the planning panel. (**Daniel Federman, Harvard University**)

Refrain from disparaging good, well-written anecdotes. Recognize that anecdotes are appropriately the precursor to rigorous scientific research. (**Daniel Federman, Harvard University**)

Connect CAM with existing institutional strengths by granting programs cooperatively. (**Daniel Federman, Harvard University**)

Develop an interdisciplinary, multi-disciplinary, interprofessional research agenda that employs social, clinical, and basic sciences, to integrate CAM and conventional medicine. **(William Meeker, Palmer College of Chiropractic, PCC)**

Train CAM scientists. Provide programs, incentives, pre and post-doc positions and career tracks for capable and interested young people. **(William Meeker, PCC)**

Create ways to encourage interdisciplinary, multidisciplinary and inter-professional collaborations between CAM institutions and tax-supported universities. **(William Meeker, PCC)**

Apply the entire universe of research project and program funding mechanisms to initiate, encourage and support CAM research, including bricks and mortar. **(William Meeker, PCC)**

Call for interdisciplinary conferences to explore scientific states-of-the-art on CAM topics and establish rigorous research agendas. Support the agendas with targeted research funding program announcements. **(William Meeker, PCC)**

Encourage the National Library of Medicine to include CAM topics and references in its indexing systems. **(William Meeker, PCC)**

Establish academic CAM clinical centers. **(William Meeker, PCC)**

Support CAM training institutions in the broadest possible sense, like all other health professions, in order to eliminate the dependence on tuition and provide the resources to develop a more effective and consistent research culture. **(William Meeker, PCC)**

Ensure that CAM professionals are routinely appointed and otherwise included in research policy making efforts. **(William Meeker, PCC)**
Consider something similar to the Centers of Excellence program in HRSA's Bureau of Health Professions to help jumpstart the research efforts of CAM professions and their institutions. **(William Meeker, PCC)**

Develop training programs and career tracks, so that people that have a natural inclination in this direction see that they can have a job and a career doing it. That has not existed in the CAM profession so far. **(William Meeker, Palmer College of Chiropractic)**

Panel IV: Research Support and Collaborations

Promote preclinical studies that look at mechanism behind a CAM intervention at the same time as studies on safety and efficacy and not merely pursue whim and anecdote. **(Stephen Straus, National Center for Complementary and Alternative Medicine, NCCAM)**

Reinforce the fact that science is a process not a philosophy. Support basic science and clinical science and encourage advocacy organizations, industry, and the broad sweep of the American public to get behind asking questions critically and credibly. This will serve the public well.

(Stephen Straus, NCCAM)

Panel V: Facilitating CAM Research and Regulatory Challenges

If a substance affects the structure or function of the body and is used to treat or mitigate disease, it is considered a drug, including dietary supplements. The intended use dictates the category. A product can be marketed as a dietary supplement, but cannot make the drug claim. The product that is shown to be clinically effective no longer has to play the label game–an advantage to consumers and manufacturers.

A barrier to CAM research is the fact that the drug development system was set up for synthetic drugs and the regulatory framework is tailored to them.

FDA has published guidelines on how to study botanicals and deal with the approval process. The guidance urges people to consider doing controlled trials and emphasizes the importance of gathering substantive information early on. If a product has been marketed as a supplement or has been used as a drug in other countries and the experiential data have been collected, that information could form the basis for conducting a clinical trial.

Regulatory changes in combination-product regulations, as identified by the FDA, could promote CAM research on botanicals. The FDA document is a good start, but takes the single chemical entity paradigm and overlays it with botanical requirements.

A hurdle for CAM is the FDA expectation that new drugs will be characterized by their criteria, including botanicals. The testing of complex substances is often difficult and additional chemistry and manufacturing standards might be required. Substances that are not plants might also be considered drugs and the same reasoning applied to them. Getting a botanical into a clinical trial is easy, but to move further, the botanical must meet every standard that a chemical entity must meet. Also, FDA will need additional staff with the appropriate background to evaluate the human research data.

FDA is prepared to provide assistance and guide people through the steps. People who submit INDs can get advise through the pre-IND program. FDA can help small and new businesses through the process. Small manufacturers can request a user-fee waiver, similar to orphan drug product waivers.

More funds are needed to adequately address integration of CAM products into a broader regulatory process, including staff positions to assist people not experienced in drug development. Staff well-versed in CAM spend their time reviewing synthetic drugs. A core team should be created that deals with CAM and has connections to the outside community. The work is labor intensive and there is no formal process for assigning resources except as Congress dictates.

Regulation should foster and direct development of good data. When regulators look for excessive data up front, they drive away good products and freeze research. The ongoing debate over regulation is encouraging.

Is there a way to allow previous human experience to count? Are changes needed in the regulations? Because it is costly to bring a substance to FDA's attention, how do we stimulate funding from the private sector, which is motivated by the profit motive. Without patent protection, manufacturers will need some form of regulatory exclusivity.

Few devices require approval; there are no separate classifications for CAM devices. Devices such as copper bracelets and similar products should have a process for submission of evidence but do not, despite the fact that they make a claim. A CAM practitioner often promotes new uses for an old device. Advertising is regulated by the Federal Trade Commission.

Congress has made the medical technology industry more responsible for the quality of their products. This has been a key component in fostering innovation, because it bolsters consumer confidence. However, bioengineering is not well funded.

FDA's goal is to fully implement DSHEA; maintain a high level of competence in labeling; and follow a science-based regulatory approach. New dietary ingredients will have to come to FDA prior to marketing. The Center has a very small staff to devote to this program and until resources are adequate, progress will be incremental. DSHEA allows a claim to be made based on evidence, without great cost. It also promotes better labels and better third-party information.

A permanent natural products OTC panel should be established, rather than using ad hoc experts, to make decisions about safety and efficacy and to allow stronger claims. This would upgrade DSHEA, and would result in a panel of experts focused on natural product health care.

FDA should allow elimination of the disclaimer on a DSHEA label if a certain level of proof is reached.

The Commission on Dietary Supplement Labels recommends setting up monograph equivalents for botanicals, setting the standard for making claims.

Botanicals, which have potential beyond over-the-counter products and the DSHEA marketplace, test the law because they are manufactured like a biological under heavy process control, sold as a food or dietary supplement by Congressional fiat, and used as therapy by the public.

There should be more focus on folk medicine, which has been used widely, but does not fall within the DSHEA model. Good anecdotal information should be considered.

There should be more international outreach and access to European safety data. Better information systems would be helpful.

Because it is difficult to give exclusive rights for substances used for many centuries, natural products research has shut down and FDA has approved very few preventive medicines.

Submit comments related to new guidelines, Botanical Drug Products, designed to open the door for the study of traditional botanicals without the barriers that currently exist, which are designed

for synthetic drugs. **(Janet Woodcock, FDA, Center for Drug Evaluation and Research)**

Provide input on proposed changes in combination product regulations, which were originally written for purified drugs and are being revised to help botanicals move through the approval stage more quickly. **(Janet Woodcock, CDER)**

Provide additional resources to assist small companies to get through the FDA drug review. **(Janet Woodcock, CDER).**

Encourage the FDA to promulgate additional chemistry and manufacturing standards to accommodate the reproducibility and stability and constant dose issues raised by plants.**(Janet Woodcock, CDER)**

Create a place in FDA with sufficient staffing that could work with groups at various levels to assess the appropriate classification of botanicals as treatments. **(Janet Woodcock, CDER)**

Define the safety standard for dietary supplements. As yet, the law is silent on the question of their benefits, and only speaks to their safety, though what degree of safety and confidence is still being determined. **(Joe Levitt, Food Center at FDA)**

Panel VI: Research in the Regulatory Framework

State medical boards protect the public from unqualified physicians. Some CAM practices lack scientific validation. Three areas of harm are outlay of money on ineffective treatments, delay in seeking appropriate care, and direct harm. Guidelines are being developed to educate and regulate all physicians. Regulators must have solid information about interventions and research on effectiveness. If chelation is effective, medical boards should hold doctors responsible for not using it. If not, physicians who use it should go before the state medical boards. Medical boards do not want to create barriers to legitimate research, but their first priority is public safety. Once the Federation establishes a process, the states pick it up.

The Federation of State Medical Boards should consider a process for state medical boards to meet with CAM practitioners who want to conduct research but whose treatments are considered nonstandard or fraudulent by the state.

A practitioner who goes through an IRB, may need help in navigating the process.

Include CAM practitioners as members or consultants on state medical boards. Also, IRBs and study sections should include panelists familiar with CAM.

CAM practitioners who believe in practice-based research need an environment that allows for thinking outside of the box and the development of new methodologies. There is precedent for waiving the gold standard. FDA did it for interleukin-2 based on a pilot study. Changes need to be made so that medical boards work with and not against people trying to validate their procedures.

Lack of insurance reimbursement, fear of losing one's license, lack of time and money, and bias in the system stand in way of moving ahead with research. Most people cannot be both a clinician and researcher. Many clinicians have data on which to build, but do not want to hand it over for fear of what is going to happen to them. More needs to be learned about these problems, while preserving the goal of protecting the public.

