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FOLDER TITLE:
WHCCAMP Meeting #2, October 5-6, 2000

2011-0568-S
kc831

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

THURSDAY, OCT 5

1. 8:30 – 9:30 a.m.

Opening Session	Topic: World View

Full Commission Discussion	1 hour

2. 9:35 – 11:45 p.m.

Panel I. Federal Support for CAM Research: Part I	**Topics: Achievements, Opportunities, Obstacles, and Solutions**
Questions for Panel A & B: (Federal Panelists) ➜	What is needed to expand current Federal efforts to bring CAM products and practices into mainstream medical research; for example, mechanisms of research support, incentives, education and training of investigators? What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, treatment)? What additional areas of opportunity exist for research on CAM interventions? What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream medical research?
Questions for Panel B ➜	How did you manage to create the center, what were the obstacles you faced, how successful were you in overcoming the obstacles, and what solutions would you offer?

Panel	**Speakers**	**Time Allotted**
A. NIH (other than NCCAM)	*9:30 – 10:30 (includes discussion)*	*1 hour*
* ODS *(Dietary Supplements)* * Other NIH Institutes *(at least 2, one supporting and one not supporting CAM research)* Discussion	(choose 4) 1. Paul Coates 2. Richard Klausner 3. Marvin Cassman 4. Claude Lenfant 5. Steve Katz	 10 min 10 min 10 min 10 min 20 min
BREAK	**10:30–10:45**	**15 min**
B. Academic Centers	*10:45 11:45 (includes discussion)*	*1 hour*
*Columbia University *Harvard University *Bastyr College *Palmer Chiropractic (IA) Discussion	Herbert Pardes Joseph Martin Joseph Pizzorno Bill Meeker	10 min 10 min 10 min 10 min 20 min

4. 11:45 – 1:00

LUNCH 12:15-1:15	**Media Briefing**

5. 1:00 – 2:00

PUBLIC COMMENT	

6. 2:00 – 4:40

Panel I. Federal Support for CAM Research: Part II	**Topics: Achievements, Opportunities, Obstacles, and Solutions**
Questions for Panels C and D: (Federal Panelists) ➜	What is needed to expand current Federal efforts to bring CAM products and practices into mainstream medical research; for example, mechanisms of research support, incentives, education and training of investigators? What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, treatment)? What additional areas of opportunity exist for research on CAM interventions? What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream medical research? *(Note: FDA, HCFA, and NLM will present on later panels that are more related to their missions)*

Panel	**Speakers**	**Time Allotted**
C. NCCAM	*2:00 –2:30 (includes discussion)*	*30 min*
*Office of the Director Discussion	Steve Straus	15 min 15 min
BREAK	**2:30 – 2:45**	**15 min**
D1. Other Federal Resrch Agencies (Group 1)	*2:45 – 3:40 (includes discussion)*	*50 min*
*CDC *AHRQ *DoD *SAMHSA Discussion	1. 2. 3. 4	10 min 10 min 10 min 10 min 10 min
D2. Other Federal Resrch Agencies (Group 2)	*3:40 – 4:40 (includes discussion)*	*1 hour*
*HRSA *NSF *EdD *IHS *VA Discussion	5. 6. 7. 8. 9.	10 min 10 min 10 min 10 min 10 min 10 min

BREAK	*4:40 – 4:50*	*15 min*

7. 4:50 – 5:15

COMMITTEE BUSINESS

FRIDAY, OCT 6

1. 8:30 – 8:40 a.m.

Welcome and Re-Cap		*10 min*

2. 8:40 – 10:00

Panel. II Non-Profit/Private Sector Support for CAM Research:	**TOPIC: Achievements, Opportunities, Obstacles, and Solutions**
Questions for Panel A and B ➜	How can the public/private sector stimulate CAM medical research? What are the obstacles/barriers and possible solutions to accomplishing this goal, e.g., incentives? How can public/private sector CAM research be better coordinated with Federally-supported CAM research?

Panel	**Speakers**	**Time Allotted**
A. Non-Profit Sector Support	*8:40 – 10:00 (includes discussion)*	1 hr; 20 min
* Philanthropic Organizations * Foundations	(Supporting) 1. PEW 2. RWJ 3. Templeton Fdn (Not Supporting) 1. Pew 2. RWJ 3. Macy 4. Kaiser Fndn	10 min 10 min 10 min 10 min 10 min 10 min 20 min
Discussion		
BREAK	**10:00 – 10:15**	**15 min**
B. Private Sector Support	*10:15 – 11:35 (includes discussion)*	*1 hr; 20 min*
* Pharmaceutical Companies * Supplements- * Herbals- * Devices Companies * Biotechnology Companies Discussion	1. 2. 3. Pfizer 4. 5. Tom Chapell 6. NIKKEN	10 min 10 min 10 min 10 min 10 min 10 min 20 min

2. 11:35 – 12:30

LUNCH	TOWN HALL BRIEFING

3. 12:30 – 2:45

Panel III. Facilitating CAM Research	TOPIC: Achievements, Opportunities, Obstacles, and Solutions
Questions for the Panel ➜	How are current regulations being applied to CAM? How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles?

Panel	Speakers	Time Allotted
Research and Its Regulatory Challenges	*12:30 – 2:45*	*2 hrs; 10 min*
* Center for Drug Evaluation and Research, FDA	1.	10 min
* Center for Devices and Radiological Health, FDA	2.	10 min
* Center for Food Safety and Nutrition, FDA	3.	10 min
* State Medical Boards	4.	10 min
(Examples of the interface between CAM research and the regulatory agencies)	(Choose 5)	
* Practice-Based Research	5. Nicholas Gonzalez	10 min
	6. Leanna Standish	10 min
* Outcomes Research	7. Dean Ornish	10 min
	8. Wayne Jonas	10 min
* Clinical Research/Clinical Trials	9. Brian Berman	10 min
	10. Marilyn Schlitz	10 min
	Bill Haskell	
Discussion	Alfred Fishman Wallace Sampson	30 min

BREAK	*2:45 – 3:00*	*15 min*

4. 3:00 – 4:00

PUBLIC COMMENT

5. 4:00 – 5:00

OVERVIEW / WRAP-UP

White House Commission On Complementary
And Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine
October 5-6, 2000
Planning and Discussion Document

PART ONE

Panels/Sessions	**Questions**	**Topics**	**Speakers**
Opening Session		World View Discussion	*(full Commission/defining itself/its mission)*
	Preface: When thinking about the questions below, please consider what has already been achieved in CAM research and the opportunities for future research, as well as the obstacles/barriers to achieving these opportunities, and what the solutions to overcoming the obstacles might be. These questions are intended to help guide--not limit--the presentations.		

