

The White House Commission on Complementary and Alternative Medicine Policy

Meeting on the Coordination of Complementary and Alternative Medicine (CAM) Research: Achievements, Opportunities, Obstacles, and Solutions

Department of Health and Human Services

October 5 and 6, 2000

Attendees

Commission Members

James S. Gordon, M.D., The Center for Mind-Body Medicine, *chair*
George M. Bernier, Jr., M.D., University of Texas Medical Branch
Thomas Chappell, Tom's of Maine
Effie Poy Yew Chow, Ph.D., R.N., East West Academy of Healing Arts
William R. Fair, M.D., Sloan-Kettering Cancer Center
Joseph J. Fins, M.D., F.A.C.P., Weill Medical College of Cornell University, New York
Presbyterian Hospital
Wayne B. Jonas, M.D., Uniformed Services University of the Health Sciences, School of
Medicine
Charlotte R. Kerr, R.S.M., Traditional Acupuncture Institute, Inc.
Tieraona Low Dog, M.D., A.H.G.
Dean Ornish, M.D., University of California, San Francisco
Conchita M. Paz, M.D.
Julia Scott, National Black Women's Health Project

Staff

Stephen C. Groft, Pharm.D.
Michele M. Chang, M.P.H.
Joseph M. Kaczmarczyk, D.O., M.P.H.
Doris A. Kingsbury
Geraldine B. Pollen, M.A.

Panelists

Teri Ades, R.N., American Cancer Society
Mark Blumenthal, American Botanical Council
Randy Burkholder, Advanced Medical Technology Association
Daniel Callahan, Ph.D., The Hastings Center
Marvin Cassman, Ph.D., National Institute of General Medical Sciences
Paul Coates, Ph.D., Office of Dietary Supplements
Elaine Cramer, M.D., Ph.D., Centers for Disease Control (*by telephone*)
John G. Demakis, M.D., Veterans Affairs

Annette Dickinson, Ph.D., Council for Responsible Nutrition
David Dorsey, JD, Food and Drug Administration
Daniel D. Federman, M.D., Harvard Medical School
David W. Feigal, Jr., M.D., M.P.H., Food and Drug Administration
Alfred P. Fishman, M.D., University of Pennsylvania School of Medicine
Nicholas Gonzalez, M.D., private practice
Steven J. Hausman, Ph.D., National Institute of Arthritis and Musculoskeletal and Skin Diseases
Dyanne M. Hayes, Conrad N. Hilton Foundation
Floyd Leaders, Ph.D., Botanical Enterprises, Inc.
Claude Lenfant, M.D., National Heart, Lung, and Blood Institute
Joseph A. Levitt, JD, Food and Drug Administration
Christine Lewis, Ph.D., R.D., Food and Drug Administration
Douglas S. Lloyd, M.D., Association of Schools of Public Health
Robert McCaleb, Herb Research Foundation
Ann McCombs, D.O., private practice
William C. Meeker, D.C., M.P.H., Palmer Center for Chiropractic Research
Devi Nambudripad, D.C., Lac, R.N., Ph.D., private practice
Joseph E. Pizzorno, Jr., N.D., Bastyr University
Anthony L. Rosner, Ph.D., Foundation for Chiropractic Education and Research
Lydia S. Segal, M.D., MPH, Kaiser Permanente (Mid-Atlantic)
Leanna Standish, N.D., Ph.D., Lac, Bastyr University Research Institute
Stephen E. Straus, M.D., National Center for Complementary and Alternative Medicine
Leon Rosenberg, M.D., Princeton University
Raymond W. Ruddon, M.D., Ph.D., Johnson & Johnson
Frank C. Sciavolino, Ph.D., Pfizer, Inc.
John M. Templeton, Jr., M.D., The John Templeton Foundation
W. Craig Vanderwagen, M.D., Indian Health Service
Jeffrey D. White, M.D., National Cancer Institute
James Winn, M.D., Federation of State Medical Boards
Janet Woodcock, M.D., Food and Drug Administration

Others

Diana Chambers
Ned Hartfield
Boyd Landry
Linda Lazarus
Monika Lenz
Charles Levy
Ingrid Luces
Antonio Martinez
Sandra McLanahan
Richard Pavek
Carl Sandler
Suzanne Scurlock-Durana
Phillip Shinnick

Thomas Staboraski

Introduction

Dr. Gordon welcomed the commission and explained the format of the meeting. People would be testifying in a series of panels, usually with 10 minutes per speaker, and commission members could then ask questions at the end of each panel. The commission will work through March 2002, with an interim report in July 2001. At this meeting, there was to be a public comment session both days, with a 3-minute time limit for speakers to allow time for the commission to ask questions. The next commission meeting was scheduled for December 4 and 5; the topic will be access to services. In the interim, communications are welcome, with e-mail being the most efficient method (Whccamp@od.nih.gov).

This meeting was dedicated to exploring issues related to research in complementary and alternative medicine (CAM), and the speakers included a wide range of people from the CAM and conventional medicine communities, who would discuss a wide range of topics. The hearings were designed in the spirit of collaboration, to allow the commission to develop an agenda to serve needs of the American people.

Session I: Research Priorities and Public Input

Dr. Leon Rosenberg, currently with Princeton University, explained that 2 and a half years ago, he was asked to chair a committee on the processes by which NIH sets its research priorities. The task force was given 6 months in which to do the study, and ultimately produced a booklet that distills the committee report. The United States is the world's preeminent medical research establishment, and the federal government is the largest single sponsor of medical research, contributing \$20 billion this year, \$17.9 billion of which went to NIH. Given the size of this investment and its likely growth, there is understandable interest in how NIH allocates these funds. The quality and quantity of excellent science at NIH and the quality of NIH trainees have advanced knowledge and the ability of medical personnel to treat people. But choices will have to be made and priorities will have to be set no matter how large the budget. When NIH discusses priorities, the first objective is to identify the public's health needs; the second is to extend the basic scientific knowledge base; and the third is to communicate the current state of scientific knowledge to the public and health providers.

NIH takes into account the interests of its many constituencies – research scientists, clinicians, consumer advocates, Congress, and the media. Setting priorities is an awesome task, and NIH must adapt to a changing policy environment, with growing scientific opportunities, changing health problems, and globalization issues. The study was set in motion due to concern from various quarters. Congress sought a balance, and disease advocacy groups wanted more focus on their priorities, but others became uncomfortable with the mandates and set-asides that dictated specific research funding. The study therefore considered factors in funding allocation, how the decisions are made, public input mechanisms, and the impact of congressional directives. The criteria NIH uses in priority setting include public health needs, scientific quality of research, the potential for scientific progress, portfolio diversification in the various realms of research, and adequate support of infrastructure.

The task force made a number of recommendations. First was a statement of support for the use of the present criteria. The second recommendation was that NIH should make clear its mechanisms for implementing those criteria when setting priorities. NIH should also strengthen its analysis and use of health data, keeping in mind the impact the research has on the public.

Several recommendations addressed the decentralization of decision making throughout NIH. The task force determined that the NIH director should play a more central role. In addition, NIH was seen as having weak interactions with the public. To address this problem, the task force advised NIH to establish an office of public liaison in the director's office, as well as in the centers themselves. Another recommendation was to create a Director's Council of Public Representatives, to be chaired by the NIH director. Finally, the public membership of NIH policy and program advisory groups should represent a broader constituency. Dr. Rosenberg closed his presentation by explaining that the recommendations are meant to enhance and reinforce successful NIH mechanisms, while ensuring that stakeholder voices are heard.

After Dr. Rosenberg's presentation, Dr. Gordon noted that the whole discussion about CAM research can be framed in this way. Dr. Ornish added that in doing innovative research, it is often hard to get started with CAM subjects, because there is a standard of initial proof that is often difficult to achieve in this area. Dr. Rosenberg asserted his belief in the process of getting answers through unbiased data. He believes that crafting good proposals and proposing good studies should draw funding. There are many ways to obtain information in scientific studies. He believes that many things now considered in the CAM realm will be tested properly and find their rightful place in the practice of medicine. He is very excited about what NCCAM is doing. The current studies are all exactly where NCCAM should be going, and they indicate an openness and desire to do important things. Dr. Jonas observed that the difference between what the alternative medicine community wants and what disease advocacy groups want comes down to a difference in world views. Western medicine looks at specific diseases, while CAM systems do not have that same system of classifications. He asked Dr. Rosenberg about the follow-up on his report, specifically whether the process developed, improved, and moved forward, and especially in area of knowledge management. Dr. Rosenberg said that he is very upbeat about the project. Initially, the recommendations caused great consternation, but there has been movement – all of the major recommendations have been enacted in a significant way since report was issued in 1998. There is still some unevenness, but there has been a major, good-faith effort to be inclusive and hear more voices, so that input comes in early and is second-guessed less often as a result. Recommendations about priority setting have been well-received. The NIH effort to be more concerned about disease costs and the illness burden has begun but has a way to go. Dr. Jonas said that he would be interested in knowing if some NIH institutes have come along to the point of being good examples.

Dr. Fins asked Dr. Rosenberg to comment on social sciences and behavioral sciences in terms of infrastructure. Dr. Rosenberg noted that these are receiving more recognition at NIH, but he is not familiar with the details of how NCCAM specifically might be addressing them. The broad agenda now framed for NCCAM augers well for infrastructure, training, broadening horizons, and the visibility of the area. Dr. Chow explained that CAM practitioners sometimes fear research, and asked if research could be introduced more gently and with outreach. Dr.

Rosenberg said that research has a beginning and end, a specific process and way of doing things. Clinical research, which is the heart of CAM research for now, also has a way of being done. Young professionals are now receiving much education to help them become familiar with clinical research, so that when studies are planned, there is a reasonable likelihood of producing results. In CAM as in traditional medicine, there is good science, not-so-good science, and non-science. NIH wants to foster good science in all areas.

Dr. Gordon asked about the NIH balance among basic, applied, and advanced research. Dr. Rosenberg explained that the task force looked hard at this issue and determined that investments in basic and clinical research have produced enormous benefits. Dr. Gordon noted that a couple of examples in the report were of important basic research projects that led to the development of patentable drugs by private industry. Many CAM treatments are not patentable. He wondered if the task force dealt with the issue of whether NIH's public funds should shift to those approaches that are not patentable. Dr. Rosenberg said that it was precisely on this point that many people feel NIH should have a larger portfolio of clinical research directed at nonpatentable modalities. Dr. Jonas asked if there had been any minority opinions on the task force regarding increased centralization at NIH? He wondered if there might not be a risk in that, regarding the balance in the types and domains of research. Dr. Rosenberg said that this was discussed, but not in great detail. The task force members all agreed to start the report by saying that NIH has been successful and should be taken care of for that reason. Many people were concerned about what would happen as the NIH budget goes up. However, the feeling prevailed that NIH has not fallen apart as its current budget has grown, so this is a good precedent. On the other hand, it is not in the best interest of the public that federal money is so concentrated at NIH – there should be greater funding for the CDC and other federal health agencies.

Dr. Jonas asked about the extent to which the task force discussed CAM specifically. Dr. Rosenberg explained that there were voices for biobehavioral, sociologic, and CAM approaches. But the task force did not view CAM as a thing apart. Dr. Chow pointed out that existing research protocols are inadequate to measure CAM, for much of it is also behavioral. So perhaps there needs to be a budget set up to explore instrumentation and strengthening protocols for field research. Mr. Chappell asked if the promotion of health, as opposed to the prevention of disease, something that can hold its own in the process, or if this point of view is too difficult for NIH to consider. Dr. Rosenberg explained that this matter was explicitly discussed. Medicine is evolving, and is taking a greater view of promoting health, toward living long lives. Mr. Chappell reiterated his concern that the benchmark is still disease, with prevention as a point of view toward disease rather than wellness. Dr. Rosenberg suggested that this was a dialectic discussion that would take more time than allowed at the meeting. Sr. Kerr pointed out that two NIH offices – for women's health and CAM – were created as a result of the intervention of Congress. She asked Dr. Rosenberg if it was possible that those two offices were not created out of NIH itself because there was not enough input from public. The point is that the solution seems to be that the lack of public input would not have allowed something to be created on its own outside of NIH. Dr. Rosenberg suggested that the public commission would be a solution to the issue of bringing in more public voices, although it will not replace the need for new organizations to be established by Congress. However, more opportunities to be heard will benefit the health of the public.