Include in the guidelines for fraudulent and deceptive practices those guidelines standards for assessing the work of a non-institution based physician who is engaged in research. (**James Winn, Federation of State Medical Boards, FSMB**)

Include on medical boards CAM consultants to assist in their evaluation of cases and any kind of complaint that comes forward. (**James Winn, FSMB**)

Invite patent lawyers to address the issue of exclusive rights to botanical extracts. . (**Floyd Leaders, Botanical Enterprises, Inc.**)

Rather than bring foreign plants to the US for research, work in a partnership within that country. (**Floyd Leaders, Botanical Enterprises, Inc.**)

Allow the elimination of the disclaimer on a DSHEA regulated label if a certain threshold of evidence is achieved, or give it over-the-counter drug status. (**Robert McCaleb, Herb Research Foundation**)

Increase the focus on traditional medicine, recognizing that DSHEA leaves that out. (**Robert McCaleb, Herb Research Foundation**)
Develop ways to look at historical information on herbs and using this information in the evaluation of their efficacy and safety. (**Robert McCaleb, Herb Research Foundation**)

Facilitate international outreach in terms of accessing the information from European and Asian clinical practice. (**Robert McCaleb, Herb Research Foundation**)

Cut through the maze of information and try to get information, especially for consumers and practitioners that is quality evaluated, so people can trust the information and utilize in their decision-making process. (**Robert McCaleb, Herb Research Foundation**)

More funding is needed for libraries and collaboration to utilize the resources that are currently untapped. (**Robert McCaleb, Herb Research Foundation**)

Appoint a panel of experts, who are really specifically focused in this area of natural product health care, to look at the evidence on herbs and make decisions. (**Robert McCaleb, Herb Research Foundation**)

Adequately fund alternative medicine research centers so that they can collaborate with orthodox medicine. (**Anthony Rosner, Foundation for Chiropractic Education and Research, FCER**)

Address anti-chiropractic sentiments in the composition and proceedings of institutional review

panels and boards. **(Anthony Rosner, FCER)**

Require an equitable number of individuals within each study section of a grant proposal, who are familiar with and sensitive to the conduct of CAM therapeutic regimes to be tested. **(Anthony Rosner, FCER)**

Place far greater emphasis on cohort studies and case series in reaching research goals rather than to assume categorically that they provide inferior guidance to the clinical decision-making than RCTs. **(Anthony Rosner, FCER)**

Panel VII: Outcomes Research Part I – Interface between CAM Research and Regulatory Agencies

The NCI best case series program is dependent on practitioners feeling comfortable giving documentation of their practices to the federal government. Changes in regulation need to be explored to change the regulations so that best case series can become more productive.

Some very excellent researchers have had difficulty getting INDs. Perhaps NIH research Institutes, such as NCI, could establish procedures to explore this concern with the FDA.

Develop a forum for alternative practitioners or scientists who believe they are being harassed unfairly.**(Nicholas Gonzalez, Private Practice)**
Use the threat of cuts in Medicare or Medicaid funding to force the states to protect new ideas.**(Nicholas Gonzalez, Private Practice)**

Use health departments to identify the top 35 public health problems in the United States and aim therapies at them, also see what is working in clinical settings and use that evidence as a starting point for understanding why. **(Ann McCombs, Private Practice)**

Explore how regulation could help the Best Case Series program become more productive since some CAM practitioners are not willing to come forward because they feel they need to practice in secret. **(Jeffrey White, National Cancer Institute, NCI)**

Learn more about problems with getting INDs for certain herbal products and the effect that is having on inhibiting some cancer research. **(Jeffrey White, NCI)**

Panel VIII: Private Sector Support for CAM Research

Develop a model for coordination of research between the Federal, private, and not-for-profit sectors.

Private industry should be encouraged to endorse coordinated research programs to transform medical science into products wanted and needed by the public. NIH should support more effective integration of Federal and private efforts. Incentives and intellectual property issues need to be resolved to allow for marketing protection, as well as appropriate regulatory pathways

Nature has been a fruitful source of new medications. The largely empirical screening methods of the natural product-derived drug discoveries have fallen into disfavor, viewed as labor-intensive and unproductive. DSHEA is allowing fresh interest in plant medicine. Impending changes in the regulation of botanical drugs could stimulate more development and research. Botanicals must be evaluated by the highest standards. The level of investment in this area needs to be comparable to that of pharmaceuticals. The return on investment is an issue; corporations need protection for their work and incentives.

A primary obstacle is the lack of recognition of the benefits of herbs. The German regulatory system recognizes the benefits and half of the herbs sold in Germany are doctor recommended or prescribed. Much of European research was done on proprietary commercial products. Some European companies are concerned about their research being "borrowed" and used unfairly by competitors.

DSHEA has been a stimulus for herbal research and there are many examples of private sector funding by the herb industry. However, incentives are needed, such as rights to exclusivity claims and market protections. Modification of the dietary supplement disclaimer allowing removal from a product that has had some clinical study review should be considered, as well as tax incentives. FDA approval of structure/function claims could promote research. The government should consider establishing an expert review panel to evaluate the safety and appropriateness of both the structure/function claims under DSHEA and as OTC drugs. Herbs do not qualify for composition-of-matter patents. Since the passage of DSHEA, some process and use patents have been granted, but use patents may not be able to withstand public domain and traditional use challenges. Trademark protection should be available as a motivator for research investment, and there should be a way to protect small companies.

Industry should also share information from incomplete studies in order to guide other efforts, provide substances for clinical trials, assist in the preparation of appropriate placebos, and offer industry-sponsored symposia with CAM practitioners. Products with defined standards should be used in studies, and industry should form partnerships with clinicians and academia and participate on NIH advisory panels.

Pharmaceuticals, OTCs, and herbals need to provide a competitive advantage; exclusivity is a major issue. Another concern is that a single study might not be accepted as sufficient. There are many intellectual property issues. The company has the ultimate responsibility for the safety of its product. FDA guidance will facilitate getting to Phase II trials. Depending on the size of the market, a process use patent would be a solid incentive.

FDA guidelines suggest that with a minimal preclinical package, moving some of these materials directly into Phase 2 studies might be possible, and instead of taking the individual components out of the plants, one can look at how the combination is working. However, there is the question of safety moving straight to Phase II. In some cases, safety documentation from elsewhere is strong, other times it is not.

Looking at the genomes of plants will eventually allow us to see what happens with the entire plant, and this is where corporate interests lie. Even when looking at health and wellness as a

unified field, the cultural aspects are not for a company to determine, but rather fall to the provider.

DSHEA requires that the product deliver what the label says. Industry is about to undertake a third-party testing program. Companies will pay a licensing fee for periodic testing in return for receiving a seal.

The Federal government should compile a primer on funding mechanisms and make funding opportunities more visible. Hold a conference on completion of relevant studies and develop a database including privately-supported study results.

To overcome barriers, meetings should be held with journal editorial boards to solicit recommendations to increase acceptance of papers submitted by industry.

Involve companies up front in developing a system of appropriate regulation. (**Randy Burkholder, Advanced Medical Technology Association, AMTA**)
Provide incentives for developing CAM related medical devices with private or public reimbursement mechanisms. (**Randy Burkholder, AMTA**)

Facilitate research collaborations with private sector research organizations, and take advantage of such mechanisms as Small Business Innovation Research grants. (**Raymond Ruddon, Johnson & Johnson, J&J**)

Provide incentives for private industry's involvement in CAM research by resolving intellectual property issues through something akin to legislative exclusivity remedies like the Ortho-Drug program. (**Raymond Ruddon, J&J**)

Provide proprietary protection around the process, extraction, production, and use of unique mixtures or combinations of agents for single herbs. (**Raymond Ruddon, J&J**)

Expand communication between traditional and conventional medical experts. (**Raymond Ruddon, J&J**)

Increase the availability of private and federal funding for CAM research. (**Raymond Ruddon, J&J**)

Develop a rigorous review process involving both academic and industry scientists to evaluate scientific-merited CAM research proposals. (**Raymond Ruddon, J&J**)

Design discovery research projects in CAM using such tools as gene expression arrays or proteolytics to identify new bioactive substances in natural products and pharmacogenomics to individualize therapies. (**Raymond Ruddon, J&J**)

Address the anti-CAM bias in subsequent editions of Goodman and Gelman's, "Textbook of Pharmacology." (**Raymond Ruddon, J&J**)
Create incentives for the private sector to invest more substantially in research and development

of natural medicines like a Waxman-Hatch type data or marketing exclusivity period that would allow the investor to fully develop the medical and commercial potential of natural medicines. **(Frank Sciavolino, Pfizer)**

Allow early access to Phase II trials to help lower attrition rates for new neutraeuticals and to reduce overall development costs. **(Frank Sciavolino, Pfizer)**

Explore the CDSL recommendation that label disclaimers mandated by DSHEA could be modified or removed if a botanical product met certain requirements for research. **(Mark Blumenthal, American Botanical Council).**

Find a viable balance among free market and competitive issues, science, regulation, and the need to respect cultural heritage, and traditional use. **(Mark Blumenthal, ABC)**
Help promote research by making structure/function claims approvable by FDA, modifying the dietary supplements disclaimer following some clinical study review, allowing process and use patents for botanicals, providing tax credits for research funding. **(Mark Blumenthal, ABC)**

Establish an expert review panel similar to Commission E to evaluate the safety and appropriateness for claims for herbal products, both the structure/function claims under DSHEA and as OTC drugs. **(Mark Blumenthal, ABC)**

Encourage the CAM industry to submit its studies to peer review journals for publication and provide data from its unpublished studies to assist in selection of therapies for further study and to contribute to study design. **(Annette Dickenson, Council for Responsible Nutrition, CRN)**

Encourage the supplement industry to cosponsor symposia or conferences to provide networking opportunities between researchers and clinicians. **(Annette Dickenson, CRN)**

Convene meetings with journal editorial boards to solicit recommendations which would increase the acceptance of papers submitted by the supplement industry. **(Annette Dickenson, CRN)**

Encourage the supplement industry to generate a clinical trials guidance document outlining the standard components and proper design of study protocols. **(Annette Dickenson, CRN)**

Encourage the supplement industry to form partnerships with clinicians or academia, depending on the type of study. **(Annette Dickenson, CRN)**

Establish a special web site to facilitate communications regarding ongoing research needs and opportunities. **(Annette Dickenson, CRN)**

Develop a primer on funding mechanisms for research and conferences within government agencies that apply to industry should also be compiled to explain, for example, cooperative research and development agreements, small business grants, investor-initiated grants, and contracts. **(Annette Dickenson, CRN)**

Develop a document for industry use, explaining, how each research agency determines its research agenda. **(Annette Dickenson, CRN)**

Develop a government-industry partnership to conduct testing to confirm the safety of the product not simply in terms of lack of any knowledge of un-safety, but in terms of proactive, positive demonstration of lack of teratogenicity and for safety during pregnancy. **(Annette Dickenson, CRN)**

Give the FDA more enforcement authority to assure that products are what they are supposed to be. **(Annette Dickenson, CRN)**

Panel IX: Not-for-Profit Sector Support for CAM Research

Not-for-profit organizations can stimulate CAM research by providing seed money; supporting grants and publication of research, offering financial awards for medical school and research training; and convening conferences. The lack of awareness of existing research is a problem. The solution is publication of studies in peer reviewed journals. To increase funding and partnerships for CAM research, improve the rigor of proposed studies. Find incentives to stimulate mentors who can help develop new CAM researchers. Include studies on mechanisms of action and cost effectiveness, and fund conferences to review strengths and weaknesses of existing research and propose new, well-designed studies.