Panels/Sessions	Questions	Topics	Speakers
Panel I. Federal Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions	What is needed to expand current Federal efforts to bring CAM products and practices into mainstream medical research; for example, mechanisms of research support, incentives, education and training of investigators? What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, treatment)? What additional areas of opportunity exist for research on CAM interventions? What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream medical research?	**A. NIH:** * NCCAM * ODS *(Dietary Supplements)* * Other NIH Institutes *(at least 2, one supporting and one not supporting CAM research* * **DISCUSSION** **B. Other Federal Research Agencies:** * (CDC, AHRQ, DoD, VA, HRSA, NSF, EdD, IHS, SAMSA *(FDA, HCFA, and NLM to be heard from during panel presentations related to their missions)* * **DISCUSSION** **C. Academic-Based Centers:** * Medical Centers *(Duke, UCSF, Columbia, MD, Harvard)* * **DISCUSSION** *(How did you manage to create the center, what were the obstacles you faced, how successful were you in overcoming the obstacles, and what solutions would you offer?)*	Steve Straus Richard Klausner Marvin Cassman Claude Lenfant Steve Katz Herbert Pardes Joseph Martin Joseph Pizzorno Bill Meeker

Panels/Sessions	Questions	Topics	Speakers
Panel. II Public/Private Sector Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions	How can the public/private sector stimulate CAM medical research? What are the obstacles/barriers and possible solutions to accomplishing this goal, e.g., incentives? How can public/private sector CAM research be better coordinated with Federally-supported CAM research?	**A. Public Sector Support** * Philanthropic Organizations * Foundations * **DISCUSSION** **B. Private Sector Support** * Pharmaceutical Companies * Supplements, Herbals, and Devices Companies * Biotechnology Companies * **DISCUSSION**	representative organizations supporting and not supporting CAM research

Panels/Sessions	Questions	Topics	Speakers
Panel III. Facilitating CAM Research: Achievements, Opportunities, Obstacles, and Solutions	How are current regulations being applied to CAM? How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles?	**CAM Research and Its Regulatory Challenges** * Center for Drug Evaluation and Research, FDA * Center for Devices and Radiological Health, FDA * Center for Food Safety and Nutrition, FDA * State Medical Boards *(Examples of the interface between CAM research and the regulatory agencies)* * Practice-Based Research * Outcomes Research * Clinical Research/Clinical Trials * **DISCUSSION**	Nicholas Gonzalez Leanna Standish Dean Ornish Wayne Jonas Brian Berman Marilyn Schlitz Bill Haskell Alfred Fishman Wallace Sampson

White House Commission on Complementary and Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine

PART TWO

Panels/Sessions	Questions	Topics	Speakers
Panel on Expanding Research Methods and Approaches: Achievements, Opportunities, Obstacles, and Solutions		* Observational Research * Health Services Research/Demonstration Projects * Frontier Research *Basic Research *Policy Research * **DISCUSSION**	

Panels/Sessions	Questions	Topics	Speakers
Panel on Dissemination of Research Results: Achievements, Opportunities, Obstacles, and Solutions		* Journal Editors * Science Writers * NLM *Popular Press *World Wide Web * **DISCUSSION**	

Panels/Sessions	Questions	Topics	Speakers
Panel on Coverage for Clinical Trials and on Research Results as a Basis for Reimbursement: Achievements, Opportunities, Obstacles, and Solutions		* HCFA *Managed Care Companies *Fee-for-Service Insurance Companies *Specialty Insurance Companies *State Medical Boards * **DISCUSSION**	

NOTE: Also Need Panel on Research Training

The following names of organizations and individuals reflect the suggestions made during the research meeting planning conference call on August 9 and additional information received after the conference call.

Foundations

Fetzer Foundation
Robert Wood Johnson
MacArthur Foundation
Macy Foundation
Gladys T. McGeary Medical Foundation
Pew Charitable Trust
Ford Foundation
John A. Hartford Foundation
Bill and Melinda Gates Foundation
Howard Hughes Medical Institute
(See list faxed separately)

Pharmaceutical/Biotechnology Companies

Pharmaceutical Research and Manufacturers of America
- Abbott Laboratories (nutritional supplements)
- Johnson and Johnson (Aflexa [glucosamine])
- Merck and Co., Inc.

Association of Biotechnology Companies (?)

Insurance Companies
- Kaiser Permanente
- Blue Cross/Blue Shield

Suggested Speakers

Berkley Bedell
Schneider (Duke)
David Eisenberg (Harvard)
Memhet Oz (Columbia)
Marilyn Schlitz (Institute of Noetic Sciences)
Nicholas Gonzalez
Berzinsky
Alfred P. Fishman (U of Penn/Integrative CAM Center)
Joseph Pizzorno (Bastyr U)
Brian Berman (MD/NCCAM Res. Center)
Wallace Sampson (Palo Alto, CA)
Bill Meeker (Palmer Chiropractic/Iowa)

Michael Cohen (regulatory issues)
Bonnie O'Connor (Brown U)
M. Brownell Anderson (Assoc. VP AAMC)
Edward Eckendfeld ?
Victor LaCerva (Medical Director, NM Dept. of Health)
Leanna Standish (Bastyr U/Naturpathic)
John Weeks (reimbursement)
Ken Pelletier (reimbursement)
Marguerite Evans (NCCAM/research)
Gladys T. McGeary (research)
Thomas E. Perez (DHHS/Office for Civil Rights)
William C. Vanderwagen (IHS physician)
Wilbur Woodis (Navajo/IHS)

Examples

NSF, organization that overcame obstacles
Columbia, turned down $s rather than conduct CAM research

NIH

Marvin Cassman, NIGMS
Richard Klausner, NCI,
Claude Lenfant, NHLBI
Steve Katz, NIAMS

Groft, Steve (NCCAM)

From: Hoover, Camille (NCCAM)
Sent: Friday, August 18, 2000 3:39 PM
To: Groft, Steve (NCCAM)
Subject: FW: CIT LISTSERV INFO

-----Original Message-----
From: Fish, Chris (NCCAM)
Sent: Friday, August 18, 2000 10:12 AM
To: Hoover, Camille (NCCAM)
Subject: CIT LISTSERV INFO

Camille-

There was no name listed on the Web site, but here is the Web site and contact information for CIT's listserv program:

http://list.nih.gov/

listmaster@list.nih.gov

Center for Information Technology <http://www.cit.nih.gov/>
National Institutes of Health <http://www.nih.gov/>
Bethesda, Maryland 20892
301 594 6248 (v) 301 496 8294 (TDD)

New lists can be requested via the Web site.

Thanks.

Chris Fish
IITRI@NCCAM/NIH
Tel: 301/496-7821
Fax: 301/402-4741

Summary of Major Themes from Research Meeting: Washington, D.C., October 5-6, 2000

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

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

- The RCT is the preferred method of clinical study (see addendum, page 10) and can be applied successfully to some CAM questions. However, traditional clinical trials may not be very informative about the efficacy of many CAM treatments. CAM research questions are hard to validate. Some CAM regimens are difficult to study because they are complex, individualized, lack uniformity, and are hard to generalize. It is difficult to acquire preclinical information on many CAM patients. Survival as the endpoint may not apply to CAM treatments. Many CAM modalities are not presently reimbursed by Medicare.

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

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

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

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

CAM practitioners and reseachers.

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

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

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

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

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

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

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

- Find ways to overcome publication bias, which prevents CAM research from reaching broader audiences, affects press coverage and inhibits further studies and ultimately reimbursement.

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

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

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

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

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

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

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

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

- More funds are needed to adequately address integration of CAM products into a broader regulatory process, including staff positions to assist people not experienced in drug

development. Staff well-versed in CAM spend their time reviewing synthetic drugs. A core team should be created that deals with CAM and has connections to the outside community. The work is labor intensive and there is no formal process for assigning resources except as Congress dictates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Lack of insurance reimbursement, fear of losing one's license, lack of time and money,

and bias in the system stand in way of moving ahead with research. Most

people cannot be both a clinician and researcher. Many clinicians have data on which to build, but do not want to hand it over for fear of what is going to happen to them. More needs to be learned about these problems, while preserving the goal of protecting the public.