Session II: Federal (NIH) Support for CAM Research

Dr. White explained that he coordinates CAM activities at the National Cancer Institute, acts as NCI liaison to NCCAM, develops and implements the NCI CAM agenda, and interfaces with the public on CAM activities at NCI. The determination of value should be evidence-based for both CAM and conventional research. NCI's priority in this area is in investigating the CAM practices that are largely used by cancer patients. CAM regimens are often complex and individualized, and many approaches are difficult to study due to their lack of uniformity. It thus becomes difficult to acquire preclinical information on many of these patients, and traditional clinical trials are often not very informative about the efficacy of CAM treatments. This situation may necessitate expensive and time-consuming quality-of-life trials. In addition, dependence on survival as the endpoint in cancer trials may not apply to CAM treatments. In addressing areas of particular interest regarding CAM, NCI is trying to capitalize on its strengths. It seems that the potential contribution of CAM approaches is in the direction of general health, rather than with direct effects on cancer cells. The potential for these approaches to improve quality of life should be examined. He is trying to open communications with CAM communities. Much CAM cancer research is related to conventional cancer research. This effort should be grown, for there is some overlap between the two approaches. For example, nutrition is important to both conventional and CAM treatments of cancer, and research in is progress in this area. Similarly, analysis of plant and animal products relates to CAM and conventional medicine. Mind-body medicine, a standard in CAM treatment modes, is expanding in conventional medicine. These all represent opportunities. We must recognize that there is a cultural difference between the two communities, so we need to foster communication. Federal efforts in this area are expanding federal efforts – the NCI best case series is an example.

Dr. Lenfant noted that much of what he had to say had been said already. Nutrition was once disregarded by conventional medicine, as was prevention. Now they are standard. One of the biggest hurdles facing CAM is bringing it into conventional practice and conventional clinical research. The public voice of alternative medicine is not yet heard very well. He believes that various groups wanting to foster more CAM research should take steps to make their voices heard more strongly. Once or twice a year, the National Heart, Lung, and Blood Institute (NHLBI) invites people to speak to their council, and no one from the CAM community has come forth as yet to express their views. CAM research is hard to validate, but there is not yet the appropriate education among those who are interested in this area – they are not researchers, and this is a significant problem that needs to be solved. There are important questions to be asked when seeking to validate an intervention. Is the treatment affordable in the real world, and what will come from this validation – can it be generalized? These important questions are often difficult to apply to CAM.

Dr. Cassman noted that the role of the National Institute of General Medical Sciences (NIGMS) is not readily apparent, for “general medical sciences” is a seemingly meaningless term. The purpose of NIGMS is to understand the fundamental elements of biological processes. Clinical research is at the heart of current CAM research, and NIGMS does not do clinical research. There is relevance, however. Much of what fundamental research on biology has done has been to understand the way things operate at the molecular level. One approach to this is to understand how systems operate in time and space. NIGMS has begun programs aimed at

complex systems, which go beyond biology. Not all the necessary research tools have been developed. The wealth of different opportunities will require measurable quantities in order to understand how various systems operate. But they are trying to bring in many different systems, and this could very well apply to CAM.

Dr. Hausman, of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), noted that arthritis and musculoskeletal ailments are chronic, common, costly, and crippling diseases. They wax and wane, and conventional medical therapy finds it difficult to deal with this area. Patients thus turn to CAM, which works sometimes. NIAMS has been involved in CAM before the term “CAM” was created. The institute has taught wellness from the beginning. Now NIAMS is working closely with NCCAM in studying glucosamine and chondroitin sulfate. The institute’s new scientific director has found a Chinese herbal treatment that caught his attention. Low back pain is a chronic problem that must be addressed – there is much opportunity for CAM research in this area. NIAMS is currently supporting a study comparing conventional treatments with alternatives, including acupuncture. Existing mechanisms of the federal research approach can be applied to CAM. Researchers trained in CAM should have training in research methodology as well. There are many overlapping areas of research – an arthritis magazine found that 70 percent of patients were interested in alternative therapies even though 89 percent were taking prescription drugs. Patients have used prayer, medication, glucosamine, Chinese medicine, etc. Some physicians make recommendations as to which of the various CAM treatments are safe and effective for their patients. But these things need to be sorted out via clinical research. In addition, NIAMS would be interested in researching such topics as aloe vera on skin, Chinese herbal teas, and devices that increase bone mass. Obstacles include validated evidence and the reluctance of established investigators to do research in this area. One way around the latter problem is to sponsor interdisciplinary workshops, conferences, and collaboration. Another potential obstacle is the current policy regarding Medicare reimbursement in clinical trials; many CAM modalities are not presently reimbursed. The diseases in his venue are diseases of elderly, and the population is aging, so Medicare reimbursement will become a more important issue. The role of public in all this is to make their views known.

Dr. Coates endorsed what had been said previously. There is an exciting array of programs at the Office of Dietary Supplements (ODS) that could be useful for CAM scholars. The dietary research program is interdisciplinary, has a collaboration component, and develops scientific evidence about botanical and herbal products. The Office employs a synergistic approach of having people from different disciplines tackling the same problems. ODS has four centers dealing with overlapping but different approaches. He likes to think that this is a contribution toward bringing CAM into the mainstream. Additional areas of opportunity are almost limitless in the area of dietary supplements. There is still a need for evidence, and those supplements that are used in CAM are approached the same as ODS approaches more conventional supplements. He finds, however, that while many CAM treatments are within the traditional research paradigm, the suspicion to the contrary interferes with communication. ODS has sponsored workshops and partnerships to help expand these efforts beyond NIH, to nonprofit organizations and private companies.

During questioning, Dr. Ornish pointed out that the NIH budget is relatively skewed away from

behavioral and CAM approaches, and asked if they had any thoughts on changing the budget. Dr. Hausman said that the number of projects submitted in this area is increasing, and program staff are working with applicants to improve the quality of submissions. He does believe they could have more workshops and conferences, however. Dr. Lenfant agreed, adding that they must comply with NIH methods to address the gap between what we know and what is used by patients. Dr. Gordon asked how we might make more of what we know about CAM available to patients. Dr. Lenfant replied that once interventions are validated, educational programs can begin. It used to be that the doctor's word was taken as the word of God, but now the voice of the patient is very important. The public education component is more important, therefore. Dr. Fair observed that there is always a session at the professional meetings he attends on how to prepare for grants and obtain grant funding. He wondered if any institutes have such programs to do this in the area of CAM. Dr. White responded that NCI has done this twice and is looking for more opportunities. Dr. Fair believes there should be an effort to involve more conventional physicians in doing CAM research, too. Dr. Coates agreed, stating that they have an obligation to support research training in this area, and to try to encourage people to recognize the opportunities. One way to do this is to make funds available.

Dr. Fins noted that of the population using CAM treatments, much of what they are using is palliative care. He wondered if the synergy with this care and the burgeoning end-of-life care modes should be explicitly addressed. Dr. White explained that the mission of his office is described as cancer and patient management. There are several research initiatives in this area addressing end-of-life issues. Mr. Chappell asked if the ODS, in conducting botanical research, is seeking exclusive compounds or blends of herbs. Dr. Coates said that both exist in ODS programs. Two centers are enthusiastically pursuing the hypothesis that mixtures have synergistic properties beyond the single substances. Dr. Bernier asked what the panelists viewed as greatest impediment to expanding CAM research. Dr. White said that attitudinal and awareness problems exist. In addition, there are two cultures, in which CAM practitioners and conventional researchers are not intersecting much. Some CAM treatments are individualized and even practiced differently from one patient to the next. This makes the development of uniform protocols difficult. Much of this can be dealt with by collaboration and education. He expects to see growth from collaboration.

Dr. Chow noted that once there was a big concern about minority and ethnic health, and advisory groups were formed to address these issues. She wondered if any of the institutes have similar advisory groups on CAM, and if advisory groups are even feasible. While Dr. White thought such groups might work, Dr. Lenfant disagreed, saying that such groups would amplify the differences between CAM and traditional medicine, and thus be counterproductive. It would be more useful to bring in individuals who have interests in these approaches. Dr. Hausman said that while he agreed with Dr. Lenfant, his organization has had interdisciplinary advisory groups that broaden the level of input.

Dr. Gordon said that it seems easier to advance research in regard to CAM approaches to cancer because of the Cancer Advisory Panel on Complementary and Alternative Medicine (CAPCAM) and the NCI focus on CAM. Dr. Lenfant noted that NHLBI has a large program and people can become very easily involved in discussions with the institute. Dr. Gordon asked if attention is being paid to some of the CAM issues like energy medicine, for example. Dr. Cassman replied

that they are looking at bioavailability and how substances find their way through body. Dr. Low Dog said that the commission has heard much about education and collaboration. But they are also hearing that many modalities do not fit the standard. In Germany, there are seminars just for CAM practitioners, to teach them from beginning how to do research. They thus developed a strong core of dedicated CAM practitioners who could also do quality research. It seems very important to do that here, as well. Dr. Hausman said that NCCAM would sponsor such training, in all likelihood. What she proposed is feasible, and while it is not easy, it can be done.

Dr. Fins asked if members of Independent Review Boards (IRBs) need training in CAM issues, since this is outside their areas of expertise. Dr. Lenfant said that he is not aware of any hurdle at the IRB level. They have recruited individuals with expertise, though it was a difficult process. Dr. Jonas asked the panel for specific suggestions in the area of training. His concern is how to motivate basic scientists to address this area. Some have ideas, but they still face a taboo that exists in basic science. Dr. Cassman noted that this difficulty exists for any discipline that is coming into the scope of fundamental research. They must start with a definable research question that can be addressed in a way that can be measured. Once the question is there, there is no particular barrier, but this criteria is never easy to meet.

Session III: Academic Centers and Support for CAM Research

Dr. Fishman explained how three years ago, the Dean of the University of Pennsylvania Health System created a working group to define the role of CAM in the Academic Medical Center. The working group included eight CAM practitioners, eight scientists, and two administrators. They went through the process as though they were setting up a new department, which involved reviews and a retreat to which they invited people who were opposed to CAM. The group developed a proposal, which then went through university channels and achieved acceptance. The working group considered clinical, educational, and research factors, which are all interrelated. To establish a new program, they must therefore build all three simultaneously. Penn remains committed to taking a scientific approach to CAM, but the institution has no problem with integrating CAM into the scientific realm. Academic scientific institutions must have rigor, however. In a survey, they found that one-third of physicians responding were using CAM treatments such as nutrition and acupuncture. Penn has developed a program to integrate CAM into each of their centers. A steering committee includes people who understand CAM and know where to go to find those with the right credentials and expertise. In respect to education, Penn has added discussion of CAM to the curriculum, and this is not always done in a lecture format — lectures have been minimized. One hundred medical students participate in a Qi Gong program. In terms of research, faculty at the Department of Internal Medicine are taking the Master's program in epidemiology and biostatistics. Each has a mentor specializing in clinical trials and a mentor with expertise in a CAM modality. Third-year medical students can also take a year out to study in this area.

Dr. Federman explained that rather than start from the top, like Penn, Harvard instead recognized what had been created by an entrepreneurial young faculty member. David Eisenberg was trained in China and Chinese, and had acquired independent funding for CAM research, showing among other things the important role of private philanthropy in this area. Education can lead to

a creative interdisciplinary research. Harvard created a CAM division, which is not within a department and can therefore cut across disciplines. There was some real opposition at first, and those interested in bringing CAM into the medical school invited the opponents and gave them time to speak. The program is now up and running. The principal obstacle was skepticism and a reluctance to look “soft.” Bringing practitioners and researchers together in common settings is very important. Good well-written anecdotes should not be disparaged, as they are often the first step in leading to the question of what can be measured. In education, there are different attitudes in area of ambulatory medicine, as opposed to acute, and CAM can play a role in this area.

Dr. Pizzorno explained that Bastyr University is dedicated to science-based natural medicine. Research has always been important at Bastyr despite the lack of funds, so the university allocates student tuition money toward research. The natural products companies have also helped. Now Bastyr has a sophisticated research institute. The key to success is in using cross-trained professionals. Barriers include exclusionary language in legislation – much legislation covers only traditionally trained physicians. There have not been mandates to include CAM practitioners, resulting in de facto exclusions due to physician gatekeepers who are not interested in CAM; sometimes, when CAM is allowed, it is not funded. This is also true of quasi-governmental institutes that work closely with government. This should be easy to fix through enabling legislation to remove the exclusionary language. Natural medicine and public health are natural partners. Patient education, prevention, and personal responsibility are mutual priorities. The difference is that public health addressed the larger population, while natural medicine is one on one. Another significant problem is that most research is isolated and nonintegrated, conducted by those trained in a drug-oriented approach. This is counter to much of natural medicine, which often relies on entire systems. In terms of research, it is hard to blind some of these systems. It would therefore be helpful to have a multi-day conference on developing CAM research methodologies. There is a desperate need to fund CAM academic health centers, but there is a lack of an appropriate training infrastructure.

Dr. Meeker noted that the chiropractic profession is the third largest health profession in the United States and the largest of the CAM professions, with 17 accredited institutions. Chiropractic delivers a huge proportion of other CAM modes, as well. Chiropractic care is a mainstream practice and cannot be ignored any longer. Conventional procedures and products are easy to integrate into conventional medical practice. It is difficult to integrate CAM on a large scale, though patients do this in their own lives. The research agenda must be interdisciplinary and elaborated explicitly in the federal agenda. Meanwhile, CAM professionals must do their own work to prove and improve their efficacy. There are many ways the government can support CAM. Funding is an obvious way, but the resources are meager thus far. The federal effort needs to be much bigger and more productive. Isolation of CAM researchers is a problem, as is ignorance by non-CAM scientists. In the private sector, major health reports do not even acknowledge chiropractic care. The most important thing that can be done is to train CAM. Dr. Meeker also suggested creating interdisciplinary collaborations between CAM and federally funded institutions, among other recommendations.