Productive partnerships should be created between Federal agencies and foundations that focus on communication and opportunities for collaboration. Each should host meetings and plan site visits to CAM research centers, where information about current research and the federal grant process is available. Agencies should seek more foundation representation on their panels, and include them on mailing lists. Foundations should stimulate CAM research by funding more small pilot studies, often a requirement for government funding, and by creating a pool of research funds among themselves to diminish risk.

Identify foundations interested in finding and supporting new, cutting-edge areas to research.

Some investigators are not affiliated with institutions, but both government and not-for-profit institutions usually do not support individuals. Should changes in not-for-profit law be recommended to permit grants to fund individuals? .

Improve funding access for CAM by improving the methodical rigor of proposed studies. **(John Templeton, Jr., John Templeton Foundation, JTF)**

Encourage new researchers in CAM therapies with mentors trained in scientific research. **(John Templeton, Jr., JTF)**

Develop better coordination between non-profit and federally supported CAM research by convening a jointly funded consensus conference to review in depth the strengths and weaknesses of existing research and propose new studies to build the science behind CAM. **(John Templeton, Jr., JTF)**

Because the scientific study of spirituality is in its infancy, and as spirituality is hard to define, I think it is important to try and pick some aspect of spirituality that a group that practices a certain type of spirituality embraces and then study their intervention. **(John Templeton, Jr., JTF)**

Promote a consensus conference to suggest ways of studying spirituality. **(John Templeton, Jr., JTF)**

Train medical students and residents to understand that it is appropriate to take a spiritual or religious history. **(John Templeton, Jr., JTF)**

Host introductory, face-to-face meetings and site visits among foundation people with representatives of existing CAM research centers currently funded by the NIH. **(Dyanne Hayes, Conrad N. Hilton Foundation)**

Be more aggressive in seeking opportunities for foundation representatives to participate on panels such as this to discuss their experiences and perceptions regarding CAM and CAM research. **(Dyanne Hayes, Hilton Foundation)**

Include foundations on mailing lists and publicize the those grants that do or have had public/private funding support. **(Dyanne Hayes, Hilton Foundation)**

Encourage foundations to be more willing to fund small pilot projects. **(Dyanne Hayes, Hilton Foundation)**

Encourage foundations interested in CAM research to create a pooled fund of monies and announce the competition for projects up to so many dollars. The collaborative would set up a scientific advisory board of reputable scientists knowledgeable in the area in which the proposals are being submitted. **(Dyanne Hayes, Hilton Foundation)**

Address the sense of separation between Eastern and Western cultures that pervades relations between the two communities. **(Dyanne Hayes, Hilton Foundation)**

Help the foundation community stay better informed on relevant symposia as well as what has been funded. **(Dyanne Hayes, Hilton Foundation)**

Conduct research on why people are drawn to CAM, what people who are drawn to it, what do they mean by what we say works, and what do they find satisfying about it that they don't find satisfying in the rest of medicine? **(Daniel Callahan, Hastings Center)**

Keep the discussion of Medicine as art and science alive. **(Daniel Callahan, Hastings Center)**

Utilize CAM as a lens to help us envision the future of medicine when an aging population with chronic ills will share the national stage with a younger population that will need to learn how to take better care of itself. **(Daniel Callahan, Hastings Center)**

Find some better ways of formalizing means of investigation other than randomized clinical

trials in which one can have confidence. **(Daniel Callahan, Hastings Center)**

Develop a think tank that brings together research methodologists, not just people interested in CAM, to discuss the methodological problems of investigating CAM. **(Daniel Callahan, Hastings Center)**

Encourage private philanthropy to fund CAM research to get things going to a point where federal funding, based on other criteria can be used. **(Daniel Federman, Harvard University)**

Develop a generally accepted definition of CAM to ensure the everyone is talking about the same thing. **(Teri Ades, American Cancer Society)**

Protect patient access to CAM, while providing oversight and accountability by governmental, public, and private entities that are needed to protect the public. **(Teri Ades, ACS)**

Support NCCAM and its stress on the importance of systematic and scientific approaches to studying various medicines, as well as the NCI's Best Case Studies program.**(Teri Ades, ACS)**

Support additional funding for mentoring programs that help those with promising therapies to collect quality data and take part in the necessary research. **(Teri Ades, ACS)**

Invest more efforts in understanding the limits of randomized clinical trials in CAM and in finding other research approaches that work better. **(Teri Ades, ACS)**

Rather than consider incentives, consider setting the expectation that all therapies must be proved to be safe and effective so the public does not have to question their therapy. **(Teri Ades, ACS)**

Have NCCAM serve as coordinator for a group of public, private, and governmental agencies convened to discuss how to better coordinate federal support for CAM research. **(Teri Ades, ACS)**

Panel X: Outcomes Research Part II – CAM Research and Experimental Design

Schools of Public Health are the ideal environment for CAM research. Many faculty are involved in CAM-related projects. Most of the schools of chiropractic health care have some course work in public health and chiropractors belong to the APHA. Their special interest section has been planning a syllabus in public health education for chiropractic colleges. A working group made up of schools of public health and chiropractic colleges will collect and analyze baseline data for developing a curriculum for future students.

Provide funding and trust-building for the Best Case Series Program. NCCAM funded centers could play a very important role in the Best Case Series Program by providing methodological support to clinicians **(Leanna Standish, Bastyr University)**

Create partnerships between CAM academic centers and CAM practitioners for developing Best Case studies, especially in the cancer area, and have that collaborative work be funded by the

NCI. **(Leanna Standish, Bastyr University)**
Encourage institutional review boards to be flexible in assessing joint CAM/conventional medicine research efforts. **(Leanna Standish, Bastyr University)**

Have practitioners develop algorithms to describe the "if then" nature of CAM treatments and formalize them, to facilitate doing individualized therapy inside of a clinical study. **(Leanna Standish, Bastyr University)**

In assessing CAM, analyze a therapeutic approach that is not too refined and examine the entire system and include elements like lifestyle, exercise, plus the addition of dietary modification or we will miss the forest for the trees. **(Elaine Cramer, Center for Disease Control and Prevention, CDCP)**

Put together an integrated team of researchers from both the CAM and conventional communities who are open-minded practitioners, who are really willing to collaborate and randomize patients to CAM treatment arms as well. **(Elaine Cramer, CDCP)**

Use integrative research to study integrative medicine. The way to properly evaluate any outcomes is through a team-based approach using existing methods. **(Elaine Cramer, CDCP)**

To implement these strategies in a community setting, solicit proposals from integrated research teams which are comprised of both CAM and conventional practitioners who demonstrate the ability to collaborate on, not just the study design, but case definitions, the selection of exposures, and the designation of CAM and conventional treatment sites. **(Elaine Cramer, CDCP)**
Assign a research mentor not only to CAM practitioners who are interested in evaluating CAM therapies, but whoever needs research and who really needs some assistance with both protocol and study design development. **(Elaine Cramer, CDCP)**

Establish experienced research teams that are comprised of scientists, subject matter experts and send them out en masse to selected research sites to really expedite development and implementation of the protocols for CAM evaluation. **(Elaine Cramer, CDCP)**

Conduct clinical outcomes research on CAM to determine what is efficacious, what is effective, what is safe, and to give the patient a wider choice of treatment modalities. **(Lydia Segal, Kaiser Permanente)**

Develop research training programs for clinicians that allow them to stay in their practice, be it a mentoring program or a partnership with academic or government institutions, while bringing researchers into the clinical environment. **(Lydia Segal, Kaiser Permanente)**

Develop research designs to accommodate the patient specific nature of CAM treatments to make different treatments statistically comparable. **(Lydia Segal, Kaiser Permanente)**

Encourage collaborative research efforts between conventional and CAM academic institutions. **(Douglas Lloyd, Association of Schools of Public Health,ASPH)**

Panel XI: Federal Agency Support for CAM Research

Increase funding for other federal health agencies involved in CAM research-related activities.

In the last 10 years, the VA has funded $60 million in CAM research, while VA. investigators have participated in other CAM research projects worth $92 million in funding during that same time. Additional CAM research has been done without funding. Among the areas studied are biofeedback, acupuncture, electromagnetic therapy, and others covering the entire spectrum. The VA is doing an omnibus report of these numerous studies. Concerns are variability of training, credentials of CAM practitioners, stability of funding, and safety.

Most research is done by the VA's intramural research scientists, and they are the only ones eligible for the grants. Initiatives come from the field. Research is organized into four basic types: basic, bench, rehabilitation, and outcomes. If they opened the door to a special interest, other groups would ask for the same treatment.

The VA is the ideal place to do demonstration projects.

To the Zuni Indian Tribe, CAM is standard. Traditional healing practices vary among the 500-plus tribes. The IHS is authorized to provide health services, not research, but some community organizations have an interest in it. NIH has funded centers for health research for Native Americans. Such centers must be governed by the Indian people, not by researchers.

IHS identifies native healers as mental health technicians. It is difficult to measure practice utilization, failure, etc. The healers are willing to push the limit rather than be constrained by conventional measures. They put their attention beyond biology and disease. This is a challenge for American Indian physicians who are researchers. The great belief is in the power of the healer.