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

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

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

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

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

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

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

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

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

- Increase the publication of valid CAM research findings in major medical journals and increase the readership of quality CAM journals.

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

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

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

- DSHEA has been a stimulus for herbal research and there are many examples of private sector funding by the herb industry. However, incentives are needed, such as rights to exclusivity claims and market protections. Modification of the dietary supplement disclaimer allowing removal from a product that has had some clinical study review should be considered, as well as tax incentives. FDA approval of structure/function claims could promote research. The government should consider establishing an expert review panel to evaluate the safety and appropriateness of both the structure/function

claims under DSHEA and as OTC drugs. Herbs do not qualify for composition-of-matter patents. Since the passage of DSHEA, some process and use patents have been granted, but use patents may not be able to withstand public domain and traditional use challenges. Trademark protection should be available as a motivator for research investment, and there should be a way to protect small companies.

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

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

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

- Looking at the genomes of plants will eventually allow us to see what happens with the entire plant, and this is where corporate interests lie. Even when looking at health and wellness as a unified field, the cultural aspects are not for a company to determine, but rather fall to the provider.

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

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

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

- Schools of Public Health are the ideal environment for CAM research. Many faculty are involved in CAM-related projects. Most of the schools of chiropractic health care have

some course work in public health and chiropractors belong to the APHA. Their special interest section has been planning a syllabus in public health education for chiropractic colleges. A working group made up of schools of public health and chiropractic colleges will collect and analyze baseline data for developing a curriculum for future students.

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

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

- The VA is the ideal place to do demonstration projects.

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

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

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

Methodology Example (addendum)

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

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

Prepared by GPollen (11/30/00)

DRAFT Coordinated Research Meeting Agenda
Thursday, October 5, 2000

7:30 a.m.	Registration	
8:30	Welcome and Introductions	*Dr. James S. Gordon*, Chair
8:45	**Session I: Research Priorities and Public Input**	
	IOM Report on Priority Setting and Public Input at NIH	*Dr. Leon Rosenberg*
	Discussion	
9:30	**Session II: Federal (NIH) Support for CAM Research**	
	National Cancer Institute	*Dr. Jeffrey White*
	National Heart, Lung, and Blood Institute	*Dr. Claude Lenfant*
	National Institute of General Medical Sciences	*Dr. Marvin Cassman*
	National Institute of Arthritis and Musculoskeletal and Skin Diseases	*Dr. Steven Hausman*
	Office of the Director/Office of Dietary Supplements	*Dr. Paul Coates*
	Discussion	
10:45	**BREAK**	
11:00	**Session III: Academic Centers and Support for CAM Research**	
	University of Pennsylvania	*Dr. Alfred Fishman*
	Harvard University	*Dr. Daniel Federman*
	Bastyr University	*Dr. Joseph Pizzorno*
	Palmer College of Chiropractic	*Dr. William Meeker*
	Discussion	
12:15 p.m.	**LUNCH**	
1:30	Public Comment	

2:15 **Session IV: Research Support and Collaborations**

National Center on Complementary and and Alternative Medicine	*Dr. Stephen E. Straus*

Discussion

2:55 **BREAK**

3:10 **Session V: Facilitating CAM Research and Regulatory Challenges**

Center for Drug Evaluation and Research	*Dr. Janet Woodcock*
Center for Devices and Radiological Health	*Dr. David W. Feigal*
Center for Food Safety and Applied Nutrition	*Dr. Joseph A. Levitt*
Office of Nutritional Products	*Dr. Christine Lewis*
Office of Chief Counsel	*Mr. David Dorsey*

Discussion

4:10 **Session VI: Research in the Regulatory Framework**

Botanical Enterprises, Inc	*Dr. Floyd Leaders*
Herb Research Foundation	*Mr. Robert McCaleb*
Foundation for Chiropractic Education and Research	*Dr. Anthony L. Rosner*
Federation of State Medical Boards	*Dr. James R. Winn*

Discussion

5:10 **BREAK**

5:20 **Session VII: Outcomes Research Part I– The Interface Between CAM Research and Regulatory Agencies**

Private Practice	*Nicholas J. Gonzalez*
Private Practice	*Dr. Ann McCombs*
	Dr. Devi Nambudripad
National Cancer Institute	*Dr. Jeffrey White*

5:50-6:10 **Discussion**

Friday, October 6, 2000

8:30 **Session VIII: World View**

Commission Discussion led by Dr. James Gordon

9:30 **Session IX: Not-for-Profit Sector Support for CAM Research**

Templeton Foundation	*Dr. John M. Templeton, Jr.*
Conrad N. Hilton Foundation	*Ms. Dyanne M. Hayes*
Hastings Center	*Dr. Daniel Callahan*
American Cancer Society	*Ms. Teri Ades*

Discussion

10:50 **BREAK**

11:05 **Session X: Private Sector Support for CAM Research**

Advanced Medical Technology Association	*Mr. Randy Burkholder*
Johnson and Johnson	*Dr. Raymond Ruddon*
Pfizer, Inc.	*Dr. Frank C. Sciavolino*
American Botanical Council	*Mr. Mark Blumenthal*
Council for Responsible Nutrition	*Dr. Annette Dickenson*

Discussion

12:25 **LUNCH**

1:30 Public Comment

2:30 **Session XI: Outcomes Research Part II– CAM Research and Experimental Study Design**

Medical Epidemiology, CDC	*Dr. Elaine Cramer*
Bastyr University	*Dr. Leanna Standish*
Kaiser Permanente	*Dr. Lydia S. Segal*
Association of Schools of Public Health	*Dr. Douglas Lloyd*

Discussion

3:30 **Session XII: Federal Agency Support for CAM Research**

Centers for Disease Control and Prevention	*Dr. William Deitz*
Veterans Administration	*Dr. James Burris*
Indian Health Service	*Dr. Craig Vanderwagen*

Discussion

4:40-5:00 Wrap-up and Adjournment

Groft, Steve (NCCAM)

From: linda lazarus [llaz2000@yahoo.com]
Sent: Wednesday, October 04, 2000 4:47 PM
To: Groft, Steve (NCCAM)
Subject: Is it too late.....

Hi Steve,

I would to make an oral presentation on using ADR to facilitate the work of the Commission. Is it too late to get on the schedule for tomorrow?

Thanks,

Linda

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http://photos.yahoo.com/

Media Advisory For:
October 5, 2000

Contact: Helen Szablya, Lisa Magnino
Fenton Communications (202) 822-5200

Press Briefing: Thursday, October 5, 2000 at 12:30 p.m.

New White House Commission on Complementary and Alternative Medicine Policy Launches Public Hearings

Focus on Research

The White House Commission on Complementary and Alternative Medicine Policy will hold public hearings on October 5 and 6. A press briefing will take place on Thursday, October 5 at 12:30 pm. This special White House commission will report to the President and Congress on how U.S. public policy can maximize the benefits of complementary and alternative medicine (CAM) to the American public. The purpose of the hearing is for the White House Commission to take at look at the latest research in complementary and alternative medicine and how public policy might enhance and apply the findings of this research to modern medical practice.