Mr. Chappell observed that they are dealing with a consumer-driven reality. He wondered at what point Harvard decided to integrate CAM into their program. Dr. Federman said that they

were asked to bring CAM into the mainstream of the school by the dean. His advocacy was key. They will probably spend another year or two working on this process. Dr. Ornish asked if they won over or overruled their opposition. Dr. Fishman said that at Penn, they did not even engage them in battle. In integrating CAM into the medical school, they did nothing out of line with how things are normally done. The skeptics listened and were impressed that the procedures were followed and fit the framework, so no formal opposition developed. The discussion was instructive and never became antagonistic. Dr. Federman described the activity at Harvard as achievement of a “reluctant suspension of disbelief” by the skeptics. Dr. Low Dog asked how the institutions deal with the CAM approaches they bring in. Dr. Federman explained that research will be approved on a project-by-project review. Dr. Fishman said that Penn takes a more deliberate approach of going through a steering committee and following an established process. Dr. Low Dog then asked about the level of collaboration between Bastyr and other medical schools. Dr. Pizzorno explained that while the community has been receptive, the local medical school has not been until recently. Now, however, many medical students want to be engaged with Bastyr and take courses there. The research community has followed in becoming more accepting.

Dr. Jonas suggested that the commonalities among the schools are dialogue, training, and dual education. However, the contrast is that the infrastructure exists for conventional medicine, but not yet for unconventional medicine. He wondered if there could be a higher level dialogue between such institutes. Dr. Meeker thought the simplest thing would be to encourage the dialogue at a conference or workshop. The relationships his institute has are all rather entrepreneurial. More people are coming together by chance and outreach. Dr. Fishman added that NCCAM has done a great job in tackling the present situation. Penn took the tack that they would have to train young people, and so never applied for funding. The time will come when there should be a meeting of people at universities who want to work together. This is something to aspire to. Dr. Pizzorno said that such a thing is critical. A grant for collaboration would make things happen.

Dr. Fair asked Dr. Meeker what he does to introduce students to research methodology. Dr. Meeker replied that the Palmer College trains students as consumers of scientific information, not as creators of it. They do not have the resources to develop research training, although he agrees that this is important. Dr. Pizzorno said that Bastyr has had students use work-study money to work with researchers. Bastyr has a Ph.D. program in CAM research on the drawing board. Dr. Federman said that he supports the consensus conference idea. He would like to see NCCAM propose co-op grant programs, which might connect organizations. Dr. Fishman said that an easy solution would be to promote a research orientation through partnering. Dr. Bernier asked if the medical student education component helped facilitate the introduction of CAM into the curriculum. Dr. Federman said that Harvard has a mandate to bring CAM into the first two years of education, whereas it was only in the third before. Dr. Fair asked if there is a need for a program similar to the MD/PhD programs that direct training. Dr. Fishman thought there was no such need, but the others disagreed. Dr. Fishman believes CAM will become conventional medicine some day, and the mechanisms are already in place for training. Dr. Meeker said that it comes down to who controls this aspect of research. Those who believe the best research will come from CAM researchers also believe there must be support.

Public Comment

The first speaker was Suzanne Scurlock-Durana, who expressed her interest in more effectively integrating the CAM and conventional research communities. She is concerned with double blind studies of hands-on therapies – it is extremely difficult to get placebo effects and reduce the variables to just one in these therapies. So the need is to examine the kinds of research being done. She has gotten tremendous results and outcomes – rather than variables – in working with Vietnam vets. Dr. Gordon said that the commission is very interested in this kind of research. Dr. Fins asked who supports her work. Ms. Scurlock-Durana said that this has been a problem. They have gotten tremendous results, but they need \$10,000 per patient. To treat 24 patients, the cost would be \$240,000.

Dr. Phillip Shinnick came as a research scientist and athlete both. He was a U.S. Olympian and former world record holder in the long jump; now he runs a research institute. Science has created a crisis in sport, in the form of drugs that short circuit the culture and model of sport. He developed techniques to compete at the world level without drugs. Children believe that steroids are effective, however. He would like to bring yoga and positive techniques to the attention of young athletes so they will use them instead. He asked the commission to help develop a plan for this kind of project. Dr. Gordon thought Dr. Shinnick had a wonderful idea. He asked him what approaches he recommends beyond professional education. Dr. Shinnick believes there are many supplements that must be evaluated. Meditation and mind/body techniques can come together to benefit athletes, while unifying practitioners. Dr. Chow suggested that all children should have this training. Dr. Shinnick added that yoga and mind/body techniques help develop strength. We need a physical culture that leads to health. We have been cut off from our history, when sports were far more important. Dr. Fair asked if there are others like him who could come to town meetings to discuss this approach. Dr. Shinnick offered to help organize this. The mind/body techniques help tremendously. Dr. Gordon said that he will follow up on this with him. Dr. Shinnick added that he also treats the New York City Ballet, and the dancers would be involved, as well. Athletes must learn how to be healthy. Dr. Jonas asked how this could be investigated, and whether Dr. Shinnick had had any dialogue with the military. Dr. Shinnick said that he could enlist people to address the methodological problems.

Richard Pavek, the next speaker, explained that he research is not medically trained, but has done much research. He has developed non-drug hands-on treatments that address anxiety disorders and other stress-related problems. The current research model is not large enough to encompass much of what is done, especially in the emotional area. Sr. Kerr asked him about a statement that the soul is the biofield. Mr. Pavek said that he has research suggestions in mind/body disciplines that would address this. Initially, for example, we dismissed acupuncture, which we now accept because we claim that it works for pain by stimulating endorphins. But acupuncture addresses more within the body. We must be open minded to understand how some of these treatments work.

Linda Lazarus introduced herself as an attorney and mediator. Her concern is conflict – some ways are better than others in resolving conflict. There is a consensus about some modalities, which are understood to be important and complex. People rely on an enormous amount of scientific information to support their positions. But when there is a conflict, the best way to

make decisions is by employing the techniques of alternative dispute resolution (ADR). Dr. Fins agreed. Science relies on peer review; he wondered how peer review compares to ADR. Ms. Lazarus noted that the facilitated exchange of ideas helps participants come closer to agreement. Talking is the first step, and it is crucial to have a focus and be open. Dr. Jonas asked her to provide specific suggestions for situations such as one in which there are major power differentials between constituencies.

Dr. Sandra McLanahan has watched the evolution of acceptance of previously unconventional techniques. There are two basic research questions. The first is how to make an impact on medical students. She suggested redoing the Chantilly report. She also suggested that NIH focus more on child rearing and end of life care. She views surgery as a place to study CAM treatment. We need to look beyond the measures of current science and consider the body as a whole.

Antonio Martinez noted that there are two key policy themes. First, professionals want licensure and coverage. Consumers want access and insurance coverage. He suggested points to bring up in discussion with the FDA. First, the goal at FDA is to keep distinctions in the law, and CAM flummoxes them in that regard. Second, the division responsible for most of these products has the least funding. It is important to note this underfunding. Finally, he felt the commissioners should be aware that when it comes to CAM treatments, the FDA is the ultimate decision maker with the doctor, not the patient with the doctor. FDA vetoes treatment options. He also wonders why the state medical boards are so anti-CAM.

Dr. Carl Sandler explained that he is not really a medical person, but a PhD nuclear scientist. A life history of polio and a long-term disability got him interested in clinical medicine. Physical medicine requires movement beyond exercise. We must build more movement into life, starting with breathing, which most of us do not do properly.

Session IV: Research Support and Collaborations

Dr. Straus has been the Director of NCCAM for one year. He explained that CAM touches on all aspects of life; NCCAM is charged with thinking about research in these areas. CAM has a broad appeal to the public, but there is enormous controversy about these modalities. We know enough about certain modalities to suggest that some work and are safe and can enhance human health. For example, St. Johns Wort has produced substantive data encouraging a larger investment in research on it. Now there is also evidence that the herb interferes with absorption of other drugs. This illustrates the opportunities and challenges in this area, which has existed in what is largely a parallel universe to traditional medicine. This challenge has been met by Congressional funding that has been generous.

NCCAM has four major goals: investment in research; training investigators in CAM; outreach in communicating findings objectively; and facilitating integration with the research establishment. Traditionally, research often moves from understandings of molecules and mice before it moves into people. In CAM, the modalities are already in field and have little preclinical support. There is a challenge in addressing this area outside the hierarchy of medicine. NCCAM is therefore not emphasizing preclinical research, but rather what is being

used by the public now. NCCAM research investments are also aimed at creating infrastructure. There is a centers program, as well as a growing portfolio of investigator-initiated research. To be successful, NCCAM needs to leverage financial and intellectual resources. One of the gratifying findings is the degree to which other NIH institutes want to collaborate. Therefore, there are far more opportunities than can be addressed at this time.

In the centers program, four are studying botanicals. The centers are assessing bioavailability, mechanisms, and doing some phase 1 and phase 2 studies. Results from this research help identify which botanicals are ready for further study. NCCAM funds 11 other centers that cover a range of topics, including two for cancer research. These reflect NCCAM's capacity to pull in the best and brightest to assist in CAM research. The Center has had no difficulty in recruiting outstanding investigators. Excellent scientists working in centers are conducting five large placebo-controlled objective trials, which would change the minds of many in traditional medicine about their capacity to do this type of thing. The large studies include shark cartilage, dementia and ginkgo biloba, acupuncture, and glucosamine and chondroitin sulfate. The capacity to leverage resources is what allows NCCAM to fund these studies.

Key principles begin by addressing the need to use the same designs in outcome instruments. Some modalities cannot be blinded, but researchers can do parallel observation in large studies with good endpoint observations. Creativity is essential. Many CAM interventions will require partnership with CAM practitioners. These are ways to develop a portfolio of aggressive and rigorous research. But there are also domains of CAM for which there are hypotheses and little preclinical data. NCCAM must be open to explore these, especially those for which there is huge interest and much anecdotal testimony. Researchers should pursue those anecdotes. There is a need for applications to study these difficult areas, and this is where the imagination of researchers is challenged. NCCAM is taking applications to study frontier medicine, including bio-electromagnetic work, spiritual healing, homeopathy, and the like. NCCAM also actively seeks ideas from the community.

There is a model in cancer, for which there is a cancer advisory panel, CAPCAM. The goal is to identify novel opportunities. They are beginning to explore best-case series. Dr. White of NCI has advertised widely for synopses of good results. That has allowed current funding for the Gonzalez regimen, and exploration of vegetable supplementation efficacy. The cancer portfolio spans the highly exploratory to requested initiatives. Current research initiatives cover pain management, botanical/drug interactions, quick trials of novel cancer therapies (expedited review), and CAM approaches for end-of-life care for patients with cancer and AIDS. There are also studies addressing arthritis, asthma, and more. The major emphasis is to develop a research portfolio that will garner the respect of mainstream medicine and that will convince the medical community and the public that they are serious, with competent investigators. There is a need to draw in new cadres of researchers. NCCAM is supporting the entire portfolio of NIH mechanisms for training, therefore. It is clear that medical students are eager for some formal training in CAM, because they know their patients will have questions. This is not meant to teach physicians to be chiropractors, but to help them know what participation in CAM means for their patients. NCCAM has funded model curricula for four medical schools and one nursing school. In the area of research training, NCCAM is calling for special grant applications to look at the community at large in order to learn what real obstacles exist to the integration of safe and

effective practices. NCCAM wants the best institutions and individuals to join in this work. A web site, clearinghouse, and citation index are all available for those who want more information. He also travels and talks to a number of organizations, and NCCAM recently began holding town meetings.

Mr. Chappell asked about how much money and time is necessary to make an impact. This is a large undertaking, and Straus makes it sound simple. Dr. Straus replied that there are certain research areas that take many years to study. He has spent his life in the science field, and believes that the long view is the only view, because it takes a long time to establish observations, for example. The ginkgo biloba study will take five years and \$16 million to do right. The St. Johns Wort study is taking two years, and an osteoarthritis study may take four years. One option is to review developmental, two-year studies, which help determine whether or not to proceed further. Studies often take a year to design, another three to four to conduct, one to analyze, and one more to publish. This is a long process. The duration depends on the topic.

Mr. Chappell asked if priorities are set by need. Dr. Straus explained that NCCAM has tied its efforts to major public health areas. Largest investments reflect opportunities for large investment. The portfolio heavily skewed with dollars to acupuncture and botanicals, where there were already more data. NCCAM is now looking for holes in the portfolio. This will dictate calls for new investment. Dr. Chow said that a problem with CAM in that many practitioners do not know the system but are getting great results, and this does not get out. Dr. Straus said that NCCAM has thought much about this, and has yet to reach an answer. Sometimes a practitioner's interest, background, and training do not support conducting research. NCCAM is therefore creating mechanisms to help practitioners learn to do science, and funding research training in CAM areas. Dr. Fins remarked that the best-case series is a good methodology for sharing observations leading to good science. He was interested in how CAPCAM works, and how the panel determines which research protocols to fund. Dr. Straus explained that a study section is a group of individuals called together to do peer review. Applications that are submitted independently go to a central office in NIH, which assigns them to a panel with expertise in studies but not necessarily in the topic. These panels will call in experts. When calling for applications, they set up their own panels.