A good contact point for Native American medicine is the National Indian Health Organization, which reflects the health interests of tribal governments nationwide. Also consider contacting the National Council of Rural Indian Health.

Work with tribal governments to establish research priorities for investigating traditional practices utilized by American Indians and Alaska Natives. Priorities and policy should set by Native Americans, not by researchers. (**Craig Vanderwagen, Indian Health Service, IHS**)

Examine how CAM might reach out to tribal communities and offer them tools and techniques for examining internally the effectiveness of their providers. (**Craig Vanderwagen, IHS**)

Methodology Example (addendum)

The preferred method is the RCT because chart documentation is uneven in observational studies and data collection will be limited by the lowest common denominator available on all the charts. In addition, there are inherent differences in patients that can be factored into a study, but only a

randomized study can deal with the unknown differences. If two patients receive the same treatment, one might also experience an improved quality of life, so qualitative survey instruments need to be in the study design from the outset. Finally, for experimental study design, the most important feature of a valid study is the comparison group. This requires expanding the study arena beyond one CAM practitioner. For these reasons we elected to move to an experimental study design of randomized treatment. If the study keeps in mind the modality being evaluated, there is no need for alternative methods or a redesign. The need is to be careful about what it is that is being measured and what the outcome is. The entire or aggregate system is analyzed rather than one unit of measure. If the entire system or modality shows promise, then go back and do the chemical analyses and basic science on those that work. The findings should be as valid and reproducible as possible. The problem is in over-interpreting data. There will be difficulties adjusting for all the differences. Data could be collected in standardized form. And patients could fill out an evaluation after they are seen.

A potential solution to the issue of individuality is to look into using an algorithm and doing flow charts on how the practitioner decides to do a type of therapy. It would be possible to do individual therapy inside a study and examine what makes certain practitioners effective and then teaching that.

MEETING SUMMARY

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

Session I: Overview

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

et al, 1998), that interest in and referrals to CAM by conventional physicians is relatively high (Astin et al, 1998; Bermen et al, 1995, 1998), and that the majority of medical schools in the U.S. are now offering at least elective courses in CAM therapies.

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

Panel Discussion:

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

Session II: Clinical and Cost Effectiveness of Selected CAM Services

Chiropractic:

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

Naturopathic Medicine:

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

NCCAM, and said it is extremely important for the Commission to recommend inclusionary language for CAM in entitlement acts, such as Medicare, Medicaid, Indian Health Service, and CHAMPUS for the military.

Acupuncture:

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

Homeopathy:

Joyce Frye, DO, MBA, FACOG, said there are an estimated 2,500 medical practitioners using homeopathy in the U.S.. Research on both clinical efficacy and cost effectiveness of homeopathy has suffered from limitations that are common to all of the CAM practices. The most useful summary of clinical efficacy, she said, is provided by the meta-analysis of 89 placebo-controlled trials published by Linde (Linde et al, 1997), which indicated that patients using homeopathy were 2.5 times more likely to have a therapeutic effect compared to placebo in a variety of conditions. The most complete data on cost effectiveness, she said, comes from the French Government Social Security statistics, which demonstrated significantly reduced costs using homeopathic versus conventional medical care. She said that these data are particularly compelling in view of France's ranking as the "number one" health care system in the world in terms of performance, in comparison to the United States, which is ranked 37th. She added that France also ranks third in life expectancy compared to 24th for the U.S.

Massage:

Tiffany Field, Ph.D., of the Touch Research Institute (TRI), testified that massage therapy, along with acupuncture, is one of the oldest therapies, dating back to Hippocrates in 400 B.C. She said that most of the research on the effectiveness of massage has been conducted at TRI during the last decade. TRI studies have demonstrated that massage can reduce prematurity and low birth rates associated with pregnancy, stress, and anxiety; can enhance the growth of preterm babies; can affect the outcomes of a number of psychiatric disorders; and can impact on immune problems, including asthma, diabetes, dermatitis, HIV, and cancer. The only study

on the cost effectiveness of massage was in pre-term infants and was able to demonstrate a hospital cost savings of $10,000 per pre-mature baby (Field et al, 1986). Multiplied by the 470,000 pre-term babies born in the U.S. each year, it equals a cost-savings of $4.7 billion per year, according to Dr. Field.

Panel Discussion:

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

training medical students and physicians in the effectiveness and cost benefits of CAM approaches as opposed to delivering the modalities themselves. Dr. Meeker said he agreed with Ms. Culliton. He added that there is an even greater need to train all health professionals, not just medical doctors, but CAM professionals as well, in how to interrelate to each other.

(Session II Continued)

Herbal Medicine:

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

Christopher Hobbs, an herbalist and a licensed acupuncturist, said that he has received funding from a pharmaceutical company to sift through the literature on a hundred herbs in great detail. He and his colleagues have researched 26 international electronic databases

and accessed a great deal of foreign material. Unfortunately, very few herb studies to date that have met high scientific standards. He recommended that well-trained herbalists be involved in studying the safety and efficacy of herbs on a scientific basis because many scientists have the view that herbs do not work until it is proven that they do work, which is the antithesis of how an herbalist would view them. He added, that although herbs can have side effects, generally speaking, herbs are far safer than drugs.

Nutritional Supplements:

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

Patsy Brannon, Ph.D., R.D., a registered dietition, testified that the recent Institute of Medicine report on the role of nutrition and malnutrition in maintaining health in the nation's elderly (Institute of Medicine, 1999) defines two tiers of nutritional services that impact the consideration of CAM. The first is basic or general nutrition education or advice that can be provided by a variety of health care professionals. The second tier is medical nutrition therapy, which involves nutritional assessment, evaluation of nutritional needs, intervention, counseling, enteral and parenteral nutrition, and other modalities, as

well as follow-up care. This type of therapy is generally provided by registered dietitians in a health care team of physicians, nurses, pharmacists, physical therapists, and psychologists. Beyond these two tiers, however, the vast majority of consumers get their nutritional information through the mass media. She said that nutrition therapy is "strongly supported" by observational studies, consensus documents, systematic reviews, and extensive clinical trials for a number of condtions. Furthermore, several recent reports have examined the cost effectiveness of nutritional therapy and have found potential savings ranging from the millions to billions of dollars for the health care system. She said there are a number of barriers to nutrition therapy, including the lack of recognition of nutritional therapy by Medicare and Medicaid and private practice health plans. She recommended the passage of legislation currently in Congress, H.R. 1187 and S. 660, to provide outpatient medical care coverage for medical nutrition therapy for diabetes and kidney disease. She also recommended the consideration of expanded Medicare and Medicaid coverage as recommended by the Institute of Medicine report for the other chronic diseases for which nutritional therapy has been documented effective.

<u>Integration Overview:</u>

Harley Goldberg, D.O., Medical Director for CAM for Kaiser Permanente in Northern California, said his job is provide information on CAM practices to Kaiser's physicians, members, and health care providers, to coordinate a research program, and to evaluate education and training needs for providers. It is also his responsibility to identify the appropriate access and delivery systems. He said that a recent Kaiser-funded survey

(Gordon et al, 1998), which found a very strong interest about CAM amongst Kaiser's members, patients, and physicians and clinicians, formed the basis of Kaiser's CAM strategy. Based on the survey, areas of modalities and conditions were identified in which to conduct systematic reviews. The systematic reviews, in turn, drive the activities of Kaiser's Education Committee, informs Kaiser's research agenda, and the consideration which CAM services to deliver. To be considered an appropriate for a specific condition, there must be reasonable evidence of safety and effectiveness. He, therefore, asked the Commission to recommend funding of organized systematic reviews in a coordinated fashion on specific CAM methods and by clinical conditions. He further suggested the need to increase research on clinical implementation of specific CAM treatments for specific conditions involving CAM practitioners and experienced researchers.

Panel Discussion

Commissioners asked Dr. Goldberg: 1) which CAM services Kaiser is currently providing, 2) who fills the role of the gatekeeper for these services, 3) what the process is for generating consensus, and 4) to explain Kaiser's system for CAM education. Dr. Goldberg replied that Kaiser is integrating acupuncture as one component of its chronic pain delivery system and provides manual therapies through Kaiser's Physical Therapy Departments. He said that the role of gatekeeper depends on whether a service requires physician referral and whether a service is available on self or patient referral. Treatments for a specific clinical condition require a primary care physician referral, although

referrals can come from any specialist or any provider in the system. He said consensus was generated by the survey he mentioned, but members were not involved in reviewing the evidence. He added that Kaiser uses many different formats for imparting information on CAM, including in written summaries of the research, full practice guideline including the bibliographies and evidence tables, summaries of clinical information, and video conference presentations.

The Commissioners also asked panel members to make recommendations for improvements in labeling regulations for herbal and dietary supplements, and on licensing and credentialling. Mr. Hobbs recommended a "traditional medicines" category that would take into account the historical and traditional use of an herb and to better educate consumers how to use them. Dr. Gaby suggested that manufacturers be allowed to put the information on the known effects of nutritional supplements on the label so that it would greatly enhance both the effectiveness and the safety. Dr. Awang noted, however, that much of the information currently put on labels is unreliable. He said that the most useful information that can be put on labels is warnings against possible adverse effects or toxicity, and recommendations as to use. On the other hand, he agreed with Dr. Gaby that limiting claims about efficacy is problematic because many people are buying herbs and nutritional supplements for treating specific conditions and they need accurate information on efficacy. For example, he noted that Saw Palmetto is often labeled as promoting prostate health rather than as a treatment for symptoms of benign prostatic hyperplasia, which is what most people buy it for. Dr. Brannon agreed with Dr. Awang that there needs to be

added focus on potential adverse effects and not focus on those that do not have adverse effects. Finally, Dr. Goldberg said because it is such a long process to conduct randomized clinical trials on herbs for specific condition, to get relatively good answer questions more quickly, one can use epidemiologic data and other types of studies in the meantime.