The two-day hearing will be held on Thursday (8:30 a.m. - 6:00 p.m.) and Friday (8:30 a.m. - 5:00 p.m.) - Oct. 5 & 6 in Room 800 of the Hubert Humphrey Building, Washington D.C. The hearing will feature leading experts in complementary and alternative medicine as well as officials from the National Institutes of Health, the Food and Drug Administration and other federal agencies.

The public is encouraged to attend the hearings. Public comment will be heard from 1:30 - 2:15 p.m. on both October 5 and 6.

Press Briefing

Who: Dr. James Gordon, Commission Chair -- a Harvard-trained physician and former research psychiatrist at the National Institute of Mental Health;
Dr. Dean Ornish -- a clinical professor of medicine at the University of California (San Francisco), best-selling author and a member of the White House Commission on CAM Policy;
Dr. Nicholas J. Gonzalez -- a New York-based physician, a pioneer in pancreatic cancer research using alternative therapies and a panel member at the White House Commission hearing
Dr. Leanna Standish -- Director of Research at Bastyr University, a trained practitioner of alternative treatments and a panel member at the White House Commission hearing;
Dr. Floyd Leaders -- CEO of Maryland-based Botanical Enterprises and a panel member at the White House Commission hearing.

When: Thursday, October 5 at 12:30 p.m.

Where: Hubert Humphrey Building, 200 Independence Avenue SW, Room 634 F
Washington DC

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, Bethesda, Maryland 20817-7707
tel. 301-435-7592 fax. 301-480-1691 whccamp@od.nih.gov

September 29, 2000

Dear Commissioner:

Please find enclosed Tab 2 from your October 5-6 White House Commission on Complementary and Alternative Medicine Policy Meeting Briefing Book, and a copy of the Institute of Medicine's "Scientific Opportunities and Public Needs." Next week's meeting, Coordination of Complementary and Alternative Medicine (CAM) Research: Achievements, Obstacles, Opportunities and Solutions, will focus specifically on coordinated research issues related to CAM practices and products.

Our broad focus is to learn of the most significant obstacles and barriers to CAM research in four major sectors: academic, corporate, not-for-profit, and Federal, and to discuss strategies and solutions for improving and expanding the current research environment to address CAM research needs, including better coordination among these four sectors. In coordination with a workgroup of Commissioners, we have developed panels of experts and decision-makers from organizations and agencies at the forefront of these issues to help you understand the conceptual and operational barriers they face or have overcome, as well as to suggest potential opportunities for CAM research in the 21st century. As mandated by Executive Order 13147, the Commission will develop recommendations to Congress and the Administration regarding CAM use in this country based on these discussions.

We are enclosing this material as early as was possible to provide you with additional time to reflect on the session objectives and formulate your questions for the panel discussions. The discussion questions noted in this document also were provided to each speaker to guide their presentation and to encourage discursive narratives, rather than recitations of program information. Please feel free to make notes on these sheets and bring them with you to be inserted in your final Briefing Book at the meeting.

Your Briefing Book will be delivered to your hotel on Wednesday afternoon and will include the final agenda (a preliminary agenda has already been sent to you under separate cover), a Speakers' Roster, Speakers Bio-sketches and Programmatic Summaries and other materials.

Thank you for your patience and attention. Should you have any questions, please contact Michele Chang or myself. We look forward to seeing you next week!

Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director

Michele M. Chang, CMT, MPH
Executive Secretary

Tab 2: Session Overview and Commissioner's Notes

SESSION I	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Research Priorities and Public Input	Dr. Leon Rosenberg, IOM	Sets the tone for this two-day meeting by stimulating a review of the factors influencing the prioritization of research, specifically CAM research. See your copy of the Institute of Medicine's publication, "Scientific Opportunities and Public Needs."	• What role should the public have in setting research priorities for CAM research? • How can public input regarding CAM research be increased?

Your Notes:

SESSION II	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Federal (NIH) Support for CAM Research	Dr. Jeffrey White, NCI Dr. Claude Lenfant, NHLBI Dr. Marvin Cassman, NIGMS Dr. Steven Hausman, NIAMSD Dr. Paul Coates, ODS	To review the overall environment at NIH for CAM research, including what may be needed to improve or accelerate the growth of such research, and how coordination with other governmental and non-governmental entities can be facilitated.	• What is needed to expand current Federal efforts to bring CAM products and practices into mainstream biomedical research; for example, mechanisms of research support, research methodologies, incentives, education and the training of investigators? • What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional biomedical research (e.g., wellness/health promotion and disease prevention, pain management, self-care, treatment, care for the terminally-ill)? • Where are the overlapping areas of investigation between CAM research and conventional biomedical research (e.g., wellness/health promotion and disease prevention, pain management, self-care, treatment, care for the terminally-ill)? • What additional areas of opportunity exist for research on CAM interventions? • What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream biomedical research? • What role should the public have in setting research priorities for CAM research?

SESSION III	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Academic Centers and Support for CAM Research	Dr. Alfred Fishman, University of Pennsylvania Dr. Daniel Federman, Harvard University Dr. Joseph Pizzorno, Bastyr University Dr. William Meeker, Palmer College of Chiropractic	To review the overall environment at academic centers for CAM research, including what may be needed to improve or accelerate the growth of such research, and how coordination with other research entities can be facilitated.	• How did you manage to create your CAM program, what were the obstacles you faced, how successful were you in overcoming the obstacles, and what solutions would you offer? How would you proceed to integrate CAM research with mainstream research? • What is needed to expand current Federal efforts to bring CAM products and practices into mainstream research; for example, mechanisms of research support, research methodologies, incentives, education and the training of investigators? • What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional research (e.g., wellness/health promotion and disease prevention, self-care, pain management, disease treatment, care for the terminally-ill)? • Where are the overlapping areas of investigation between CAM research and conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, self-care, disease treatment, care for the terminally-ill)? • What additional areas of opportunity exist for research on CAM interventions? • What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream research? • What role should the public have in setting research priorities for CAM research?

SESSION IV	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Research Support and Collaborations	Dr. Stephen E. Straus. Director, NCCAM (NIH)	To review the efforts of the National Center for Complementary and Alternative Medicine for CAM research within a broader research environment, including what may be needed to improve or accelerate the growth of CAM research, particularly how coordination with other research entities can be facilitated.	• What continue to be the primary obstacles faced by NCCAM and how are you overcoming such obstacles; what solutions would you offer to other agencies in setting up CAM-focused programs? How are you integrating CAM research with mainstream research? What is needed to facilitate your efforts? • What is needed to expand current Federal efforts to bring CAM products and practices into mainstream research; for example, mechanisms of research support, research methodologies, incentives, education and the training of investigators? • What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional research (e.g., wellness/health promotion and disease prevention, self-care, pain management, disease treatment, care for the terminally-ill)? • Where are the overlapping areas of investigation between CAM research and conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, self-care, disease treatment, care for the terminally-ill)? • What additional areas of opportunity exist for research on CAM interventions? • What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream research?