Sr. Kerr asked for Dr. Straus's thoughts on Dr. Pizzorno's suggestion for a consensus conference. Dr. Straus said that this is handled elsewhere in NIH, and it is not done lightly. There are very strict criteria. Dr. Low Dog asked if NCCAM is collaborating on studies of botanicals with other organizations. Dr. Straus said that NCCAM is funding major botanical studies. Dr. Ornish asked about how researchers keep control in these studies. Dr. Straus replied that they ask people not to take the substance. Most patients do not want to interfere with the test. Dr. Jonas asked about funding for the five-arm arthritis trial, which Dr. Straus said is being co-funded by NIAMS. Dr. Jonas was also concerned about the risks of focusing on clinical research. Dr. Straus agreed that the issues are complex. There are risks, and they would rather do a study well than be second guessed. The lack of the broad underpinning of science creates the greatest challenge to CAM research. Dr. Fair asked what kinds of recommendations the White House commission could make to help NCCAM. Dr. Straus said that NCCAM is still a young enterprise. First thing needed is patience, therefore. NCCAM seems to be on track,

which should be encouraged and supported. Science should be left to the scientists. Science is a process, not a philosophy. Anything they can do to encourage critical and credible questions from all parties will help. Dr. Bernier asked how they would research hard areas like massage therapy. Dr. Straus explained that there are hard trials and easy trials. NCCAM is funding several massage therapy studies, and these are not easy. The answers might not be ones they like, and some effects might not be robust or produce strong results, but science does not lie. Not all trials are positive. Negative data are useful.

Session V: Facilitating CAM Research and Regulatory Challenges

Dr. Woodcock explained that her division, the Center for Drug Evaluation and Research, deals with regulatory challenges for drug-like products. If they are ingested or topically applied, botanicals fall into the drug definition because they treat, mitigate, or address disease. Investigational New Drug (IND) status is an exemption from standard approval requirements in order to do a study. Barriers to research in this area include the fact that the drug development system was set up for synthetic developed drugs, and the regulatory framework is tailored to this. The FDA solution for dealing with botanicals is a document published in August, “Botanical Drug Products.” It provides guidance – nonbinding advice – on how to study botanicals and go through the approval process. The FDA wants to open the door for products that are outside the regulatory framework. This is just a proposal, however, and final guidance will be based on comments. The document presents a cookbook approach.

If a product has been marketed as a supplement or has been used as a drug in other countries and the experiences have been collected, that information could form the basis for conducting a trial. FDA is prepared to provide assistance in this area. The guidance urges that people consider doing controlled clinical trials. It is very important to start gathering substantive information early on. Regulatory changes that FDA has identified that could help promote CAM research is in the area of combination products regulations, which is typified by cold and cough medicines. FDA is now working on addressing botanicals in this area. Without a change, testing could still occur, but approval might be lacking. FDA resources are somewhat strained, and people who are not experienced in drug development require considerable assistance. In anticipation of this, they have rewritten some internal procedures, and they might be able to hand off some CAM treatments to the OTC area. FDA is trying to form a group that would deal with most of the botanicals. The OTC group now has a position that will deal with botanicals – a physician with a background in Chinese medicine. But limited resources are strained nonetheless. Approvals would be given to those products proven to be safe and effective, and FDA would expect new drugs to be characterized by their criteria, including botanicals. Therefore, additional chemistry and manufacturing standards might be required. Other substances that are not plants might be considered drugs, and FDA would apply the same reasoning to them.

Dr. Fins asked what kind of funding would be necessary to alleviate the state of strained resources at FDA. He also wanted to know how they determine that a botanical is considered a drug. Dr. Woodcock assured him that FDA will respond to people who submit INDs, and there is a pre-IND program in place. It is labor intensive, and there is no formal process on assigning resources except when Congress dictates. In answer to the second question, she pointed out that a drug is any substance used to treat, mitigate, etc., disease. Substances could be dietary

supplements or drugs. Dr. Gordon asked if ginkgo biloba is a drug and a food. Dr. Woodcock explained that it is the claim that makes it what it is - the intended use. Mr. Chappell observed that these are new developments. He asked if companies should partner or work through attorneys. Dr. Woodcock said that FDA can help small and new businesses through the steps.

Dr. Paz said that she sees people on multiple OTC drugs in addition to medications. Dr. Woodcock noted that FDA has issued health advisories on drug interactions. Dr. Jonas expressed interest in what else FDA might need to keep moving forward. Dr. Woodcock explained that her experience is that it is best to have a core team that deals with specific areas and understands and has connections to the outside. There are practitioners in FDA who are well-versed and interested in CAM, so would they would be moves to appropriate areas. She has talked to the Canadians and Australians about their regulatory structure to see what we can learn from them. Dr. Chow noted that it is enormously expensive just to get one drug on the market. Dr. Low Dog asked what would happen if, for example, a trial on St. John's Wort indicated that it is equivalent to Zoloft, and companies continue to make it and she has it in her garden. Mr. Dorsey said that it could still be marketed as a dietary supplement, but other formulations could not make the drug claim. There could be a drug under the drug claim, and supplements as well. Dr. Low Dog asked to confirm that this means there could be identical products, one sold through the hospital and one through the grocery store. Mr. Dorsey agreed that this was the case.

Dr. Feigal explained that he works with approval of medical devices. Each day, about 50 new devices come onto the market, about half of which are exempt from FDA approval processes. Others are approved in the 5-10-K process, which clears devices based on a standard of showing equivalency to a predicate device. Device amendments did not exist until 1976. These were the original predicates, the devices that existed before 1976. There are about 5,000 device classifications. The level of evidence is now allowed to change – contact lenses are an example in that they once had to be studied on people and that is no longer the case. There are well-characterized hip joints that do not need approval because they are knock-offs of previous products. The bottom line is that very few devices require approval. There are no separate classifications for CAM devices. A device is a device, regardless of intended use. Copper bracelets and the like should have a process but do not, despite the fact that they make a claim. Usual the FDA framework will work with a manufacturer. But with CAM devices, a practitioner often promotes new uses for an old device. This is complicated by fact that advertising is regulated by the Federal Trade Commission. Many devices are not even on the FDA radar screen. Finally, many predicate devices did not have specific designations to specific purposes.

Mr. Levitt explained that FDA staff is not sufficient to warrant a separate dedicated staff for this area. DSHEA was controversial. About a year and a half ago, they decided that although there was a lot of activity after DSHEA was passed, they needed to call a time out and ask what it would take to fully implement DSHEA. What they found from talking widely was that there is a need for education, and a need to look at marketing of products to vulnerable populations. His group went back and formed teams on labeling, enforcement, research, and other topics. They came up with a series of insights: first, this is not something they can fix overnight; second, science has to be more central to the process; and finally, this is doable. Their objectives are now to fully implement the law; maintain an ultimate goal of a high level of competence in labeling; hold to a science-based regulatory approach; and recognize that this will be a long-term

effort. One sleeper provision is that not everything has been invented yet. For that reason, they will need to deal with these products early on. There was a mistaken assumption that DSHEA would be low maintenance, which is not the case at all. FDA has a very small staff on this program; until they have additional resources, progress will be incremental.

Dr. Feigal added that with devices, there have been different approaches within FDA at different times as different features were added. The device paradigm is a step scale. General controls require a reporting mechanism. Class 2 devices require some clinical evidence. He sometimes sees claims that were never made before or are hard to verify. Reclassification has also complicated things. Dr. Jonas asked if a step approach is being discussed for dietary supplements. Mr. Levitt explained that some of the testing has been done outside of the FDA purview. A new step approach is definitely being considered. Mr. Chappell asked about the FDA vision for substances being science based. Mr. Levitt said that the FDA stance is that they have to convince consumers that products are safe and the claims are justified. Dr. Fins asked how they learn of different uses with devices that are not approved. Dr. Feigal explained that they hear about things in a number of ways. They will hear from practitioners, or someone will refer copy cat devices. It is not easy, but information does filter to them and they do follow up through field staff. Sr. Kerr said that she is perplexed about the FDA definition of food, given that they approved olestra. It makes her wonder how their world view informs what they are doing. Mr. Levitt said that the issue of food safety is a paramount concern. Consumers have the expectation of safe food. One area FDA needs to hone in on more is what expectations are for supplements. This would be in terms of safety, not effectiveness.

Session VI: Research in the Regulatory Framework

Dr. Winn explained that he represents the state regulators. Their goals are to reinforce medical board responsibility to the public, and to protect the public from unqualified physicians. This means that only qualified individuals can deliver care. Physicians have responsibilities, one of which is to maintain professional standards and behavior. To do that, they must know medical practice. This leads into the topic of CAM and concerns it raises. There is no argument about the proliferation of CAM. However, rapid proliferations raise concerns about whether the public is being exposed to unsafe practices. Many of these practices lack scientific validation, and some are outright fraudulent and deceptive. Some proliferate due to demand and the willingness of traditional practitioners to embrace these therapies. In addition, technology advances have created a greater distance between patients and their practitioners. Medical boards are concerned about adverse impacts. There are three basic areas of harm: economic harm from spending money on treatments that do not work; indirect harm, caused by a delay in seeking appropriate care; and direct harm. In 1997, the Federation of State Medical Boards convened a committee to provide guidance about deceptive health care practices. This committee developed a guide on how to assess conventional and unconventional care, though this should not be mistaken for comparing CAM treatments with allopathic care. The bottom line is that the physician must abide by rules of good medical practice. The committee has looked at different practices so that medical boards can remain updated. Now the Federation will be able to determine what is responsible CAM utilization. Guidelines should be complete in 6 to 8 months and sent to state medical boards. These boards have the expectation that doctors address their responsibilities first and foremost, only participating in investigations that are responsibly sponsored.

Investigative fraud is a concern to his organization. He would like the Commission to keep in mind that medical regulators must have good, solid information about reliable CAM interventions. Some of these therapies, such as chelation, are controversial. The medical boards want good research that tells the whether or not this treatment is effective. If chelation does what it says it does, then medical boards should hold doctors responsible for not using it. If it is not effective, then those physicians who use it should go before their state medical boards.

Dr. Low Dog asked how many complaints have been registered by patients against physicians in situations involving CAM treatments. Dr. Winn said that this was data he could get for her. Dr. Jonas said that access is an issue that has to accompany accountability. It would be extremely interesting and useful to know what the state medical boards would like to see on the research agenda. He asked Dr. Winn two questions. The first dealt with how state regulators might get their concerns into the loop. The second was how CAM researchers can deal with a practitioner they to investigate who is conducting treatments that are considered nonstandard or fraudulent. Dr. Winn said that the state medical board should meet and find out what is being done by the practitioner. Otherwise, practitioners can go through an IRB. Dr. Gordon explained that there are people trying to do research who are happy to deal with IRBs but who are in private practice and sometimes need help in facilitating the process. They do not want the people doing research to run afoul of state medical boards. This is something he would like Winn's organization to consider, and Dr. Winn said he would be happy to work on it. Dr. Paz asked how they might encourage more states to develop CAM policies. Dr. Winn replied that the Federation will be developing these guidelines. Typically, once the Federation establishes a process, the states pick it up. It is likely that states will make changes within 24 months. Dr. Fins said that he has seen this kind of thing happen with pain management therapies, and wondered if it would be helpful to have CAM practitioner participation on the state medical boards. Dr. Winn agreed that this would be a good idea.

Mr. Leaders told the Commission that his organization is committed to bringing botanicals to FDA as drugs. He believes botanicals have much more potential than just for the DSHEA marketplace. Currently, they are conducting research within the regulatory framework. Within that framework are problems with a lack of resources and a skeptical mindset. Dr. Woodcock's guidance from FDA is a major step forward, but the mindset is extremely important. While the FDA document is a good start, it nonetheless takes the new chemical entity paradigm and places it over botanicals. Another issue is how standards can best address safety and efficacy. There is a need to learn how to evaluate human data, and FDA does not have enough of the right personnel to do this. In the guidance document, 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. He would like the Commission to consider how resources can be brought to bear to allow previous human experience to count. In addition, this research cannot be funded by government alone, and the private sector is motivated by the profit motive. Without patent protection, manufacturers will need some form of regulatory exclusivity. It is very costly to bring a substance to FDA's attention. Also, DSHEA has turned out to be a major impediment that inhibits research. When the act was passed, it looked at the primary subjects as if they were foods. Botanicals test the law, however. The problem is that the process defines the product.