Session III: Use of CAM for Selected Health Conditions

Substance Abuse/HIV-AIDS

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

Denise Drayton, a graduate of the ARRIVE training program, and currently a staff member at Exponents, testified that she was first introduced to CAM during detoxification for heroin addiction. Her treatment including conventional treatment methods along with acupuncture for stress and pain management, which she continued using on an outpatient basis. She said the ARRIVE program also taught her visualization and deep breathing meditation and she has been drug-free for 10 years as a result. She said that in her

community, however, CAM therapies are not readily available and even when it is, there a natural distrust of anything that is not traditional (i.e., conventional).

Cancer

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

Jeanne Andrews, a cancer patient, testified that 21 months ago she was diagnosed with Stage IV colon cancer, after which she underwent colon resection and six months of chemotherapy. She was first introduced to CAM when a friend recommended that she see massage therapist. After her oncologist gave her the book, Comprehensive Health Care, she read it and contacted its author, Dr. Jim Gordon [Commission Chairman] and began attending programs at Dr. Gordon's center. There, she learned deep meditation, visualization, and a number of other forms of relaxation and also began undergoing acupuncture and intensive medical Qigong at another center. She said she is currently

cancer-free and that she believes CAM treatments played a major role in her recovery. She said, however, there were a number of obstacles to her gaining access to CAM, including lack of insurance coverage and no central location for gaining credible information on CAM.

Heart Disease

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

Walter Czapliewicz, a 45-year-old participant in Dean Ornish's program for reversing heart disease, testified that he came to the program after having had three heart attacks

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

Hospice Care

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

Panel Discussion

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

The Commissioners asked Mr. Czapliewicz and Dr. Collins to make recommendations on how best to educate people of the benefit of lifestyle changes on the prevention and treatment of heart disease. Mr. Czapliewicz said that developing effective programs to educate people about what they are doing to their bodies through their diet is key. Dr.

Collins added that it is extremely difficult to get people to listen to lifestyle advice until they are faced with the reality of increased risk. He said, however, that the new emerging technology, such electron beam CT scanner that can detect plaque in peoples' arteries and veins and determine total plaque load may change that. He cautioned, however, that lifestyle changes can only affect heart disease if an artery has not been touched. "There is evidence that once an artery is touched, either through a stent or angioplasty, lifestyle cannot control it," he explained

Commissioners asked Mr. Josepher to elaborate on the ARRIVE program's efforts to reach out into the jails and prisons, and how such efforts may help prevent recidivism as well as prevent increasing illness from HIV, and if good studies existed that indicate there is a positive value of using CAM approached to help manage individuals in drug withdrawal. Mr. Josepher answered that ARRIVE does a substantial amount of outreach in the institutions in New York, primarily by engaging prisoners before they are released. Therefore, a whole new area that is being developed in addiction work with the criminal justice population is transitional planning, where the idea is to engage people in the institution and inform them of the various kinds of services that are available out in the communities. He added that most of the innovation and inroads that are currently occurring in addiction treatment are because of HIV and AIDS. In regard to research, Mr. Josepher said a Dr. Mike Smith from New York City, who developed auricular acupuncture has a substantial documentation on its effectiveness for managing drug withdrawal. However, he noted, that in the substance abuse field evidence of effectiveness

often does not mean very much because it is a field that still prefers to treat drug use primarily through incarceration.

Commissioners asked Ms. Drayton if there was a single, key ingredient that helped her the most and to suggest ways that the Public Health Service and other agencies can get the message out to the African-American community that CAM is not necessarily second-rate medicine

Ms. Drayton answered her first contact with ARRIVE gave her a newfound sense of self-worth and spirituality, which then led her to the use of acupuncture. She said that the most influential way to deliver health messages in her community is through peer education. "If it is coming from someone who has experienced it and has a working knowledge of it through first-hand experience, they tend to believe it," she explained. Mr. Josepher added that although race is sometimes a barrier, if teachers had information and have conviction, they can transcend those barriers.

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

Session IV: Issues in Integrating CAM in Service Delivery

Richard B. Miles of Health Frontiers testified that 30 years ago he began organizing and managing major conferences on CAM, including the first national symposium on acupuncture at Stanford in 1972. He said the prevailing attitude of our conventional medical system has been that when an individual presents with a disease, they are essentially ill and need to be made well with interventions. There is an emerging perspective, however, that people are essentially well and need to be made ill. If one can get the factors that are contributing to this illness out of the way, the system will heal itself. He said that he is currently working with organizations and programs that are trying to develop this particular kind of concept. Mr. Miles said that doctors should be better listeners and to help people reestablish connections with nature and allow the diseases of this culture to heal themselves rather than try to fix them.

Berkeley Bedell, former congressman from Iowa and current president of the National Foundation for Alternative Medicine, testified that he believes the Commission has a genuine opportunity to make a difference. He said that 3 years ago, he and his wife formed the National Foundation for Alternative Medicine to conduct CAM field trials that NIH was unwilling to conduct itself. He said the Foundation currently is focused on cancer treatments and is sending teams led by a medical doctor to visit alternative cancer clinics and go over their patient records. He said the foundation is finding clinics in Europe

administering low-cost, non-toxic cancer treatments with success that would not be expected at major cancer clinics here in the United States. He, therfore, pleaded with the Commission to recommend passage of The Access to Medical Treatment Act, which would make it possible for these non-toxic treatments to be tried under strictly controlled circumstances. He also said the Commission should recommend that any medical treatment that has been in use in another country, where there is no evidence of it posing a danger to the patient, to be allowed here in the United States.

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

Panel Discussion:

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

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

Commissiors then asked Mr. Bedell to elaborate on his proposal to allow acceptance of use of therapies that have been shown to be relatively safe in other countries. He replied that because there are not good treatments for most degenerative diseases, people with such

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

Session V: Meeting Public Needs/Systems of Delivery

<u>Private Practice Integration</u>:

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

arts. He said that complementary medicine offers the Federal government an opportunity to solve its most pressing health problem: controlling spiraling health care costs.

Nursing Integration of CAM:

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

Stand-Alone CAM Center:

Mort Rosenthal, chairman and founder of Well Space, a for-profit CAM clinic, said that Well Space has been open in Cambridge Massachusettes for 27 months. It has 21 treatment rooms, 70 practitioners, and offers massage, acupuncture, Chinese herbs, chiropractic, naturopathic medicine, and nutritional classes. To date, the clinic has served approximately 10,000 patients and will take in approximately $2 million year, a very small amount of which is profit. He said 45 percent of the Well Space visits are related to stress or the need for relaxation. The rest of the condition range form headaches, back and neck pain, sleep disorders to fibromyalgia, fatigue, and cancer. He emphasized that Well Space

is complementary, not integrated, and that Well Space's patients, for the most part, are not interested in integrative care. He said that in more than 40,000 visits, no patient has asked to have information sent back to their conventional physician. He added, however, that Well Space has an excellent relationship with local physicians, whom often give them informal referrals, as opposed to a traditional referral. He said that in a recent six-month pilot study, among 2,000 people who essentially offered free CAM care without referral, 70 people took advantage of the program and 50 of those, or 71%, continued their care even though they now had to pay out of pocket. From a policy perspective, he said he believes that the delivery system for CAM will continue to be largely stand-alone. He suggested that any policies that are made should not be biased in favor of full integration.

Panel Discussion:

Commissioners asked Dr. Atkins to describe some of the obstacles he faced in setting up and implementing his practice. He answered that there were many areas that they believed their methods were getting good results, but that the insurance companies would not reimburse for them. For example, he said, he and his colleagues often use a high resolution microscope for diagnosing the presence of various bacteria, yeasts, and parasites, but that they could not get reimbursed for the use of this expensive equipment because there was not an insurance code for it. He added that very few of the cancer treatments he and his colleagues use as alternatives to chemotherapy and radiation are eligible for insurance reimbursement. Furthemore, he said that he and his colleagues us a number of treatments that have been approved in Europe but that have not been approved here in the U.S. for

various conditions that are not being reimbursed. The solution to all of these obstacles is to fund the kind of research that will allow everyone to see the two systems of medicine—conventional and CAM--compared side by side with a matched group of subjects to determine which gets better results and at lower costs.

The Commissioners asked Mr. Rosenthal: 1) what Well Space was doing to increase access for low-income people; 2) if it has an approach for improving the dissemination prevention materials; 3) why more people didn't take advantage of its pilot program; 4) why Well Space chose to be complementary rather than integrative; and 4) to make recommendations for research. Mr. Rosenthal said Well Space does provide discounts to needy patients but that its prices are fairly inexpensive already. In terms of prevention information, he said that there are great deal of preventive CAM and non-CAM treatments that are not reimbursed, so reimbursement of these approaches certainly would enhance their access and delivery. Although the pilot program was not a great success, it was still worth trying. He said that education is key because the people who know about CAM seem willing to pay for it and those who don't know much about it are not willing to pay for it. In terms of Well Space's model, he said there were three basic reasons that Well Space chose to be complementary rather than integrative: 1) concerns that physicians would be reluctant to treat CAM practitioners as equals; 2) there are several other clinics who have physicians in their models and they have not done too well; and 3) in order to be profitable, Well Space did not want to spend too many resources dealing with issues of reimbursement and the other problems inherent in a traditional health care system. In terms of research,

he said that Well Space has more than 40,000 computerized records that should be useful for research purposes.

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

(Session V Continued)

<u>Community Based Center</u>:

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.

<u>Hospital-Based Center</u>:

Sylver Quevedo, M.D., Director of the Center for Integrative Medicine at the O'Connor Hospital in San Jose, California, testified that he believes integrative medicine is THE MEDICINE of the future. Any hospital not considering an integrative approach will be seen as obsolete within 10 years from now, he asserted. On the other hand, programs that take a proactive and serious look at integration will have a competitive advantage. Indeed, integrative medicine offers advantages over the narrow biomedical model of care because it takes seriously the notion that culturally appropriate care in our increasingly pluralistic society is a necessity rather than an afterthought. He said that although there was initially resistance from the hospital medical staff, which was due primarily to unfamiliarity with

CAM, once the dialogue began, such resistance largely disappeared. Now, the hospital medical staff are asking the Center to organize a department of integrative medicine to bring these therapies into the in-patient setting.