SESSION V	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Facilitating CAM Research and Regulatory Challenges	FDA Panel: Dr. Janet Woodcock, Center for Drug Evaluation and Research Dr. David W. Feigal, Center for Devices and Radiological Health Dr. Joseph A. Levitt, Center for Food Safety and Applied Nutrition (CFSAN) Dr. Christine Lewis, Office of Nutritional Products, CFSAN	To review the overall regulatory environment for CAM research, including what may be needed to better facilitate such research in order to more quickly identify safe and effective products, treatments and devices.	• How are current regulations being applied to CAM? • How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles? • What resources are needed at FDA to accommodate anticipated increases and diversity of CAM research activities? • Should changes, if any, be made in the regulations? If so, what should these be and can you project the impact of such changes on CAM research?

Your Notes:

SESSION VI	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
CAM Research in a Regulatory Framework	Dr. Floyd Leaders, Botanical Enterprises, Inc Mr. Robert McCaleb, Herb Research Foundation Dr. Anthony Rosner, Foundation for Chiropractic Education and Research Dr. James R. Winn, Federation of State Medical Boards	To review the overall regulatory environment for CAM research, including what may be needed to better facilitate, or even stimulate such research in order to more quickly identify safe and effective products, treatments and devices.	• How do current regulations applied to CAM affect your efforts to facilitate research for botanicals, herbal products, and other interventions or devices? • How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles? • Should changes, if any, be made in the regulations? If so, what should these be and what impact might they have on your support of CAM research?

Your Notes:

SESSION VII	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Outcomes Research Part I--Interface Between CAM Research and Regulatory Agencies	Dr. Nicholas Gonzalez, Private Practice Dr. Ann McCombs, Private Practice AND Dr. Devi Nambudripad, Private Practice Dr. Jeffrey White, National Cancer Institute	To review the overall environment for CAM research, including what may be needed to better facilitate, or even stimulate such research in order to more quickly identify safe and effective products, treatments and devices. Particular focus on reviewing practice-based outcomes research.	• How do current regulations applied to CAM affect your research efforts? • How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles? • Should changes, if any, be made in the regulations? If so, what should these be and what impact might they have on your support of CAM research?

Your Notes:

SESSION VIII	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Guiding Principles of CAM Perspective and Practice ("World View" Discussion) ONE HOUR	Roundtable discussion led by Chair: 2 minutes per Commissioner* (this discussion will continue in each subsequent meeting)	To initiate a discussion on the basic principles and values of CAM therapies and develop an underlying framework to shape the Commission's report to the President and Congress.	• What do you consider to be fundamental, profoundly integral aspects of CAM practice and research that must be reflected in any policy recommendations we make? • What are the perspectives (values, principles, etc) that should shape and guide the integration of CAM into our health care system?

Your Notes:

SESSION IX	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Not-for-Profit Sector Support for CAM Research	Dr. John M. Templeton, Jr., Templeton Foundation Dyanne M. Hayes, Conrad N. Hilton Foundation Dr. Daniel Callahan, Hastings Center Ms. Teri Ades, American Cancer Society	To review the overall environment for CAM research in the not-for-profit sector, including what may be needed to better facilitate, or even stimulate such research in order to more quickly identify safe and effective products, treatments and devices.	• How can the Not-for-Profit Sector stimulate CAM research? • What are the obstacles/barriers and possible solutions to accomplishing this goal, e.g., incentives? • How can Not-for-Profit Sector CAM research be better coordinated with Federally-supported CAM research?

Your Notes:

SESSION X	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Private Sector Support for CAM Research	Dr. James Benson, Advanced Medical Technology Association (Invited) Dr. Raymond Ruddon, Johnson and Johnson Dr. Frank C. Sciavolino, Pfizer, Inc. Mr. Mark Blumenthal, American Botanical Council Dr. Annette Dickenson, Council for Responsible Nutrition	To review the overall environment for CAM research in the private sector, including what may be needed to better facilitate, or even stimulate such research in order to more quickly identify safe and effective products, treatments and devices.	• How can the private sector stimulate CAM research? • What are the obstacles/barriers and possible solutions to accomplishing this goal, e.g., incentives? • How can private sector CAM research be better coordinated with Federally-supported CAM research?

Your Notes:

SESSION XI	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Outcomes Research Part II--CAM Research and Experimental Study Design	Dr. Elaine Cramer, Medical Epidemiology, CDC (By Phone) Dr. Leanna Standish, Bastyr University Dr. Lydia Segal, Kaiser Permanente, Mid-Atlantic Dr. Douglas Lloyd, Association of Schools of Public Health	To review practice-based outcomes research, including how such research fits into the overall research environment, and what may be needed to better facilitate, or stimulate such research in order to more quickly identify safe and effective products, treatments and devices and increase what is known about effective CAM practices and products.	• Based on your work, what are your major conclusions as to the value and effect of practice-based outcomes research? • What obstacles/limitations would you identify as common for all practice-based outcomes research? • What is the next step for practice-based outcomes research? What is needed to move such research forward? • What instrinsic differences do you observe between CAM and conventional medical research, and how might these affect how we approach practice-based outcomes research? • What is the greatest value gained from practice-based outcomes research? • How can such research best fit into existing research methodologies?

Your Notes:

SESSION XII	SPEAKER/PANEL	FOCUS	DISCUSSION QUESTIONS
Federal Agency Support for CAM Research.	Dr. William Dietz, Centers for Disease Control and Prevention (By Phone) TBA, Veterans Affairs Dr. Michael Trujillo, Indian Health Service	review the overall environment in the Federal Sector, including what may be needed to improve or accelerate the growth of such research, and how coordination with other governmental and non-governmental entities can be facilitated	• What is needed to expand current Federal efforts to bring CAM products and practices into mainstream medical research; for example, mechanisms of research support, research methodologies, incentives, education and the training of investigators? • What is needed for the Federal sector to coordinate CAM research efforts between the Federal and private sectors? • What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, self-care, treatment, care for the terminally-ill)? • Where are the overlapping areas of investigation between CAM research and conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, self-care, treatment, care for the terminally-ill)? • What additional areas of opportunity exist for research on CAM interventions? • What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream medical research? • What role should the public have in setting research priorities for CAM research?

RESEARCH MEETING II

Sessions we discussed are:

Expanding Research: Methodologies and Approaches

Areas of research

clinical research/clinical trials
health services research/demonstration projects
observational research
frontier research
qualitative research
basic research

Research training of CAM practitioners and mainstream clinicians and investigators

data collection, methodology, team building
study design, protocol development, application preparation
investigators (laboratory, clinical, practice-based)
medical schools (include AAMC)
expanding approaches to research

Agencies/Organizations

AHRQ
HRSA
SAMHSA
VA
DoD
Dept of Ed
insurance companies and managed care (Oakland Kaiser here?)
(HMO's, PPO's, etc.)

Disseminating Research Results

Publications and Other Methods

journal editors
science writers
NLM
professional society newsletters
stand-alone publications
popular press
world wide web

Research Results as a Basis for Reimbursement (including Clinical Trials)

Other Topics

Utilization of Cam-Access to Services (Eisenberg)
(Here or Access and Delivery?)

Couldn't attend October meeting but interested or may be interested in next meeting

- Fetzer Foundation wants to be invited to this meeting.
- Ruby Hearn (RWJ) has it on her calendar.

David Lawrence, Oakland, CEO Kaiser western region couldn't attend or find an appropriate replacement, could be interested in a future meeting.

Michael Sieverts, NSF, not sure at first about NSF fit, but beginning to see they may be able to contribute. If can't participate in October, would work on participation in April.