Dr. McCaleb suggested that when something has been used for many centuries, it is difficult to

give exclusive rights to that substance, and he does not believe the right should be given. Essentially, natural products research has been shut down. There has not been approval of a new drug from plants in 50 years. In addition, FDA has approved very few preventive medicines. This is one reason why we turn to alternative therapies and substances. DSHEA works in that it allows the ability to make a claim based on evidence, without high expenditures. It also promotes better labels and better third-party information. The path to stronger claims needs improvement. FDA should allow the elimination of the disclaimer on a DSHEA label if a certain level of proof is reached. One way to stronger claims is through OTC drug status. FDA did not do this, though it was urged to do so, and even though this is done successfully in Germany. All dietary supplement products are sold OTC now, but there should be a natural products OTC panel to make decisions about safety and efficacy and to allow stronger claims. There should be more focus on folk medicine, which has been used widely. Many of the anecdotes have come along over numerous generations, which is a higher level of evidence. There should also be more international outreach and access to European safety data. Better information systems would be extremely helpful. There are “scare” stories, and the truth should come out in these situations, to provide consumers with quality, evaluated information. Greater library funding would promote access to private collections. He advises caution in statements by federal regulators. Truthful cooperation can help toward a more effective and safer use of CAM.

Dr. Rosner presented his concerns in a handout, with a discussion of solutions. The Foundation for Chiropractic Education and Research has been around for 50 years and has supported research fellows and residents. One of the significant barriers to research efforts in alternative medicine is the situation in which collaborative arrangements requirements prevent funding from going straight to alternative medicine organizations. The requirement that research be done by domestic institutions impedes research with established sources beyond U.S. borders. Another issue is that IRBs, which can stop a study, often do not have panelists familiar with CAM. Similarly, study sections seldom have representation by CAM practitioners or sympathizers. Publication bias and quotas prevent CAM research from reaching the necessary audiences, which in turn affects the press and leads to the wrong conclusions being stated in the popular press. Dr. Rosner also questions the categorizations used in discussing “mainstream” and “alternative” treatments, especially regarding chiropractic care. Intervention paradigms often reduce CAM to something less than what it is. Finally, he is concerned about over-reliance on the RCT approach in research – there are other kinds of clinical evidence that are sometimes preferable.

Dr Gordon would like to encourage future panelists to produce documentation as Rosner has done. Dr. Fair asked Mr. McCaleb about his statement that no natural products have been approved in decades. He thought taxol was a natural product. Mr. McCaleb explained that taxol was approved as an orphan drug for one kind of cancer and is being used for other types of cancer that are more common. It would not have been approved as an orphan drug for those uses. Mr. Chappell asked Mr. McCaleb to expand on the OTC panel idea. Mr. McCaleb explained that there should be a similar CAM panel, but with experts as needed instead of having separate panels for each area. This would be an upgrade of DSHEA, and would result in panels with expert opinions. Dr. Jonas asked how to motivate the private sector. He wondered if there might be obstacles in the patent process that need scrutiny. Dr. Leader explained that he was thinking of this for the less common botanicals. Dr. Jonas asked if there were a network for chiropractors. Dr. Rosner said that they tend to be organized locally, rather than nationwide.

Palmer has tried to organize a database. Mr. Chappell noted that single herbs are being researched, which is expensive. Mr. McCaleb said that some companies are looking at both formulas and single herbs. Dr. Leader said that his organization is looking for unique blends and unique perspectives. Dr. Fair asked if there is a problem with going to another country and bringing back plants. Dr. Leader advises working with partners from the country in question.



Session VII: Outcomes Research Part I — Interface between CAM Research and Regulatory Agencies

Dr. began by explaining that at the time of the initial experiments with radiation, there were also successful studies involving pancreatic proeolytic enzymes in fighting cancer. Although the hazards associated with radiation became known later, interest in enzymes was revived but for many years could not get a hearing. Dr. Gonzalez himself began researching this area in a five-year, exhaustive project. He did a thorough literature review, went over patient records, and did analysis, and yet could not get it published. He began treating patients with enzyme therapy himself. In 1993, NCI invited him to present selected cases from his practice to show how it worked. In gauging success of the therapy, he considers quality of life in addition to or even instead of tumor reduction. After his presentation, NCI suggested he conduct a pilot study with pancreatic cancer. The Nestle Corporation agreed to fund a trial of 11 pancreatic cancer patients. All of these patients were very sick, and all lived longer than expected, some as long as four years. The study was published in 1999. NCI then suggested a large-scale randomized trial. However, he could not get his patients to agree to be randomized. Only 1 of 260 agreed to chemotherapy instead of the enzymes, and she dropped out. So he made it into a case control study. At same time NCI was suggesting this larger study, he was served with a subpoena from his state medical board because he was using unconventional treatments. The White House Commission has an extraordinary mandate to protect new ideas like this and to serve as forum for those harassed for having those new ideas.

Dr. McCombs finds that the obstacles to trying innovative treatments are substantial. She has had to face her state medical board, and there is an element of fear involved. When treating cancer patients with CAM therapies, she does it quietly with patients she trusts. She lets them know in advance that there is no research data to show them regarding the effectiveness of her treatment, but she has good clinical outcomes. However, she has been reminded by the authorities that a medical license is a privilege, not a right. Insurance reimbursement is another factor. It limits the medicine she can practice. She believes that people must be open minded and look at new methodologies. Managed care issue is another big issue. She cannot treat Medicare patients or work in tax-supported clinics. She cannot mastermind research of her approach, for she is too busy quietly treating patients through the back door. Dr. Nambudripad said that she is a chiropractor and acupuncturist. Patients come to her and she treats them. She cannot have a best case series because she does not treat cancer, and if she treats cancer, she will step beyond her license in California. Many patients want treatment. But she has not published

data. Dr. McComb added that she has provided information about this treatment, originating from Germany. The Internet has also spread the word about this treatment. It stimulates her to learn more. There is a group of 15 to 20 percent on the fringes who do not respond to conventional treatment, and this is the group that she treats.

Dr. White said that NCI's best case series program is very dependent on practitioners feeling comfortable giving documentation of their practices to the federal government. NCI goes to great lengths to keep information confidential, and it is reviewed in a closed forum. It has been edifying to hear these concerns. He did not know the degree to which this has affected submissions to the best case program. He would be happy to explore with them ways to change the regulations so that best case series could be more productive. Also, NCI has learned that INDs for herbal products have inhibited some cancer research. He plans to meet with FDA to explore this more fully. He is concerned about the problems in this area. Some very high quality cancer researchers have had difficulty getting INDs. Then they can start learning more about the safety and efficacy of CAM products, and try to improve that side of the equation. He would be amenable to work on that as well.

Dr. Fins asked if the enzymes are taken orally. Dr. Gonzalez said that proof that they are not destroyed in stomach goes back to the 1970s. Dr. Fins added that Dr. Gonzalez's story is compelling. He asked what Dr. Gonzalez would have done differently had he known how things would turn out. Dr. Gonzalez replied that he would have done it more simply. However, many of these therapies were developed with patients. There are also animal studies going back a long time. This therapy has been ignored, and it does not offer drug companies an opportunity for a patentable substance. He believes that market forces and disbelief in science are the problems. Dr. McCombs said that she first heard about her treatment in 1994. A conference on the approach was held outside the United States so that they could talk freely. People from all over world were there. Enzymes were being sold on black market for exorbitant price. Dr. Bernier asked what other cancers this was used against. Dr. Gonzalez said that he has worked across board and treats across the board in his practice. His NCI study dealt with pancreatic cancer because that is one that cannot be affected by traditional therapy. Dr. Chow asked if Dr. Kelley, one of the advocates of the enzyme therapy, is still alive. Dr. Gonzalez answered that Dr. Kelley is on the Internet and claims that Dr. Gonzalez had stolen his therapy. The harassment he faced changed him. Dr. Gonzalez has never taken credit for Dr. Kelley's work. Everyone on the Commission is invited to spend a day in his office. He is totally booked and turning people away. He needs help. The treatment is only available in his office, but he believes in the scientific process and does not want to show other practitioners the approach until it has proven in a clinical trial. This is a terrible dilemma.

Dr. Fair asked why this has not been picked up in other countries, like Germany. Dr. Gonzalez said that they do use enzymes in German clinics. Dr. Kelley perfected it as an oral therapy. Dr. Low Dog then asked why he didn't use his enzymes in Germany. Dr. Gonzalez said that no one has asked him. In addition, the treatment goes beyond the enzymes. It includes diet, nutrients, and other factors. Dr. Jonas said that it is too bad that the individuals setting priorities were not there. It would be useful to hear not only about public input but also how they can get better clinician input. Dr. McCombs said that this was an excellent point. She is looking at public health problems and addressing those issues. There is a need to think outside the box in this

area. Dr. Jonas asked if there are appropriate methodologies for providing the information they think is important. Dr. Gonzalez said that government can and does waive the gold standard of RCTs whenever they want. They did it for interleukin-2, and eventually found that it was equal to a placebo when they finally did a study.

Dr. Kerr wanted their ideas on ethics. Dr. McCombs said that she fields phone calls all the time, and there are those who cannot afford treatment. It is heart-rending. She wants to keep doing this, but she needs help so that her licenses are not jeopardized. She wants efficacy and safety as much as the researchers do. Practitioners all have an obligation to do something about this. Dr. Chow said that this panel discussion has brought up an extremely important area. She wondered how we can continue to research when there are conflicts indicating this doubt, yet they have evidence that it is successful. People are dying, and the dilemma is how to balance the need to research first. This issue faces many practitioners. Dr. Fins said that there is a paradox here. Dr. Gonzalez was an example of a victim of science, but he has nonetheless stayed true to science. If they are going to bring in CAM practitioners, perhaps there should be immunity legislation to let them share their best practices. Dr. McCombs said that this is mandatory. They will not get what they are after if they do not guarantee protection. Not everyone can be clinicians and researchers both. Many clinicians have data, and do not want to come out of their closets and hand it over for fear of what is going to happen to them. Dr. Fair asked why they cannot bring their best case series to Dr. White. Dr. McCombs said that she will, because she is tired of dealing with this situation. Dr. Gonzalez said that he believes in doing research. NCI has been wonderful and has taken a lot of flack to test these therapies. Mr. Chappell asked to go on record with his statement. Understanding the discovery process is important; it is a unique beast. The process is championed by belief, passion, and intimacy. They cannot expand into the system until the therapy is ready to be believed. He recommends that the Commission present the fact that discovery has to be given permission, and nurtured in small working groups. Dr. Gordon asked the group to come so the Commission could learn how to midwife this kind of discovery. They can all see that these people have to speak indirectly. This panel was meant to set a new path for the Commission. They must address protection for people committed to their work. The Commission should come back with suggestions and proceed with recommendations to foster and nourish this kind of research.

The meeting adjourned for the day at 7:40 p.m.

Session VIII: Guiding Principles of CAM Perspectives and Practice

The second day of the meeting began with an hour of discussion among the Commission members. Dr. Gordon told them that there would be two minutes for each person to make a statement, then another round of short statements would be taken. This is the beginning of the process, which began with the first meeting, of building a common understanding of each other, work doing together, and determining the Commission's views.

Dr. Jonas identified several core issues affecting research in CAM. First is the public impact and what research does in this area. This involves the social transformation of science. They must determine how the public and practitioners can have a seat at the table. Second is multiculturalism – seeing different world views in which individuals see a different part of the

elephant, so to speak. The third issue is chronic illness. Western medicine can manage acute illness very successfully. However, in the areas of other problems, such as the prevalence of chronic illness and aging problems, there are few evident solutions. Next is health promotion. Salutogenesis is the term he uses – studying the process by which health occurs. We need to understand this process. Finally, we are no longer in the modern, materialistic age; we are now in information age, so knowledge management is key. He would hope to exchange wisdom, but first it needs to be created. What this means for research is that the research agenda must rigor and relevance. The more focused researchers become in terms of the current gold standard, often the less relevance research becomes.

Sr. Kerr sees two major paths. She believes that the founding documents of this country can inform the work here. In addition, a British doctor felt that current the biomedical model is dualistic, mechanistic, and reductionistic. While it is useful in many ways, recent shifts in thinking have not been incorporated well into the biomedical model, and she agrees. New scientific thinking is necessary.

Dr. Low Dog stated that she always believed in herbal medicine. As an adult, that never changed. When she came home from medical school, she had a feeling that all she knows is right and that science and spirit were not mutually exclusive. She does not believe in separating medicines – it is all medicine, whether alternative or Western, patients really want the physician's time, hands, heart, and expertise. They do not care what the remedy is. They just want to know that she's there for them and makes a safe place for them. That is the medicine of the future. Science can help get there, but there are some things that the double blind RCT cannot add.

Dr. Ornish said that he is always asking about the cause, and usually there is a whole causal chain of events. The body has a remarkable capacity to heal itself. Many dimensions are involved individually and on a social level as well. He does not want to treat just the symptoms that come up first, but rather get to what is really going on. In a way, comparing herbs and drugs keeps us in that same mechanistic model.