Integrated Academic Centers:

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

care providers, and, by doing so, it actually allows for many of these patients to come back into the traditional medical care model.

Panel Discussion:

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

The Commissioners asked the panel about funding strategies that would facilitate integration and whether they believed they were at an economic disadvantage compared to other CAM stand-alone models. Dr. Merrell said he thinks it is very difficult for these types of centers to exist without private funding and government grants, because it is very

difficult to make money for the first three years of operation. He added that his Center is lucky because Beth Israel made the development of integrative medicine an integral part of it mission statement. By doing this, the Center gained access to the hospitals donor lists and the development office resources. Dr. Quevedo said that being associated with a hospital increases the value of what his Center is doing because it increases their visibility but is also adds additional burdens because of the heavy overhead and administrative costs inherent to being part of a hospital system. He said that for many reasons, however, his group decided against developing a proprietary model for its center. Mr. Trumpeter said having both conventional and CAM modalities under one roof has been a big boost for his program. He added that his group developed a rather elaborate protocol for informing patients of their options and their choices and ways of making sure that people knew what they wanted. However, he said they gave it up because people absolutely knew what they wanted to choose. Dr. Merrell added that the quality of the practitioners is key to success.

(Session V Continued-Reimbursement)

<u>Oxford Health Plan</u>:

James Dillard, M.D., said that in the mid-1990s, he was asked by Oxford Health Plans to help build a comprehensive CAM program inside the insurance company. To date the program has credentialed almost 3000 CAM providers in six areas. Although the program has, in many ways, been successful, the company had some financial challenges at the end of 1997, which has led to an incomplete experiment in building a CAM program. Oxford has had very remarkable financial turnaround recently. However, the widespread

financial problems that have occurred throughout the managed care industry, making it a challenge to build these kinds of programs within a managed care environment. In terms of integration, he said there are a number of barriers, including resistance on the part of the physicians, resistance on the part of the CAM practitioners, and resistance on the part of patients. He said that many patients simply do not want their primary care physician to know that they are seeing a CAM practitioner and, thus, often are resistant to having their records shared by both their conventional and CAM physicians. Overall, he said, it is appropriate to create access to the therapies that are considered to be safe. However, reimbursement should only be embraced those therapies that have strong evidence supporting their effectiveness.

Highmark Blue-Cross/Blue-Shield:

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

average of 22 points); and a 10% reduction in body. Most importantly, there has not been a single heart attack or death since 1997, when the program was implemented. There has been only one bypass surgery, one stroke, and four angioplasties among these 400-plus very high risk patients. Moreover, there has been a cost saving of $17,000 per patient, which translates into a little over $8 million in savings for the entire group of patients. As a result, Highmark has started a new company, called Lifestyle Advantage, to significantly influence the way heart disease is managed and financed in this country. She asked the Commission to: 1) continue to support scientific investigations into CAM treatments to help separate what is effective from what is not; 2) promote proven CAM interventions to the public; and 3) influence health plans to reimburse for evidence-based CAM interventions.

<u>Washington State Office of Insurance</u>:

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

Panel Discussion:

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

generally considered to be the most generous payer in the Mid-Atlantic, so consequently there hasn't been much of a problem in terms of limiting access.

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

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

(Session V Continued—CAM Systems of Medicine)

Ayurvedic Medicine:

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

the Commission to recommend Federal grant to educational institutions of higher learning for the training of Vedic medicine practitioners.

Naturopathic Medicine:

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

Traditional Chinese Medicine:

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

Panel Discussion:

The Commissioners asked Mr. Duggan to elaborate on his comments about the regulation

of herbal therapies as well as his proposal about educating people about wellness and lifestyle choices. Mr. Duggan replied that he believed it was wrong to turn plants into products. He said the policy issue for the Commission would to look at ways restore an awareness of plants as healing and then begin to define where is that line between what is food and what is medicine and must be professionalized. That is why he believes there needs to be a separate agency from the FDA to address the questions about herbs differently that it is currently being dong. Mr. Duggan said that education about wellness and healing needs to start from the first grade, by teaching children an awareness of breathing, of drinking, of sleeping, of eating. He added that there need to be incentives for people to learn how to take care of themselves.

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

Session VI: CAM Integration in Existing Delivery Systems

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

Milton Hammerly, M.D., of Catholic Health Initiatives (CHI), said that the system he represents encompasses more than 100 facilities in 22 states, employing more than 75,000 people. He said the incorporation of CAM services into this system has been an evolutionary process, beginning with a steering committee consisting of CAM proponents Early on, there was a steering committee, but now there is a more heterogeneous cross-section of the organization involved, including skeptics. He said CHI now has unanimous organizational buy-in and support of the philosophy of integration. He said the essence of CHI's philosophy, which is to provide comprehensive mind-body spirit care which personalizes care and which has to be, of necessity, collaborative. He said, however, CHI faces a number of barriers in integration. The first is research. CHI has not been successful in accessing research funding, which seems to be mostly finding its way to academic centers, he said. In an effort to remedy this, CHI have approached pharmaceutical companies with synergistic combinations of supplements and pharmaceuticals which are, in fact, patentable, providing an incentive for them to want to pay for the research. Another barrier is the issue of reimbursement. He said, however, that reimbursement is only a barrier because the system is still trying to put the new clinical model of integrative health care in the old reimbursement model. He said clinicians can have far greater impact by working together as an orchestra than they can by practicing as individuals. He said that the Commission, by helping to break down the barriers to collaboration as well as the barriers to reimbursement in clinical areas, can actually help lead that orchestra.

Panel Discussion:

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

Commissioners asked Dr. Hammerly if CHI has any ongoing data monitoring program

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

Public Comments:

Francine Butler, Executive Director of the Association for Applied Psychophysiology and Biofeedback, said that biofeedback is one of the most well-established of the CAM therapies, and here is a large body of scientific work demonstrating its treatment efficacy without adverse side effects. She said largest problem with access and delivery of biofeedback is denial by third-party payers because biofeedback is still branded as experimental. Nancy Dolores Kolenda, Director of the Center for Frontier Sciences at Temple University, said that it is important that the major medical schools and research centers throughout the United States have access to funding to set up models to study various CAM therapies, such as herbal medicine and homeopathy and acupuncture. Because our nation's major medical schools are facing critical financial crises, they are now more open now than ever to incentives to advance the research in CAM. Diana Chambers, of Friends of Health, said "whole person healing" as best describe most CAM practices, which primarily focus on prevention, wellness, and health. She said that Friends of Health wants the Commission to focus carefully on issues of language and philosophy of CAM as well as access and delivery issues for the poor, both urban and rural. Rustrum Roy, a representative of the University of Arizona Program for Integrative Medicine, said there are three primary communities that need to have better access to knowldege about CAM: 1) the approxmately one-half million practicing physicians, 2) academic research scientists, and 3) the general attentive public. He said there is a need for an emergency, crash education program for these groups. Bruce Nordstrom, on behalf of the American

Chiropractic Association, encouraged the Commission to focus on wellness and to recommend policies for reimbursing CAM providers for health promotion. He said a good example of how prevention is cost effective can be found in an HMO in Illinois called Alternative Medicine, Inc., (AMI), which utilizes doctors of chiropractic as traditional gatekeepers and has reduced the rate of hospitalization for its members by about 75 percent. Neal Barnard, President the Physician's Commission for Responsible Medicine, said that nutrition is the most fundamental medical treatment, and esearch proves that when patients change their diets, in combination with other lifestyle changes, they can reduce cholesterol levels, reverse heart disease, improve and sometimes even cure Type II diabetes, and hypertension. He recommended that the Commission promote initiatives to integrate nutrition into the core curricula at American medical schools, encourage the Public Health Service issue grants for research on the effects of vegetarian and vegan diets for a number of chronic illnesses, and encourage the Department of Agriculture review of federal policies that conflict with healthy nutritional goals. Doreen Chen, chair of the Chinese Medicine Advisory Council of the American Association of Oriental Medicine, said that integrative medicine is the future of medicine and asked that the services rendered by an Oriental Medicine physician be covered by any health insurance, both Federal or private. Gary Sandman, founder of a community-based alternative medicine referral service in the Washington, D.C., area, said CAM tends to teach empowerment, and individuals that are empowered tend to heal. He said there needs to be a 20-year plan to

integrate conventional medicine into patient-centered, whole-person health care. Danny Freund, a cancer survivor, said he has tried many CAM therapies in the course of his recovery and now teaches a course on CAM. He said there is a great deal of information on CAM but there is no central source on information to help people decide how to find and interpret it. Melinna Giannini, Director of Alternative Link, said that her company has developed about 4,000 codes that describe what is said, done, ordered, prescribed, or distributed by alternative care practitioners, and each one of these codes has a relative value unit attached to it so that a rate can be developed for each procedure. She asked that the Commission promote the incorporatation of this code into Federally funded CAM research so that cost-effective CAM treatments can be identified as a solution to escalating health care expenses, especially where these procedures could have an impact on Medicare/Medicaid recipients. Jane Hersey, Director of the Feingold Association, said that a the Feingold Association show families how to reduce or eliminate many behavior, learning, and health problems in their children by eliminating synthetic dyes, artificial flavors, and certain preservatives from their diet. Despite the potential of this healthy option to help medical and social problems, and despite all of the supporting evidence, it is opposed, ignored, or misrepresented by Government agencies and professional organizations that should embrace it. She asked that the Commission urge the National Institutes of Health and the Department of Agriculture to conduct new research on the efficacy of the elimination diet. Boyd Landry, Executive Director of the Coalition for