- Kohlberg Foundation not able to participate in October but may be interested in a future meeting.

Adrienne Bendich, Smith Kline Beecham (clinical studies on vitamins, minerals and supplements) can't make this meeting but knows about next meeting and will work with us to send a colleague to the next research meeting because she knows already that she will be out of the country.

- May be a slightly open door with Gates Foundation, not sure.
- George Foundation looking at possible participation. Had talked to Jim.
- Bob Rose, MacArthur Foundation, (Network on Mind-Body Interactions), interested in 4/01 mtg.

White House Commission on Complementary
and Alternative Medicine Policy

Meeting on the Coordination of CAM Research:
Achievements, Opportunities,
Obstacles, and Solutions

September 6, 2000

TO: Members, White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP)

FROM: Committee Management Specialist, WHCCAMP

SUBJECT: Update of Financial Interests and/or Institutional Affiliations (OGE-450)
DUE SEPTEMBER 21, 2000

In preparation for the October 5-6, 2000, Commission meeting, attached is a Conflict of Interest List pertaining to your financial interests and institutional affiliations. Please review these documents and note any **additions or deletions** on the ***Update Verification of Review Form.*** For your convenience, presented below are some helpful hints to remember when completing the update form.

Remove one-time events or activities that may no longer be applicable. Such "one-time" activities may include past speaking engagements, consultant work, or your role in organizational entities, other than those solely of an honorary nature. One-time conflicts remain in effect for one year after the date of the event/activity.

Report earned income over $200. Please report sources of earned income such as salaries, fees, honoraria, which generated over $200 in income during the reporting period. Earned income sources of your spouse must be reported if greater than $1,000 (greater than $200 for honoraria). It is no longer necessary for you to list savings accounts.

Report assets with a fair market value greater than $1,000 at the close of the reporting period or producing income over $200. Assets may include: stocks, bonds, tax shelters, real estate, mutual funds, pensions, annuities, IRAs, trusts, commodity futures, trades and businesses, and partnership interests.

Report any positions, whether or not compensated. Positions may include: an employee, officer, director, trustee, general partner, proprietor, representative, executor, or consultant for a business, non-profit organization, or educational institution.

Report any non-Federal research/training support. Please refer to the attached *OGE-450 Supplemental Instructions for Reporting Non-Federal Research/Training Support.*

The updated Verification Form must reflect **any changes** that have occurred since your last filing and up to **30 days** prior to the October 2000 meeting. Please sign the form where indicated and return it to me in the enclosed Federal Express mailer no later than **September 21, 2000**. WHCCAMP ethics officials must review the information prior to the meeting in order for you to participate in the upcoming Commission discussions.

We appreciate your patience and willingness to complete this form and hope you recognize that obtaining this information is a Federal requirement. The confidentiality of the information you provide will be maintained in a manner consistent with the Privacy Act of 1974. If you have any questions or need additional information, please contact me at 301-435-6910 or Mary Plummer at 301-594-7233.

Mandy Stoneberger

Attachments: (1) Conflict of Interest List
(2) Update Verification Form
(3) Supplemental Instructions for Reporting Non-Federal Research/Training Support
(4) Return Federal Express Mailer

cc: Dr. Stephen C. Groft, Executive Director, WHCCAMP
Ms. Michele Chang, Executive Secretary, WHCCAMP

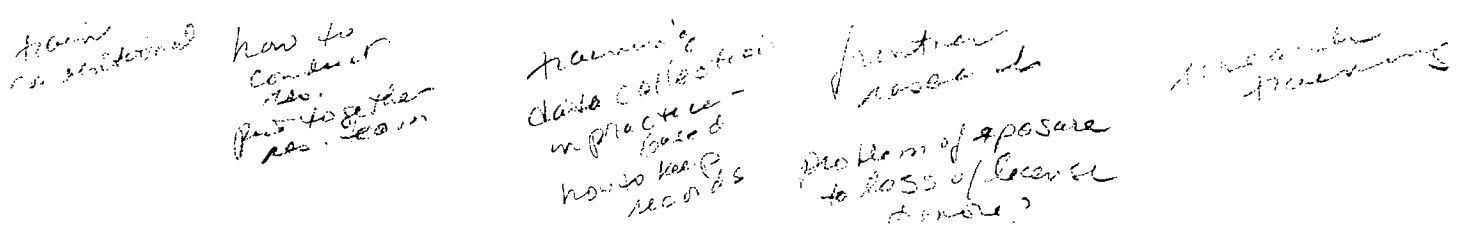
White House Commission on Complementary and Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine

PART TWO

Panels/Sessions	Questions	Topics	Speakers
Panel on Expanding Research Methods and Approaches: Achievements, Opportunities, Obstacles, and Solutions		* Observational Research * Health Services Research/Demonstration Projects * Frontier Research *Basic Research *Policy Research * **DISCUSSION**	

Panels/Sessions	Questions	Topics	Speakers
Panel on Dissemination of Research Results: Achievements, Opportunities, Obstacles, and Solutions		* Journal Editors * Science Writers * NLM *Popular Press *World Wide Web * **DISCUSSION**	



Panels/Sessions	Questions	Topics	Speakers
Panel on Coverage for Clinical Trials and on Research Results as a Basis for Reimbursement: Achievements, Opportunities, Obstacles, and Solutions		* HCFA *Managed Care Companies *Fee-for-Service Insurance Companies *Specialty Insurance Companies *State Medical Boards * **DISCUSSION**	

NOTE: Also Need Panel on Research Training

The following names of organizations and individuals reflect the suggestions made during the research meeting planning conference call on August 9 and additional information received after the conference call.

Foundations

Fetzer Foundation
Robert Wood Johnson
MacArthur Foundation
Macy Foundation
Gladys T. McGeary Medical Foundation
Pew Charitable Trust
Ford Foundation
John A. Hartford Foundation
Bill and Melinda Gates Foundation
Howard Hughes Medical Institute
(See list faxed separately)

Pharmaceutical/Biotechnology Companies

Pharmaceutical Research and Manufacturers of America
- Abbott Laboratories (nutritional supplements)
- Johnson and Johnson (Aflexa [glucosamine])
- Merck and Co., Inc.

Association of Biotechnology Companies (?)

Insurance Companies
- Kaiser Permanente
- Blue Cross/Blue Shield

Suggested Speakers

Berkley Bedell
Schneider (Duke)
David Eisenberg (Harvard)
Memhet Oz (Columbia)
Marilyn Schlitz (Institute of Noetic Sciences)
Nicholas Gonzalez
Berzinsky
Alfred P. Fishman (U of Penn/Integrative CAM Center)
Joseph Pizzorno (Bastyr U)
Brian Berman (MD/NCCAM Res. Center)
Wallace Sampson (Palo Alto, CA)
Bill Meeker (Palmer Chiropractic/Iowa)

Michael Cohen (regulatory issues)
Bonnie O'Connor (Brown U)
M. Brownell Anderson (Assoc. VP AAMC)
Edward Eckendfeld ?
Victor LaCerva (Medical Director, NM Dept. of Health)
Leanna Standish (Bastyr U/Naturpathic)
John Weeks (reimbursement)
Ken Pelletier (reimbursement)
Marguerite Evans (NCCAM/research)
Gladys T. McGeary (research)
Thomas E. Perez (DHHS/Office for Civil Rights)
William C. Vanderwagen (IHS physician)
Wilbur Woodis (Navajo/IHS)

Examples

NSF, organization that overcame obstacles
Columbia, turned down $s rather than conduct CAM research

NIH

Marvin Cassman, NIGMS
Richard Klausner, NCI,
Claude Lenfant, NHLBI
Steve Katz, NIAMS

White House Commission On Complementary
And Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine
October 5-6, 2000
Planning and Discussion Document

PART ONE

Panels/Sessions	**Questions**	**Topics**	**Speakers**
Opening Session		World View Discussion	*(full Commission/defining itself/its mission)*
	Preface: When thinking about the questions below, please consider what has already been achieved in CAM research and the opportunities for future research, as well as the obstacles/barriers to achieving these opportunities, and what the solutions to overcoming the obstacles might be. These questions are intended to help guide--not limit--the presentations.		