Dr. Paz said that the body is not a separate unit. The psyche has a very big role, and just treating medical problems does not work. Some therapies in modern medicine are not always sufficient. They need to encourage research and support practitioners already doing those therapies. It is important to facilitate research in that area..

Ms. Scott said that she agrees with everything said so far. Values and principles are important as a foundation. This is an opportunity for a perspective of wellness instead of illness. Everyone agrees that they want rigorous science, and devices and substances that are safe and effective. Her concern is that sometimes suggestions of different methods are suggestions to not do good science. But the existing paradigm does not always work. They must look at different techniques of measurement. What CAM brings to wellness and health care is validation of the patient's experience and the practitioner's experience. She would like the group to acknowledge their differences without seeing it as a division.

Dr. Bernier reminded the commissioners that when they received their charge from the President, he noted that millions of people seek CAM treatment every year. It is critical that they establish

ways to have rigor in CAM research to obtain the optimal output. They must distinguish the helpful from the unhelpful. The single most important message of CAM is that the focus is shifted to the patient to a substantial degree. When he saw cancer patients, he always made a house call. This gave patients confidence in him and was important bonding effort for him. How much modern CAM becomes future mainstream medicine will depend on how carefully the research is done and how critical that research is. The better it is, the greater the likelihood that health care workers will adopt it.

Mr. Chappell said that he sees involvement in CAM as an opportunity to be part of the world view in which all things are related to each other. The hierarchical model promotes distinct and separate levels. Inter-relatedness celebrates the different gifts of each person. This is an opportunity to be part of that way of looking at the world. Some of the principles are openness and collaboration, but particularly openness to new ideas and new attempts, so that discovery can happen without being stifled by the day-to-day management of different functions. He likes the term complementary because it adds onto the good work done to date by Western medicine. Safety and efficacy should still be key, but we need new protocols of effectiveness, otherwise we will be frustrated.

Dr. Chow explained that they must look at a new paradigm along with old one. They must be creative, brave, and courageous about recommending new things, even what seems ridiculous. She believes people are born perfect and in harmony with nature. We cannot learn from cadavers – the Qi is all gone. Science has to look at the past to talk about the future. In 1969, the first training for acupuncture occurred at Stanford. There were arrests afterwards, but the charges were thrown out because they were not “practicing medicine,” they were “practicing acupuncture.” She gave examples of patients she has healed. People should look at CAM as miracles. She believes in the rigors of research, but there should be other paradigms of establishing rigor. She prescribes eight hugs and three belly laughs a day.

Dr. Fair told the Commission that his introduction to this field was both professional and personal. He has looked back on things he considered the truth that were proven not to be. With mind/body therapies, some of his observations have astonished him. He wondered if we really know what questions to ask. His personal goal is to bring these approaches in as a complement. He does not think we need a new specialty of CAM physician. Instead, we need to enlighten doctors about CAM so they can learn to coordinate with CAM practitioners. He looks forward to establishing a new medicine.

Dr. Fins said that he comes from a traditional background in medicine. It has seemed to him like there are two parallel universes, each motivated by the desire to heal. But there should be a unified field theory, because patients do not make the same distinctions. The Commission should try to create enduring structures to sustain and promote the dialogue here. He also appreciates the varying structures that foster the scientific method. The scientific method will be the coin of the realm, and this is something they will need to address and work with. They also need to focus on social sciences to promote discovery and knowledge. They must understand better where there has been successful effort in integration and overcoming this false dichotomy. If they can do this, CAM and traditional medicine will both change for the better and join together to become the healing arts.

Dr. Gordon said that it was wonderful to listen to everyone. There were a few things he wanted them to focus on. First is the uniqueness of each individual and his or her journey through life. Their work is that of helping people become themselves. Next is integration of whatever works. He has learned to integrate many different traditions in his own work. Third is a focus on wellness, health, and education. It is very important to help people help themselves and show them possibilities. Fourth is outreach, and connection to other people. They need to encourage the establishment to reach out and share. Finally, and most fundamental, is to create a healing community and a community of healing. They must heal what ails medicine and health care through this Commission. So as they work with people and formulate recommendations, they should also welcome them into circle of healers.

Commission staff spoke at the request of the Commissioners. Dr. Groft said that he was trying to stay low key and provide for their needs. He believes we do not have control when we come into and leave world, but he likes to think that we have some control in interim. In last 9 years, he has tried to create a safe environment for people to present their views in a nonconfrontational manner, so they can talk and listen and move ahead. It is a struggle to go against organizations that are threatened by what we know is right, but wellness is a part of our own being.

Ms. Chang said that her guiding principles are to learn and teach, and have fun doing both.

Pollen noted that her father was a doctor beloved by his patients and learned in the art of medicine. She believes that we have lost the art of medicine. We need to feel we are being cared for by our doctors.

Ms. Kingsbury said that she was happy to be there.

Doctor Kaczmarczyk noted that he has never had to articulate his own views because he has been a voice for those who do not have access. He related most to what Ms. Scott said about equity. They are at a unique and wonderful point of creating access to CAM therapies for everyone. They are also at an intersection to reform health care and education – all education. They should include health care professionals and children in their efforts.

Sr. Kerr added that she had heard challenges and opportunities. The linear model of cause and effect is only partly applicable to health, and this sends up a yellow flashing light and makes her wary. She does not think in terms of cause and effect. If we see interconnectedness, we are driven to look at public health issues. So it is important to spend time on principles. She did not feel they were congruent. Dr. Gordon said that he was not looking for congruence yet, for they are just beginning. Dr. Jonas said that he was still concerned that they lack the time to really fundamentally deal with some of these issues. Dr. Gordon assured him that they can talk about how much time to set aside. Sr. Kerr also expressed concern about the need for Commissioners to get on board with one another. They are all doing their best, but they have different backgrounds. Dr. Groft noted that : future agendas will have additional time for Commissioners to talk among themselves. The initial meetings had an urgency to cover different aspects of CAM, and this meeting in particular had an ambitious agenda. The opportunity to talk is forthcoming, and one voice will develop over time. They want variability in statements right

now. Harmony will come even if there is still some disagreement. Dr. Gordon said that part of their work is to come together among themselves, but he wants them to have their own realities as well. He suggested more time at meetings, if the Commissioners are willing to do so. Dr. Chow agreed, saying that she would like to know where they agree and respect where they disagree. Dr. Fins said that agreements and disagreements can be about ends and means. Dr. Jonas suggested that they may find that they do not have the skills they need, and thus may want to bring in more talent at some point.

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

Dr. Templeton began by stating that he shares an interest in science-based research. He is primarily interested in health, healing, mind/body therapies, and how spiritually related CAM treatments can contribute to better health. The growing recognition of the need to be honest with patients began in the 1960s, but spirituality was not considered acceptable as a treatment at that time. Since then, we have learned that patients want their doctors to know what their beliefs are. Studies are also showing the role of spirituality in healing. Only a few studies address the mechanism of action by which spirituality can affect health outcomes. Working with a patient's beliefs would not usurp traditional medicine but rather would complement it. Some early studies examine how religion might contribute to good outcomes. Through his foundation, Dr. Templeton has funded two studies on the efficacy of prayer. The first dealt with arthritis, and found those who were prayed for were helped. The second is looking at remote prayer for bypass surgery patients; this study will be completed in the next year. Not-for-profit organizations can stimulate CAM research by providing seed money; supporting publication of research through awards; offering financial awards for medical schools and training; and convening consensus conferences. Obstacles include the lack of awareness of existing research. The solution is publication of studies in peer reviewed journals. The lack of funding for CAM research could be best addressed by improving the rigor of proposed studies. Mentors would help deal with the lack of new researchers in this area. Not-for-profit research can be better coordinated with the federal government through more well-designed studies.

Ms. Hayes explained that she is a foundation executive working closely with organizations worldwide to alleviate suffering. CAM research seems to be the stepchild of NIH. She wondered if NIH is trying to pass along this responsibility to the private sector. As CAM becomes more widely accepted, many people incorporate it into their lives. Many more people are influenced by their family and friends rather than by science. It becomes difficult to make informed choices. Some believe that government and philanthropy should always keep separate roles, yet this attitude inhibits productive partnerships. Government can be difficult to work with; federal agencies should focus on communication. One idea for government is to host introductory meetings among foundation people, and use the opportunity to inform them as to how to navigate the federal grant process. Government should also seek more foundation people for panels, and include them on mailing lists. Foundations can stimulate CAM research by funding more small pilot studies, which is often a requirement for government funding, and by creating a pool of funds among themselves for studies, in order to diminish risk factors. A fundamental obstacle to CAM research is the sense of separation between Eastern and Western medicine. Other obstacles are the slow dissemination of data from NIH, which could be speeded up; the fact that NIH is not letting the foundation world know what is been funded; and less-

than-optimal communication among and from foundations. For better coordination between government and not-for-profit agencies, both sectors have to assess how to be more flexible. Perhaps CAM review committees will rethink the timeframe for research. She believes that both the public and private sectors seek solutions and both care about good practices.

Dr. Callahan explained that his organizations receives grants. They became interested in CAM a few years ago when they began wondering why doctors are often hostile to CAM. Probably that hostility is the biggest obstacle. The discipline needs a stronger status and more middle range people making contribution. Many of the researchers in CAM are on somebody else's turf. There are four areas of interest: safety and efficacy; what public interest in CAM says about what people think about what they're getting, not getting, and want; the limits of evidence-based medicine, which are problematic and the results of which results are probabilistic, with little or no information about what will work for an individual patient; and, CAM can helpful in envisioning what our future in medicine will be, especially with the aging of society and with need for wellness among younger people.

Ms. Ades said that the American Cancer Society (ACS) is dedicated to eliminating cancer. There are many definitions of CAM. ACS defines alternative treatment as treatment used in place of mainstream treatment; complementary treatment is used in addition to mainstream treatment. The lack of consistent definitions can be problematic in communications, and ACS does not see alternative medicine and complementary medicine as grouped together. ACS wants all cancer interventions to withstand the scrutiny of scientific review. The organization supports patient access and accountability both. Many cancers can be cured if caught early and if the patient gets the right treatment. The potential for serious drug interactions must be recognized, as well. ACS supports NCCAM and is encouraged by the comments Dr. Straus made. They would like to see the Commission support NCCAM. ACS also supports NCI's best case series, which is very important for research in this area. ACS would like the Commission to recommend additional funding for CAM research. Barriers include attitudes and perceptions, with funding as a distant third. Some believe RCTs cannot be done in some kinds of CAM. If that is so, they need to identify what is and is not appropriate for RCTs. There should be more published research. They hope the Commission will ask that all therapies be proven safe and effective regardless of their source. ACS also recommends an educational strategy to break down barriers. Finally, ACS would like to see development of a model to coordinate research between the federal government and the not-for-profits.

Dr. Ornish asked Dr. Templeton if he distinguished between religion and spirituality in his research. Dr. Templeton replied that it is hard to design good studies in terms of defining this, and it is hard to quantify religion. People compare themselves to each other and the result is very vague when talking about religion. He believes the early assessments will be correlational. Dr. Ornish asked what the panelists were currently doing in the way of CAM research. Ms. Hayes said that her foundation has nothing in works at this time. The previous study took longer than expected by a factor of two. The board found this to be a giant step forward. She hopes they will continue to be open to this kind of thing. Dr. Ornish asked if they thought it was ethical to do RCTs in researching CAM therapies? Dr. Callahan said that in some cases they do not work, and therefore researchers will need to develop other evidence. Enormous need is another way to formalize research. If researchers cannot do gold standard research and yet find that testing is

important, they may have to pick another methodology rather than do nothing at all if they have come across a promising cure. Dr. Ornish asked if ACS is doing CAM research. Ms. Ades said that they have some activities in behavioral research on the frequency of use of CAM, professional perceptions, and quality of life. Dr. Jonas noted that a different dilemma is that of being able to address the need for new methodologies in new areas. He asked if they had any ideas along these lines as to what else could provide valid information. Dr. Callahan suggested they bring in experts in the area of methodologies to talk about this and to develop alternatives, in a think tank effort. Dr. Jonas asked if there are ways to bring together resources in researching spirituality. Dr. Templeton thought a conference would be helpful. Sr. Kerr asked if the panelists had opinions on world views. Dr. Callahan observed that spirituality is something that would not be evaluated the same way as herbs. He could not think in terms of one uniform purpose methodology. Dr. Templeton added that an increasing number of medical students are taking spiritual history. Dr. Fins raised concerns about methodology. Some investigators are not affiliated with institutions. He wondered if a not-for-profit institution could support them with infrastructure. Ms. Hayes said that supporting an individual demands proportionately more staff time. The Hilton Foundation rarely funds individuals. Dr. Templeton agreed. Mr. Chappell asked if any of them had explored 12-step therapy? Dr. Templeton said that it has been studied, and his foundation is trying to find new, cutting-edge areas to research. Dr. Gordon asked what they would recommend to the Commission. Dr. Callahan said that they need a better understanding about what attracts people to CAM. Ms. Ades advised a working group on methodology. Ms. Hayes suggested they facilitate conversation among and with foundations. Dr. Templeton urged a consensus conference not on CAM in general, but on several components, bringing in foundations and research experts.