Natural Health, said the Commission needs to seize the opportunity "to look outside the box," rather than looking at ways to fit CAM inside the box. He said the Commission should focus on what consumers want, not what practitioners want. He, therefore, urged the Commission to seek out consumer input. Lawrence A. Plumlee, M.D., President of the National Coalition for the Chemically Injured, said there is a great need to conduct research on the role of toxic chemicals in syndromes, such as multiple chemical sensitivities, auto-immune diseases, fibromyalgia syndrome, and chronic fatigue syndrome. Currently, he said, patients with these conditions are subjected to dangerous and ineffective psychiatric drugs which prolong the illnesses, because the causes are not recognized and eliminated. There also is the need for research to investigate the role of nutritional supplements in enhancing improved metabolic function in these syndromes. Another area requiring scientific research and better medical education is the induction of mild immunodeficiency by some toxic chemicals with resultant super infections by viruses, bacteria, parasites, and fungi. Appropriate diagnosis and treatment of these infections will enable substantial gains in health. Michael John Rohrbacher, Director of music therapy at Shenandoah University in Winchester, Virginia, said that music therapy is the use of music in the accomplishment of therapeutic gains, the restoration, maintenance, and improvement of mental and physical health. He said there are over 3,700 individuals currently hold American Music Therapy Association membership, and mationwide, there are 69 undergraduate music therapy programs, 25 graduate programs, and 159 internship

sites approved by AMTA. Andrew Rubman, of the American Association of Naturopathic Physicians, said the present needs of our citizens and the enormous body of emerging medical information leaves us no choice but to produce a better model of health where no one approach to medical care is forced to stand in judgement of others. He said that incorporating naturopathic medicine as a guiding principle to help shape and implement the new medicine will allow our citizens to become better, more objective consumers, limiting high-priced procedures and pharmacy by increasing their wellness and thereby avoiding disease. Marshall Sager, President-elect of the American Academy of Medical Acupuncture, said that medical acupuncture, which is the practice of acupuncture by fully trained and licensed physicians, falls within the scope of the practice of medicine. The fact that most health care plans do not reimburse for physician acupuncturists services has forced patients from their primary medical care providers and out of the health care system. Medical students and physicians must be educated about the use and effectiveness of all complimentary medical modalities, especially medical acupuncture and must understand that medical acupuncture is not a threat to their practice. Diana Miller, an attorney, said she is committed to research, education, and designing laws that take away the legal barriers for consumers for access to alternative health and other kinds of health care that they deem necessary for their healing. She said the current system is disempowers consumers, and anything that disempowers consumer makes healthcare more expensive and impedes wellness. She said the exception is the State of Minnesota, which believes

consumers have the right to access any person or treatment they deem helpful to bringing them to full health. Courtney Banks, a former Hodgkin's Disease patient, said that CAM saved her life. After radiation therapy, she began exploring and using acupuncture, eating only organic fruits and vegetable and whole foods, and using homeopathy. She said she has never felt healthier, had more energy, and a more positive outlook. Richard Pavek, from the Biofield Research Institute, said that he was concerned that the movement toward integration would disenfranchise alternative practitioners who are not doctors. He said that every alternative practice, teaching, method, or philosophy was developed outside of conventional medicine. He recommend that alternative practitioners be enfranchised with as much legal right to practice as possible.

Session VII: Commissioners' Discussion:

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

Commissioner Bresler said that another recurring theme appears to be the need for early education the let people know two things: first, what are they doing that is deleterious to their health, and second, what they can do in order to enhance and improve their health. Commissioner Gutierrez said that it would be helpful for her to know what is the intent and purpose of each provider group. Commissioner Rolin emphasized that the Commission needs to focus on those that aren't being served, such as Indian tribes living on reservations, because she said those are areas where CAM can make vast improvements within the communities. Commissioner Kerr said that in the future she would like to hear from agencies and organizations that may be impacted by the Commission's recommendations, such as the Department of Agriculture or a Fortune 500 company or a pharmaceutical company or public health people. She said such agencies and companies are willing to help and want to be called to service. Commissoner Chow said that the Commission is talking about more than health care but also about lifestyles. She agreed that the conversation needs to be expanded and more skeptics included. She added that new paradigms and spiritual issues also needed to be considered. Commissioner Fins endorsed Commissioner Kerr's comments and added that he there needs to be a broad articulation of principles that will set the agenda for the next 20 years, in addition to concrete recommendations. He also said that the Commission needs a better sense of the sociology of CAM and to consider the mechanisms and agencies and collaborations that

will allow dialogue to continue when the Commission is no longer around. Commissioner Paz said that as culture here in the U.S. becomes more and more diverse it will be necessary to continually expand the list of potential CAM therapies. Commissioner Bernier said the time is ripe to take a major step in integrating CAM. Nevertheless, there remain a number of issues, including guaranteeing the safety and efficacy of treatments of all types. One of the problems, he said, is that the term "CAM" means so many different things, and many CAM disciplines are not necessarily eager to see themselves integratied with convetional medicine. Chairman Gordon suggested that the Commission should begin to dialogue more with the conventional medicine community, particularly the American Medical Association and the American Association of Medical Colleges. Commissioner Bernier agreed to help begin the dialogue with those groups. Commissioner Scott said she would like to see many more African-Americans both as panelists and speaking in the open debate, because she saw it as a real "gap." She also was concerned that CAM is often viewed a second-class medicine for conditions affecting people who are not valued in the community. Commissioner DeVries encouraged the Commission to create recommendations tcan be applied to multiple tracks, regardless of which way our country moves forward with its health care policy. Commissioner Low Dow said that there have to be social policies in place that allow for healthy communities and healthy families and healthy children. She said that as the Commission discusses various issues, she hoped it didn't lose track of the bigger issues. Commissioner Fair expressed concern that there was

a great need for education but that the Commission had heard nothing concrete about how to increase education. He said the Commission should stress the develop of plan for universal health education. By educating people universally, the personal, family and community improvements will follow, he said. Chairman Gordon reminded the Commission that the next two meetings were going to focus primarily on professional education and on public information, which includes education in the schools and in other places. Commissioner Jonas added that the most effective use of resources may be health care advertising, maybe even more than education. He added that the two types of activities that can lead to more specific items that deal with wellness are the area of health support and health promotion. He added that a focus on accountability was also necessary, including accountability of care and services on the part of the CAM providers. Commissioner Low Dog agreed, saying that she hopes the Commission looks at access as givng people the freedom to seek the practitioners they want as long as there is some type of accountability.

Commissioner Chappell added that he would like to see a focus on bringing health promotion and health support to the public in an affordable way. He said his concern about the discussion on reimbursement is that it is not in the control of the consumers' hands. So affordability is the language to use as a goal to try to get that. Commissioner Tian said the Committee has to make sure that it adequately defines the CAM modalities what it is considering. It also needs to answers three important questions: where we are;

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

Selected References:

Astin JA, Marie A, Pelletier KR, et al. A review of the incorporation of complementary and alternative medicine by mainstream physicians. *Arch Intern Med* 1998; 158(21):2303-10

Astin JA. Why patients use alternative medicine. *JAMA*. 1998;279(19):1548-1553.

Berman BM, Singh BK, Lao L, et al. Physicians' attitudes toward complementary or alternative medicine: A regional survey. *J Am Board Fam Practice*. 1995;8:361-366.Berman BM, Singh BB, Hartnoll SM, et al. Primary care physicians and complementary/alternative medicine: Training, attitudes, practice patterns. *J Am Board Fam Practice*. 1998;11(4):272-81

Eisenberg DM, Davis RB, Ettner SL, et al: Trends in alternative medicine use in the United States. *JAMA*. 1998;280:1569-75.

Eisenberg DM, Kessler RC, Foster C, et al. Unconventional medicine in the United States: Prevalence, costs, and patterns of use. *N Engl J Med*. 1993;328:246.

Field T, Schanberg SM, Scafidi F, et al. Tactile/kinesthetic stimulation effects on preterm neonates. Pediatrics 1986; 77:654-658.

Gordon NP, Sobel DS, Tarazona EZ. Use of and interest in alternative therapies among adult primary care clinicians and adult members in a large health maintenance organization. West J Med. 1998; 169(3):153-61.

Institute of Medicine, Food and Nutrition Board, Committee on Nutrition Services for Medicare Beneficiaries. The Role of Nutrition in Maintaining the Health of the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population. National Academy of Sciences, 1999.

Linde K, Clausius N, Ramirez G, et al. Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. *Lancet* 1997; 350(9081):834-43.

Ornish D, Scherwitz LW, Doody RS, et al.Effects of stress management training and dietary changes in treating ischemic heart disease. *JAMA* 1983;249(1):54-9.

Ornish D, Scherwitz LW, Billings JH, et al. Intensive lifestyle changes for reversal of coronary heart disease. *JAMA* 1998;280(23):2001-7.

Paramore LC. The use of alternative therapies: Estimates from the 1994 Robert Wood Johnson Foundation National Access to Care Survey. *J Pain Sympt Manage.* 1997;13(2):83-89.

World Health Organization. The promotion and development of traditional medicine. In *Report of a WHO Meeting. Technical Report Series 622.* Geneva: World Health Organization; 1978.

Specific Recommendations from December, 2000, WCCAMP Meeting

Panel 1: Clinical and Cost Effectiveness of Selected CAM Services

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

- Institution 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**)

- 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**)

- 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**)

- Require the FDA to recognize a "trad itional 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**)

- 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**)

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

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

Panel 2: Use of CAM for Selected Health Conditions

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

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

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

- 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**)

Panel 3: Issues in Integrating CAM in Service Delivery

- 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)**

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

- 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)**

- 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)**

Panel 4: Meeting Public Needs/Systems of Delivery

- The Federal government should use the investigation of CAM as an 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.,)**

- 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)**
- 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)**
- 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)**

- 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)**

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

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

- 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**)

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

- Allow certified Vedic practitioners should be allowed to practice in their areas, 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**)

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

- 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**)

- 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**)

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

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

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

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

Panel 5: CAM Integration into Existing Delivery Systems

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

- 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**)

Public Comment:

- 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**)

- Establishment an emergency, "crash" educ ation 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**)

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

- 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 vean 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**)

- 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**)

- The development of 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)**

- 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)**

- 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)**

- 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)**

- **Specific Recommendations from February, 2001, WHCCAMP Meeting**

Plenary Session I: CAM Education and Training: Establishing Educational Programs

Panel 1

- There needs to be a greater emphasis on CAM educational standards to make them consistent across diverse regions and states. **(Dr. Louis Orzack, Rutgers University)**.