Panels/Sessions	Questions	Topics	Speakers
Panel I. Federal Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions	What is needed to expand current Federal efforts to bring CAM products and practices into mainstream medical research; for example, mechanisms of research support, incentives, education and training of investigators? What can CAM perspectives and approaches contribute to investigations where there is overlap with conventional medical research (e.g., wellness/health promotion and disease prevention, pain management, treatment)? What additional areas of opportunity exist for research on CAM interventions? What are the obstacles (conceptual and otherwise) and possible solutions to accomplishing the goal of integrating CAM products and practices into mainstream medical research?	**A. NIH:** * NCCAM * ODS *(Dietary Supplements)* * Other NIH Institutes *(at least 2, one supporting and one not supporting CAM research* * **DISCUSSION** **B. Other Federal Research Agencies:** * (CDC, AHRQ, DoD, VA, HRSA, NSF, EdD, IHS, SAMSA *(FDA, HCFA, and NLM to be heard from during panel presentations related to their missions)* * **DISCUSSION** **C. Academic-Based Centers:** * Medical Centers *(Duke, UCSF, Columbia, MD, Harvard)* * **DISCUSSION** *(How did you manage to create the center, what were the obstacles you faced, how successful were you in overcoming the obstacles, and what solutions would you offer?)*	Steve Straus Richard Klausner Marvin Cassman Claude Lenfant Steve Katz Herbert Pardes Joseph Martin Joseph Pizzorno Bill Meeker

Panels/Sessions	Questions	Topics	Speakers
Panel. II Public/Private Sector Support for CAM Research: Achievements, Opportunities, Obstacles, and Solutions	How can the public/private sector stimulate CAM medical research? What are the obstacles/barriers and possible solutions to accomplishing this goal, e.g., incentives? How can public/private sector CAM research be better coordinated with Federally-supported CAM research?	**A. Public Sector Support** * Philanthropic Organizations * Foundations * **DISCUSSION** **B. Private Sector Support** * Pharmaceutical Companies * Supplements, Herbals, and Devices Companies * Biotechnology Companies * **DISCUSSION**	representative organizations supporting and not supporting CAM research

Panels/Sessions	Questions	Topics	Speakers
Panel III. Facilitating CAM Research: Achievements, Opportunities, Obstacles, and Solutions	How are current regulations being applied to CAM? How can research methods and approaches be expanded to address the safety and efficacy of CAM products and practices, and what are the obstacles?	**CAM Research and Its Regulatory Challenges** * Center for Drug Evaluation and Research, FDA * Center for Devices and Radiological Health, FDA * Center for Food Safety and Nutrition, FDA * State Medical Boards *(Examples of the interface between CAM research and the regulatory agencies)* * Practice-Based Research * Outcomes Research * Clinical Research/Clinical Trials * **DISCUSSION**	Nicholas Gonzalez Leanna Standish Dean Ornish Wayne Jonas Brian Berman Marilyn Schlitz Bill Haskell Alfred Fishman Wallace Sampson

White House Commission on Complementary and Alternative Medicine Policy

Proposed Agenda
Research on Complementary and Alternative Medicine

PART TWO

Panels/Sessions	Questions	Topics	Speakers
Panel on Expanding Research Methods and Approaches: Achievements, Opportunities, Obstacles, and Solutions		* Observational Research * Health Services Research/Demonstration Projects * Frontier Research *Basic Research *Policy Research * **DISCUSSION**	

Panels/Sessions	Questions	Topics	Speakers
Panel on Dissemination of Research Results: Achievements, Opportunities, Obstacles, and Solutions		* Journal Editors * Science Writers * NLM *Popular Press *World Wide Web * **DISCUSSION**	

Panels/Sessions	Questions	Topics	Speakers
Panel on Coverage for Clinical Trials and on Research Results as a Basis for Reimbursement: Achievements, Opportunities, Obstacles, and Solutions		* HCFA *Managed Care Companies *Fee-for-Service Insurance Companies *Specialty Insurance Companies *State Medical Boards * **DISCUSSION**	

NOTE: Also Need Panel on Research Training

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release March 8, 2000

EXECUTIVE ORDER 13147

WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to establish the White House Commission on Complementary and Alternative Medicine Policy, it is hereby ordered as follows:

Section 1. Establishment. There is established in the Department of Health and Human Services (Department) the White House Commission on Complementary and Alternative Medicine Policy (Commission). The Commission shall be composed of not more than 15 members appointed by the President from knowledgeable representatives in health care practice and complementary and alternative medicine. The President shall designate a Chair from among the members of the Commission. The Secretary of Health and Human Services (Secretary) shall appoint an Executive Director for the Commission.

Sec. 2. Functions. The Commission shall provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine. The recommendations shall address the following:

(a) the education and training of health care practitioners in complementary and alternative medicine;

(b) coordinated research to increase knowledge about complementary and alternative medicine practices and products;

(c) the provision to health care professionals of reliable and useful information about complementary and alternative medicine that can be made readily accessible and understandable to the general public; and

(d) guidance for appropriate access to and delivery of complementary and alternative medicine.

Sec. 3. Administration. (a) To the extent permitted by law, the heads of executive departments and agencies shall provide the Commission, upon request, with such information

and assistance as it may require for the purpose of carrying out its functions.

(b) Each member of the Commission shall receive compensation at a rate equal to the daily equivalent of the annual rate specified for Level 1V of the Executive Schedule (5 U.S.C. 5315) for each day during which the member is engaged in the performance of the duties of the Commission. While away from their homes or regular places of business in the performance of the duties of the Commission, members shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701-5707).

(c) The Department shall provide the Commission with funding and with administrative services, facilities, staff, and other support services necessary for the performance of the Commission's functions.

(d) In accordance with guidelines issued by the Administrator of General Services, the Secretary shall perform the functions of the President under the Federal Advisory Committee Act, as amended (5 U.S.C. App.), with respect to the Commission, except that of reporting to the Congress.

(e) The Commission shall terminate 2 years from the date of this order unless extended by the President prior to such date.

WILLIAM J. CLINTON

THE WHITE HOUSE,
March 7, 2000.

# # #

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

White House Commission on Complementary and Alternative Medicine Policy

Notice of Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of a meeting of the **White House Commission on Complementary and Alternative Medicine Policy.** The purpose of the meeting is to convene the Commission for a public hearing on coordinated Research and Development activities relating to complementary and alternative medicine practices and products, and to receive public testimony from individuals and organizations interested in the subject of federal policy regarding complementary and alternative medicine. Comments received at the meeting may be used by the Commission to prepare the Report to the President as required by the Executive Order.