Session X: Private Sector Support for CAM Research

Mr. Burkholder explained that his organization deals with medical equipment. They have become aware of certain health trends. Consumers are spending more on health care, and an increasing portion of that is being spent on CAM, as we shift toward a patient-oriented health care delivery system. Along with their new clout, consumers need reliable information. The fundamental elements of medical technology are that it is diverse, dynamic, and rapid. These developments have occurred in concert with the strengthening of the regulatory system. Congress has made them more responsible for the quality of their products. This has been a key component in innovation, because it bolsters consumer confidence. Despite these breakthroughs, there is a lack of funding in this area. Bioengineering is not well funded. Regulation can be a barrier, and in CAM it can be either excessive or inadequate. Regulation must foster and direct development. When regulators look for excessive data up front, they drive away good products and freeze research. Some encouraging trends include the ongoing debate over regulation; the increasing number of medical school students interested in CAM; and the increasing integration of CAM and traditional technologies in medical technology companies.

Dr. Ruddon noted that meetings like this one will help focus public policy. Johnson & Johnson has addressed CAM research in a number of ways. As more and more people become better informed, these products will represent a new area for companies. Johnson & Johnson has been involved in CAM for 3 years. A task force did literature review, identified leaders in the various fields and consulted with them regarding research, then ranked the best avenues of opportunity

for Johnson & Johnson. The need for further research was assessed, and the company established a number of ways to support and bring to market new products in this area. Johnson & Johnson is funding academic investigators and a seed grant program. The task force monitors the field and interviews key CAM investigators. Another area of investigation is prevention, along with health and wellness programs. The need for solid, basic research in this area is clear. NIH can help by promoting collaborations; there are mechanisms available. Incentives are needed, and resolution of intellectual property issues is essential to allow for marketing protection. There is also a need for strong regulatory pathways. He would like to see more effective integration of federal and private efforts; better communication between traditional and CAM practitioners; increased collaboration and cooperation; improved scientific merit reviews; and protected marketing rights. His company endorses coordinated research programs to transform medical science into wanted products for the public. Another need is for more basic research in this area. Finally, a necessary area of investigation is how to individualize therapy.

Dr. Sciavolino addressed drugs from botanical or herbal sources. Pfizer has a research program in this area. Nature has been a fruitful source of new medications. The largely empirical screening methods that approved many early drugs have fallen into disfavor - they are labor-intensive and unproductive. Instead, synthesized compounds have been developed and screened. But the link between this process and clinical effectiveness is not always fully understood. The road from a new idea to a new medication is long, treacherous, and expensive. It can take 10 to 15 years and hundreds of millions of dollars. One key factor is attrition. Most drug candidates fail to become registered pharmaceuticals. Only one in five or six succeed in the research process. 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 with no compromise. 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 of their work. He urged the Commission to recommend incentives for development.

Mr. Blumenthal represents a nonprofit organization concerned with herbal products. Manufacturers lack incentives because there are no proprietary privileges in this area. FDA might consider developing guidance for removal criteria for DSHEA labels. Most of the herbs that are popular in this country have been well-researched abroad, especially in Germany. We should look at the German regulatory system, which recognizes that there are benefits to herbs. Half of the herbs sold in that country are doctor recommended or prescribed. Our government does not allow the information that Germany encourages. Much of the research there was done on specific products, and it would be interesting to know if any or all of that research is transferrable to comparable products. Some European companies are concerned about their research being "borrowed" over here. DSHEA has supported research in this country. Incentives such as rights to exclusive claims and market protections would be helpful. There should be research on dietary supplements, although that could become unwieldy. Herbs do not currently qualify for patents, and that is problematic. Trademark protection should be available, and there must be a way to protect the small companies in the business.

Dr. Dickenson spoke on behalf of a trade association for the dietary supplement industry. She would like to see industry submit studies to peer review journals. Industry should also share

information from incomplete studies in order to guide other efforts, provide substances for clinical trials, and offer industry-sponsored symposia with CAM practitioners. To overcome barriers, she suggested they meet with journal editorial boards to solicit recommendations to increase acceptance of papers submitted by the industry. Her organization would also like to see a clinical trials guidance document and a mechanism for sharing study results that have proprietary information. She endorsed the use of standardized products in studies. Industry should form partnerships with clinicians and academia and participate on NIH advisory panels. The federal government can help by compiling a primer on funding mechanisms and making funding opportunities more visible. NCCAM does a good job of promoting its initiatives on the web, which could serve as a model for a larger database including private study results. It would also be helpful to have a conference on completion of relevant studies.

Mr. Chappell asked about the gradations of exclusivity. Dr. Ruddon said that there are pharmaceuticals, OTCs, and herbals. All three need to provide a competitive advantage. Mr. Blumenthal agreed that exclusivity is a major issue. Another concern is that a single study might not be acceptable as sufficient, which complicates matters. There are many intellectual property issues. Dr. Gordon asked for an example of a new product. Dr. Ruddon suggested new components of green tea, possibly extracts. Mr. Blumenthal added that it is no longer an herb at that point. Dr. Sciavolino added that Pfizer is pursuing an opportunity with an herb from South Africa that reportedly mutes the appetite. The company is pursuing it as a mixture, as it is used in South Africa. Pfizer is looking for medicines that could be potentially useful, but all parties need incentives. Dr. Low Dog asked who is responsible for determining safety. Dr. Dickenson replied that the company has the ultimate responsibility. But there are many questions regarding use in pregnancy and other consumer issues. Mr. Blumenthal noted that 550 herbs commonly sold in the United States now have a baseline within industry. Dr. Sciavolino noted that FDA guidance will facilitate getting to Phase 2 trials.

Dr. Jonas asked for an explanation of the costs involved. Dr. Sciavolino suggested that early Phase 2 data would contribute to outcomes, and attrition would be reduced, thus lowering costs. Dr. Jonas asked for more discussion about patents. Mr. Blumenthal explained that a process patent depends on industrial issues. Patents have been high on their agenda for a while, though a trademark is the best asset. Dr. Ruddon said that depending on the size of the market, a process use patent would be a solid incentive. Dr. Jonas thought the process patent seemed limited. Mr. Burkholder noted that acupuncture needles go through the equipment process.

Dr. Fair asked about the purpose of a dietary supplement information center. Dr. Dickenson said that it would provide a third-party source for consumer information, and there is a demand for that. Ideally there would be a web site and other means of access. Dr. Fair stated that there are many plants on the planet that have not yet been identified for medicinal purposes. He asked about the disincentive for studying them. Mr. Blumenthal agreed that only a fraction of all plants have been studied, but many have been screened. Many of the unscreened plants are those that native peoples have not used. Dr. Sciavolino added that it is very labor intensive and unproductive to screen plants. Pfizer advocates moving some of these materials directly into Phase 2 studies. Molecular processes more expedient. Dr. Chow noted that there is a cultural aspect in using some herbs. She asked if they had any thoughts of researching herbs as part of a larger whole, along the lines of an herb studied in context of lifestyle. Dr. Sciavolino said that

this is more an issue for a patient's physician. Looking at the genomes of plants will eventually allow them to see what happens with the entire plant, and this is where corporate interests lie. Dr. Ruddon agreed that even when looking at health and wellness as unified field, the cultural aspects are not for a company to determine, but rather fall to the provider. Mr. Blumenthal added that compounds are of interest in Chinese medicine and some other systems.

Dr. Fins asked if applications for NDAs indicate where they are seeking exclusivity. He also wondered if they can really assume safety in moving straight to a Phase 2 trial. Dr. Ruddon said that an NDA would have to offer some exclusivity. Dr. Sciavolino said that in some cases, safety documentation from elsewhere is strong, but other times it is not. His company would not go directly into Phase 2. Dr. Gordon noted that he hears skepticism among patients. Dr. Dickenson said that DSHEA requires that the product deliver what the label says it has. The industry is about to undertake a third-party testing program. Companies will pay a licensing fee for testing, and they may do a seal program. Both are necessary. There will always be those who do not meet their responsibilities, and FDA must enforce the rules. FDA should have more enforcement resources on the food side. Mr. Blumenthal agreed.

Public Comment

The Commission held another public comment session on the second day. Charles Levy introduced himself as a clinical psychologist in private practice who does mind-body treatment, developing deep hypnotic states. He would like to see research focus on mind-body practice. The role of mind and spirit is vastly underestimated. Innovations such as energy healing, meditation, hypnosis, and more traditional therapies are applied differently. There are too few CAM practitioners in this area. The Commission should contact relevant professional societies to discuss this. He supports research, but the public needs scientifically based CAM interventions. They must do a better job of making procedures available. The Commission should develop recommendations for the relevant professional societies. He has promoted traditional methodologies in innovative ways, and innovative methodologies in more traditional settings.

Ingrid Luces said that NCCAM should receive greater funding. She believes they should query programs as to what they need to expand their research efforts. Double blind tests are not always appropriate for CAM; it would help if their use were tempered. The Commission should expand their contact with Dr. Rosner and Dr. Meeker, who spoke the previous day. They should also ensure that there is coverage of chiropractic care, by encouraging Congress to instruct HCFA to reimburse participants in clinical trials involving CAM.

Diana Chambers came on behalf of Friends of Health, an organization addressing the whole person and CAM. Friends of Health hopes to promote coordination and cooperation. Given the breadth of representation, she hopes to bring CAM people together in the organization. She has heard references to the frustration engendered by the limitations of the language. Friends of Health is discussing this, and examining the role of poetry and drama in health. The group is committed to pulling in all views, and has a scientific advisory committee. Each doctor on the board has strong credentials and depth. The effective integration of CAM and conventional medicine cannot be a shotgun marriage brokered by money. It should be a stepwise process. It

is also essential that reviewers be knowledgeable. Only a few scientists are aware of what has been done in CAM. She believes medical faculties should be exposed to these new ideas. She would also like to see national conferences covering the same ground. Dr. Fins suggested that she seek funding in conjunction with the National Endowment for the Humanities. Dr. Jonas observed that for all the talk about science and rigorous methodology, science must have credibility, which is a social process.

Monika Lenz has done research on cancer, but no one is interested because it is unconventional. She has analyzed herself alone. She has had cancer three times, and at one point she went to Russia, where the doctors could not explain how she created the cancer. She felt that if the doctors could explain how she created it, she could make it go away. This happened three times. She is a philosopher, not a doctor. She invites researchers to ask new questions. She was not sick in her body, she was sick in spirit. She is with a group in Colombia (SA) and is working with children who have cancer. It is a wonderful experience that brings life back. Dr. Jonas asked for more details of her experience. She said that she learned that one cannot stop cancer like one would stop a car. She did Ludwig diet. Her family and friends were afraid of their own deaths, not hers. She hopes to soon have a smorgasbord of possibilities so that each person has their own experiences.

Ned Hartfield asked the Commission to stand and stretch. He works with Life Foundation International in Europe, teaching body-heart-mind techniques. He helps transform emotional pain. Each chapter of the foundation's book shows what movements and techniques can be used for each emotion. He gave the Commission a gift, a candle that was lit from an eternal flame, to give unity, hope, and light. Dr. Low Dog asked how he got support for his work. Mr. Hartfield said that they have training centers where they offer courses. They teach these techniques and have amazing results.

Boyd Landry spoke next. He is the executive director of the Coalition for Natural Health. Vocabulary is extremely important. Descriptions of Western medicine as "traditional" are wrong, it should be called "conventional" instead. CAM therapies have more claim to the word "traditional." If there is no significant harm, people should have the right to access therapies and practitioners should have the right to heal. He favors openness by conventional healers. They cannot force CAM into a conventional box. They must keep CAM's integrity and distinction. Dr. Gordon asked about Landry's organization. Mr. Landry said he represents 2,500 natural and holistic practitioners. They do a lot of work on the state level. Members live in fear of conventional medical regulation. Drawing them out is something the Commission should look at. Dr. Ornish asked what research methodologies he would recommend. Mr. Landry said that the public will figure out what works more quickly than science. Dr. Ornish asked him to confirm that he thought there should be no research at all, with the market sorting it out. Mr. Landry said that if there is a propensity of harm, something ought to be determined. But practitioners will study their work among themselves. The current process doesn't work. Dr. Ornish asked if he was also recommending no licensure or regulation. Mr. Landry said that except for invasive practices, the public domain works very well. They should empower people with their own health. Dr. Low Dog said that she is sympathetic to much of what he said, but noted that even in Europe, there are restrictions on access to certain herbs that are toxic. Efficacy will indeed sort itself out, but safety remains an issue. Sometimes harm can be difficult

to assess, and science can be the appropriate means to determine that.

Richard Pavek said he had two intersecting thoughts. More of the population is turning to drugless, hands-on therapies. The concept of research to reduce medications does not appear to be an NIH priority. But there is a need to research drugless treatments. He also believes that reviewing these therapies with the same system that reviews drugs with toxic side effects is not right. It is inconceivable that there would be one measuring tool for everything – this is not the case in engineering, for example. A method that filters individual characteristics should not be used when there is a need for focus on individual characteristics.