Panel 2

- The creation of an easily accessible, evidence-based data resource on CAM therapies designed for educators and clinicians. **(Geraldine Bednash, American Association of Colleges of Nursing)**

- The development of a generic curriculum for health professionals on complementary and alternative therapies and the skills necessary to assess their use by patients and their families with an emphasis on the therapeutic relationship and interpersonal skill development **(Geraldine Bednash, AACN)**

- A source for consumers that provides accurate and timely information about complementary and alternative therapies. **(Geraldine Bednash, AACN)**

- Continued federal support for research to assess CAM therapies to develop the evidence base for practice . **(Geraldine Bednash, AACN)**

- A communication vehicle for health professionals to provide a consistent stream of information on these therapies **(Geraldine Bednash, AACN)**

- A train-the-trainer initiative to provide faculty and nursing or other health professions' education programs with the skill to teach the future clinician about these therapies. **(Geraldine Bednash, AACN)**

- Continuing CAM education for practicing nurses and other health professionals. **(Geraldine Bednash, AACN)**

- The Federal Government should become involved in convening medical education leadership conferences, encouraging the development of standards of CAM education, and positioning Titles 7 and 8 as vehicles for faculty development and curriculum development initiatives. **(Neil Sampson, of the Health Resources and Services Administration)**

- a minimum levels of post-graduate education should be required for all non-allopathic and non-osteopathic physicians, which leads to state certification or licensure. **(Neil Sampson, HRSA)**

- Stricter licensing and controls among CAM practitioners. **(Neil Sampson, HRSA)**

- Increase federal funding for both research on the efficacy of CAM and an educational initiative on both CAM and evidence-based medicine. **(Sara Collina, National Breast Cancer Coalition)**

- Consistent educational standards for CAM practitioners and accountability within the licensing and credentialing process. **(Sara Collina, NBCC)**

- National standards for CAM health care that are comprehensive, evidence-based, updated regularly, and accessible to everyone. **(Sara Collina, NBCC)**

Plenary Session II: Continuing CAM Education and Training: Building Knowledge and Skills

Panel 1

- Endorse medical acupuncture's current training, credentialing and accountability system. **(Joseph Helms, American Academy of Medical Acupuncture)**

- Develop "exposure programs" on medical acupuncture for medical students, residents, fellows and practicing physicians in all specialties of medicine. **(Joseph Helms AAMC)**

- Greater recognition of Oriental Medicine's level education, training, licensure and certification infrastructure, and its status as a comprehensive medical system that should be accepted into the greater "the health care team." **(Lixing Lao, Maryland Institute of Traditional Chinese Medicine)**.

- Reimbursement for acupuncture delivered by Oriental Medicine practitioners by Government programs including Medicare and the military. **(Lixing Lao, MITCM)**

- A basic understanding of acupuncture and its ability to complement conventional treatment among conventional health care professionals. **(Lixing Lao, MITCM)**.

- All health care professionals receive some form of medical education in herbal therapies. **(Mark Blumenthal, American Botanical Council)**

- Course materials on herbal remedies should include the history of botanical medicines and how it fits in the history of pharmacology. Information on the regulation of herbal medicines also needs to be included as many health care practitioners are misinformed or ignorant about the regulation or under-regulation of herbal medicines. **(Mark Blumenthal, ABC)**

Panel 2

- The development of a national core curriculum for CAM so there would be a more standardized body of knowledge. **(Denise Edwards, Oncology Nursing Society)**

- Nursing education in CAM should be foundational at the undergraduate level, with opportunities for developing more sophisticated skills at the graduate level. It should also be interdisciplinary. **(Denise Edwards, ONS)**

- For practicing clinicians, it is essential to include information in professional continuing education and financial barriers to CME need to be considered. (Denise Edwards, ONS)

- CAM practitioners and educators should be involved in creating sources of complete information on herbs and drug interactions. **(Denise Edwards, ONS)**

Plenary Session III: CAM Credentialing and Licensure: Assuring Quality and Accountability in CAM Practice

Panel 1

- Articulate the following five principles to help guide states in developing regulations: (1) many providers want licensure to gain legitimacy and avoid criminal liability under medical license laws; (2) licensure is largely a matter of state law--states rely on the professional organizations to set standards and structures; (3) licensure has a potential dark side, in terms of diminishing the heart and soul of CAM practice; (4) several licensed CAM professions may share legal authority to practice a given modality; and (5) adopt one of several different models for licensing CAM providers based on the state's interest: (a) mandatory licensure, (b) title licensure, (c) registration, (d) exemption, (the Minnesota model), or (e) some variation or combination of the first four. **(Michael H. Cohen, Center for Alternative Medicine Research and Education)**

- Increased education for conventional medical practitioners about CAM, both to encourage collaboration in patient care and to avoid possible adverse effects caused by treatment interactions. **(Sharon Hall, Washington Casualty Company)**

- State licensure or certification of CAM practitioners to regulate and provide a common standard of practice. **(Sharon Hall, WCC)**

- Evidence based research to promote the safety and efficacy of CAM therapies. **(Sharon Hall, WCC)**

- Evidence-based research to promote the efficacy and safety relative to conventional therapies. **(Sharon Hall, WCC)**

- Confidential, nondiscoverable CAM quality improvement and peer review research to enhance the quality of care. **(Sharon Hall, WCC)**.

Panel 2

- Define massage in the broadest terms possible, while being cognizant of legislator sensitivities and other professions that overlap massage therapy. **(Steven C. Olson, American Massage Therapy Association)**

- Consider CAM in terms of the two goals contained in the Healthy People 2010 report: longer years of healthy life and the elimination of health disparities. **(Clement Bezold, Institute for Alternative Futures)**

- Develop controlled clinical trials to evaluate the efficacy and safety of CAM therapies, as well as information sharing resources and educational initiatives to further enhance the awareness of the benefits and/or risks associated with such therapies. **(Dr. James Winn, Federation of State Medical Boards)**

- Research and educational efforts to identify and eliminate questionable and deceptive health care practices, whether they are traditional or alternative, and those practices that are adverse to the public's health, safety, and welfare. . **(Dr. James Winn, FSMB)**

Public Comment

- The creation of a federally sponsored task force whose principal goal would be to ease access to existing data, coordinate the creation of new databases on a collaborative basis, and set standards for data including an exchange specifically in the field of CAM. **(Robert Scholten, Beth Israel Deaconess Medical Center)**

- A joint NSF/Public Health Service/Dept. of Education entity to provide funding for public education on CAM practices. **(Rustom Roy, Penn State University)**.

- Use the Minnesota model, which provides patients was extensive information and binds practitioners to safe and professional conduct, as a way of giving consumers access to all healers, unlicensed and licensed, in a safe manner. **(Diane Miller, National Health Freedom Coalition)**

- Seek out natural medicine professional associations that are working on developing standards for training and care. **(Susan Herschkowitz, natural medicine advocate)**

- Develop a system of "harmonized standards," which have proved successful in Europe, to achieve some minimum acceptable standards and allow the states would develop their own versions. **(Michele Forzley, a private-practice attorney)**

- For CAM telemedicine, utilize the International Treaty on Telemedicine of the International Bar Association, which seeks to set harmonized standards internationally, as a model for setting standards so that medicine can be practiced electronically. **(Michele Forzley, a private-practice attorney)**

- Establish programs to teach CAM practitioners how to run a business. **(Michele Forzley, a private-practice attorney)**

- Establish educational licensing that allows for vocational schools, degree programs, and apprenticeship training in naturopathy, which should not come under the stringent guidelines employed by higher education facilities. **(Victoria Mary Goldsten, Washington Institute of Natural Health)**

- Create a committee or task force that brings together educators and practitioners to develop a set of clear and consistent guidelines for CAM education programs. **(Emily WhiteHorse, Association for Physician Assistant Programs)**

- Formal recognition of chiropractic as a health care paradigm that enhances performance and function. **(Brian McAulay, Sherman College of Straight Chiropractic)**

- Loans and debt relief for chiropractors who practice in underserved areas or caring for underserved populations. **(Brian McAulay, Sherman College of Straight Chiropractic)**

- Federal funds to support chiropractic facilities, training, and technology. **(Brian McAulay, Sherman College of Straight Chiropractic)**

- Allocate Federal funds for chiropractic college-based research programs. **(Brian McAulay, Sherman College of Straight Chiropractic)**

- Hold all CAM providers to equivalent criteria as other licensed health care providers in the areas of education, licensure, oversight from licensing boards, and public opinion. **(Bruce Nordstrom, chiropractor)**

- Maintain the principles of each CAM practice and do not supplant them with allopathic philosophy. **(Bruce Nordstrom, chiropractor)**

- Provide CAM providers with direct access to patients so that they can diagnose and refer to and/or co-manage the patient's treatment if the condition is beyond the scope of their expertise. **(Bruce Nordstrom, chiropractor)**

- Provide opportunities for students studying at accredited CAM institutions to observe and, where appropriate, co-manage a broad spectrum of conditions and/or diseases as is typically seen in teaching hospitals. **(Bruce Nordstrom, chiropractor)**

- Provide students from any accredited institution, traditional or CAM, the opportunity to broaden their knowledge and clinical expertise. **(Bruce Nordstrom, chiropractor)**

- Develop CAM guidelines, whether condition- or modality-specific, through consensus by the profession, and reflect mainstream practices.Guidelines should not be treated as absolute limitations on services. Practitioners should be the ultimate arbiters of what is necessary. **(Bruce Nordstrom, chiropractor)**