Thomas Staboraski came representing a company that has developed targeted nutritional products for migraine prevention. He is concerned that the standard of scientific research is imperfect. An individual practitioner's ability to observe is important. He is also concerned about the disease state focus. He asked how they would define and heal diseases of unknown cause. His targeted nutritional approach solves these problems. He believes in empowering patients. An organization that may be of value is Medical Outcomes Trust. He is not sure if their work has been widely publicized. They have measurement instruments for CAM that have been through scientific review. Dr. Jonas said that he would like to further discuss outcomes measurement. There must be validated measures for relevance.

Session XI: Outcomes Research Part II - CAM Research and Experimental Study Design

Dr. Standish has seen amazing advances since the start of OAM. CAM research now has funding and credibility at NIH. Obstacles remain, however. There is a need for research infrastructure and training at CAM centers. FDA policies and procedures must address CAM issues, as well. She gave an example of seeking an IND waiver in order to study homeopathy. But after 5 years, FDA has still not made a judgment on it the waiver. This is not an isolated problem; it has happened more than once. She believes the situation will improve significantly over time. Another issue is that IRBs at non-CAM institutions lack understanding of CAM research issues. Yet the IRBs make the decisions to go forward or not. A fourth obstacle is in the area of practice-based outcomes research. There has been little progress in this area, although not for lack of trying. The best case series needs increased funding and a trust-building effort. She has heard powerful stories about this kind of research. She would like to see partnerships between CAM academics and CAM practitioners, with NCI funding them for best case series. Outcome studies are hard, too. To get the numbers needed takes a tremendous effort of consortium development. All of the issues are on the table here. For first time, she feels a wonderful optimism about ability to solve them.

Dr. Cramer spoke to the Commission by speaker phone. In 1997, OAM asked the CDC to do methodological research pilot studies. They drew a number of conclusions about observational research in CAM, primarily that it is relatively easy and inexpensive. These data will lay the foundation for priority-setting. But there are inherent methodological limitations. Observational methods do not control exposures. 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. 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, which must be in the study design from the outset. Finally, for experimental study design, the most important feature of a valid study is having a comparison group. They need 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 measured and what the outcome is. The entire system is what is analyzed. It is also possible to evaluate entire modalities, then go back and do the chemical analyses and basic science on those that work. She recommends assembling an integrated team of clinicians with allopathic and CAM expertise to be researchers in randomized studies. She recommends three ways to implement strategies: solicit proposals from integrated research teams; assign a research mentor to interested CAM practitioners; and send experienced research teams to CAM sites. Dr. Ornish noted that these are issues researchers struggle with. The CDC pilot study implies they know how much to adjust for and for what. Dr. Cramer said that they had a lot of data, and were thus able to adjust with a lot of mathematical expertise. The problem is in over-interpreting data. They could collect data in standardized form. And patients could fill out an evaluation after they are seen. It is possible to use the patient as his or her own control group. Dr. Jonas asked her to confirm that she does not recommend observational research. Dr. Cramer said that it is limited, although it is possible to do prospectively. Dr. Jonas asked about the time and cost of her study. Dr. Cramer said that they screened 600 patients, extracted 240, and had 80 in the study, which took 8 months. It was impossible to analyze the subgroups. The project cost \$60,000 total.

Dr. Segal asked the Commission to imagine back pain and think through the escalation of the process, finally finding all these other modalities after exhausting the conventional system. But on a return trip to a physician, the patient will be to a specialist instead of getting help with the issue of CAM modalities. We cannot know what works in the end unless we do clinical outcomes research. The ultimate value for patient is to know what is effective. Collaboration with someone like Dr. Cramer would be wonderful. It is that kind of quality research that provides credibility, that allows a person to visit the clinician and find out what works and what does not. Rigorous research leads to acceptance and acceptance leads to use. This is not happening because although it looks easy, there are three obstacles: time, energy, and expertise. Someone like Dr. Cramer needs to help design the study, then fill out a 30-page grant application, set up the study, collect data, analyze it, and finally write it very carefully and rigorously to be accepted in a credible journal. The next limitation is theoretical – when we look at cause and effect, we might not actually get cause and effect in a person. On a technical level, the studies need to be huge. Big studies establish credibility. Finally, there needs to be a paradigm shift to respect the modality under study. We cannot dictate to CAM practitioners through the conventional paradigm. Her suggestions are to have a research training program for clinicians that allows them to stay in practice, and with clinical research outcomes, establish a broader array of treatment modalities to enter the system.

Dr. Lloyd introduced himself as a preventive medicine and public health physician representing 28 schools of public health. Training centers are tailoring their curricula to deal with more community issues. Public health is multidisciplinary. Departments of biostatistics, epidemiology, and behavioral sciences are in all their schools. Many faculty are involved in

CAM projects. Deans in these schools have established new agenda. Their priorities reflect the public health problems facing the country. They have a new project with the Health Resources and Services Agency and are working with chiropractors. The purpose is to optimize health. They are teaching chiropractic students public health, and the working group will disseminate the resulting workbook. Member schools recognize that CAM is in a growth phase. Public health schools are an ideal environment for CAM.

Dr. Fair noted that Dr. Segal addressed the problems one deals with in this research. She also provided a solution, which is to collaborate with schools. He wondered about the extent to which this is done. Dr. Segal said that there are relationships in some areas, but they scratch the surface. If she had a skilled researcher, she could get the patients and practitioners. Dr. Jonas noted that there is an umbrella organization for health insurance plans, the Health Insurance Plan Association. He wondered why they did not provide funding, as their counterpart does in Germany on the provision that there is an evaluation component. Dr. Segal said she did not know why HIPA does not fund research, but she could find out. Within her organization, there is a small research fund. Dr. Jonas asked Dr. Lloyd how to facilitate schools research. Dr. Lloyd replied that this is evolving, but it takes a nudge. An RFA encouraging this would help. Dr. Fins asked about NCQA, an accrediting body. Dr. Segal explained that NCQA likes data that prove a program makes a difference. This is why a measurement program is so important.

Dr. Chow asked for comments on individuality. Dr. Segal observed that if a patient requires hernia surgery, there are multiple ways to do it. One surgeon may use multiple means of repair. The same should apply to something like acupuncture. There are ways to go about research and look at acupuncture as part of a whole or alone. Dr. Standish said that this issue has the potential solution of looking at it 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. Dr. Low Dog noted that most studies work hard to remove the role of the healer. But the role of the healer is very important. She suggested looking at what makes certain practitioners effective, then teaching that. But it would be hard to measure something like a home visit. Dr. Standish noted that the practitioner effect is very important. In her work, she wants to know if what she does make a difference. And if so, what part of what she does is having the impact. Dr. Gordon noted that NCCAM currently funds centers. He wondered how they might provide some of the assistance Dr. Segal mentioned. Dr. Standish suggested that they could play a big role in the best case series, but has not happened to the extent NCCAM hoped. Dr. Fins noted that this problem is not unique to CAM research. Dr. Chow added that the only thing that makes a difference here is the energy and adaptation of ancient theories of energy.

Session XII: Federal Agency Support for CAM Research

Dr. Demakis explained that the Veterans Administration has a line item in its budget to do research in its hospitals. The VA runs over 170 hospitals and 200 nursing homes and provides all kinds of care to over 4 million veterans. The research budget this year was over \$320 million, and VA physicians received additional money from other sources. The VA does many cooperative trials and has its own IRBs. In the last 10 years, the VA. has funded \$60 million in CAM research, while VA. investigators have participated in other CAM research project 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 so on, through the entire spectrum. The VA is doing an omnibus report of these numerous studies. The main concerns are about the variable training and credentials of CAM practitioners, the stability of funding, and safety.

Dr. Vanderwagen is from the Zuni, in New Mexico. In their world, CAM is standard and standard is CAM. IHS has a small amount of funding, which on a per capita basis comes to less than half of Medicare per capita funding. The IHS is authorized to provide health services, not do research. The Service has had some success in increasing lifespans. Infant mortality is now close to national average. The reason IHS has been successful is because it empowered the Indian people to take charge of their own health. The role of traditional healing practices varies among the 500-plus tribes, which are not homogenized and cannot be treated as a block. The moral basis on which IHS operates would prevent the organization from expropriating the Indian processes into a federal system, because they often emanate from the indigenous religions. He works closely with indigenous health organizations. In regard to research, IHS does not fund or support, but some community organizations have an interest in it. If the Commission is interested, they will need to work with the tribal governments. Some have been researched to death. They know what IRBs are. NIH has funded centers for health research for Native Americans – such centers must be governed by the Indian people, not by researchers. Some facilities have a healing room set up according to tribal standards.

Dr. Gordon asked how the VA selects research projects. Dr. Demakis said that they can put out a solicitation. There are oversight committees that recommend filling certain gaps. Most research is done by the VA's internal clinicians, and they are the only ones eligible for those grants. Dr. Fins asked about the VA infrastructure. Dr. Demakis explained that there is not an organized approach. Instead, the initiative comes from the field. Dr. Fins asked if the VA would be interested in having an internal CAM research office. Dr. Demakis told the Commission that research in the VA is organized into four basic types: basic, bench, rehabilitation, and outcomes. If they opened the door to a special interest, others would ask for the same treatment. Dr. Fair asked how to contact the Society of Medicine Men. Dr. Vanderwagen said that Commission member Bufford Rolin, who was unable to attend the meeting, would be of help on that. The National Indian Health Organization reflects the health interests of tribal governments nationwide. That is a contact point. The power of an individual healer is memorialized in many of the tribes. They should also consider talking to the National Council of Rural Indian Health.

Dr. Jonas asked about the research budget at the VA. Dr. Demakis said it was \$321 million for intramural, with no salaries or indirect costs out of that. By other calculations, then, it would be closer to \$700 million, and clinicians get another similar amount from other sources. Dr. Jonas thought the VA seemed the ideal place to do demonstration projects. Dr. Demakis agreed. They expect investigators to come forward with ideas and put out a lot of RFAs. Some of the physicians are not trained to do research. Dr. Ornish asked what percentage are RFA directed. Dr. Demakis did not know. They pulled together a team to look at what research findings have not been translated to practice and have made an effort to improve the quality of care by translating findings into practice. Dr. Jonas observed that health care for IHS sounds like it is decentralized. He assumes they do not license practitioners. He wondered if there have been any increases in adverse effects or missed appropriate practices due to their use of CAM

therapies. Dr. Vanderwagen said that it is hard to know about the latter. There is no evidence that the quality of care has deteriorated, and all facilities are accredited. The tribes have a lot of latitude. They can tap other money, beyond what the government gives. Providers have to be fit into a GS slot, and IHS calls the native healers “mental health technicians.” The family and patient put into the traditional healing more effort. Dr. Jonas suggested that there might be value differences. Dr. Vanderwagen said that the experience has been they are willing to push the limit.

Dr. Bernier noted that the VA has achieved an enormous prominence in terms of its research. He wondered what it is about the VA system that lends itself to rapid change. Dr. Demakis said that most studies come from the investigators themselves. The VA does not think in terms of CAM per se, they think about how well the study is proposed. If it is worth looking at, there will be a committee that puts together a proposal after an initial five to seven page paper. This is not easy to do, but it is done and is probably as good as it can be. It is rigorous, and it should be. Dr. Bernier said that the VA was once concerned about its future. He wondered if the presence of these programs has helped keep it going. Dr. Demakis said he likes to think so. Dr. Chow said that she likes the power the VA has. She asked if a study done with the VA or IHS could be moved to different sites. Dr. Vanderwagen said that if the Indian people felt ownership, they would do it because they are pragmatic. Decentralization is swinging back, so they want to share resources laterally. Dr. Demakis said that the VA is able to diffuse research findings to the field quickly.

Dr. Fins noted that Dr. Vanderwagen raised a question about protection of religious freedom. Regulation of some practices in context of religious belief raises a constitutional issue. Dr. Vanderwagen said that the law protects Indian people in their religious practices. Moral leadership is involved as well. They do not want to expropriate practices and give power to the pharmaceutical companies. Dr. Fins added that they had heard earlier from a pharmaceutical company looking for products from indigenous communities. He wanted to know what might be appropriate recompense. Dr. Vanderwagen said that recompense often has nothing to do with material wealth and has more to do with freedom and empowerment. The obligation is to think of the wellness of the people. Dr. Gordon asked if any research had been done on the use of peyote in Native American churches. Dr. Vanderwagen was not aware of any. Dr. Jonas said that the cultural perspective is extremely important. Dr. Vanderwagen agreed. The great belief is in the power of the healer. They put their attention beyond biology and disease. Tribal medicine has a holistic perspective. Dr. Demakis added that early Christians did not believe they should go to doctors. Early hospitals had chapels and the early doctors were monks.

Dr. Gordon adjourned the meeting at 5:40 p.m.