Comments should focus on **Coordinated Research and Development Activities To Increase Knowledge of Complementary and Alternative Medicine Practices and Interventions**. Issues to be discussed include the following: Research Priorities and Public Input; Federal, Private Sector, and Not-for-Profit Sector Support for CAM Research; Facilitating CAM Research and Regulatory Challenges; Practice-based Research and Outcomes Research. Discussion also may focus on the following questions:

(1) What can be done to expand the current research environment so that practices and interventions that lie outside conventional science are adequately and appropriately addressed?

(2) What types of incentives are needed to stimulate the research of CAM practices and interventions by the public and private sectors?

(3) How can we more effectively integrate the CAM and conventional research communities to stimulate and coordinate research?

Some Commission members may participate by telephone conference. The meeting is open to the public and opportunities for oral statements by the public will be provided on October 5, from about 1:15 p.m. – 2:15 p.m.; and on October 6, from about 2:40 p.m. – 3:40 p.m. (approximate times).

Name of Committee:	The White House Commission on Complementary and Alternative Medicine Policy.
Date:	October 5-6, 2000
Time:	October 5 – 8:30 a.m. – 5:30 p.m.

October 6 – 8:30 a.m. – 4:00 p.m.

Place: Hubert H. Humphrey Building
Room 800
200 Independence Avenue, S.W.
Washington, D.C. 20201

Contact Persons: Michele M. Chang, CMT, MPH
Executive Secretary
OR
Stephen C. Groft, Pharm.D.
Executive Director
6701 Rockledge Drive
Room 1010, MSC 7707
Bethesda, MD 20817-7707
Phone: (301) 435-7592
Fax: (301) 480-1691
E-mail: WHCCAMP@nih.gov

Because of the need to obtain the views of the public on these issues as soon as possible and because of the early deadline for the report required of the Commission, this notice is being provided at the earliest possible time.

Supplementary Information: The President established the White House Commission on Complementary and Alternative Medicine Policy on March 7, 2000 by Executive Order 13147. The mission of the White House Commission on Complementary and Alternative Medicine Policy is to provide a report, through the Secretary of the Department of Health and Human Services, on legislative and administrative recommendations for assuring that public policy maximizes the benefits of complementary and alternative medicine to Americans.

Public Participation

The meeting is open to the public with attendance limited by the availability of space on a first come, first serve basis. **Members of the public who wish to present oral comment may register by calling 1-800-953-3298 or by accessing https://safe2.sba.com/whccamp/index.cfm no later than September 29, 2000.**

Oral comments will be limited to five minutes. Individuals who register to speak will be assigned in the order in which they registered. Due to time constraints, only one representative from each organization will be allotted time for oral testimony. The number of speakers and the time allotted may also be limited by the number of registrants. All requests to register should include the name, address, telephone number, and business or professional affiliation of the interested party, and should indicate the area of interest or question (as described above) to be addressed.

Any person attending the meeting who has not registered to speak in advance of the meeting will be allowed to make a brief oral statement during the time set aside for public comment if time permits, and at the chairperson's discretion. Individuals unable to attend the meeting, or any interested parties, may send written comments by mail, fax, or electronically to the staff office of the Commission for inclusion in the public record.

When mailing or faxing written comments provide, if possible, an electronic version on diskette. Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact the Commission staff at the address or telephone number listed no later than September 29, 2000.

Dated:
LaVerne Y. Stringfield,
Director, Office of Federal Advisory Committee Policy.

[Billing Code: 4140-01]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
White House Commission on Complementary and Alternative Medicine Policy

Notice of Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of the first meeting of the White House Commission on Complementary and Alternative Medicine Policy. The purpose of the meeting is to convene the Commission and to begin receiving public testimony from individuals and organizations interested in the subject of federal policy regarding complementary and alternative medicine. Comments received at the meeting will be used by the Commission to identify and frame the issues and develop the agenda for subsequent meetings. Comments should focus on the following issues:

(1) The education and training of health care practitioners in complementary and alternative medicine;

(2) Coordinated research to increase knowledge about complementary and alternative medicine practices and products;

(3) The provision to health care professionals of reliable and useful information about complementary and alternative medicine that can be made readily accessible and understandable to the general public; and

(4) Guidance for appropriate access to and delivery of complementary and alternative medicine.

Some Commission members may participate by telephone conference. The meeting is open to the public and opportunities for statements by the public will be provided on July 14, from 11:30 a.m.-12:30 p.m.

Name of Committee: White House Commission on Complementary and Alternative Medicine Policy

Date: July 13-14, 2000

Time: July 13 - 2:00 p.m. - 5:30 p.m.
July 14 - 8:30 a.m. - 5:00 p.m.

Place: Hubert H. Humphrey Building
Room 800
200 Independence Avenue, S.W.
Washington, DC 20201

Contact Person: Stephen Groft, Pharm. D.
Executive Director
6701 Rockledge Drive
Room 1010
Bethesda, MD 20817-1813
Phone: (301) 435-6199
Fax: (301) 480-1691

Because of the need to obtain the views of the members as soon as possible and because of the early deadline for the report(s) required of the Commission, this notice is being provided at the earliest possible time.

Supplementary Information: The President established the White House Commission on Complementary and Alternative Medicine Policy on March 7, 2000 by Executive Order 13147. The mission of the White House Commission on Complementary and Alternative Medicine Policy is to provide a report, through the Secretary of the Department of Health and Human Services, on legislative and administrative recommendations for assuring that public policy maximizes the benefits of complementary and alternative medicine to Americans.

Public Participation

The meeting is open to the public with attendance limited by the availability of space on a first come, first serve basis. Members of the public who wish to present oral statements should contact Dr. Stephen C. Groft by telephone, fax, or mail as shown above as soon as possible, but at least 4 days before the meeting. A one-page summary of the presentation should accompany any request. The chairperson will reserve time for presentations by persons requesting to speak and asks that oral statements be limited to five minutes. The order of persons wanting to make a statement will be assigned in the order in which requests are received.

Individuals unable to make oral presentations can mail their written comments to the staff office of the Commission at least 4 business days prior to the meeting for distribution to the Commission and inclusion in the public record.

Any person attending the meeting who has not requested an opportunity to speak in advance of the meeting will be allowed to make a brief oral presentation at the conclusion of the meeting, if time permits, at the chairperson's discretion.

Due to time constraints, only one representative from each organization will be allowed to present oral testimony.

Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact the Commission staff at the address or telephone number listed below as soon as possible.

Dated: _____

_____

LaVerne Y. Stringfield
Director, Office of Federal Advisory Committee Policy

[Billing Code: 4140-01]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
White House Commission on Complementary and Alternative Medicine Policy

Notice of Meeting

Notice is given of the first Town Hall Meeting of the White House Commission on Complementary and Alternative Medicine Policy. Additional Town Hall meetings are anticipated at future dates and other locations. The purpose of the meeting is to convene the Commission for a public hearing and to begin receiving public testimony from individuals and organizations interested in the subject of federal policy regarding complementary and alternative medicine. Comments received at the meeting will be used by the Commission to identify and frame the issues and develop the agenda for subsequent meetings.

Comments should focus on the four areas that follow. Questions for consideration include, but are not limited to those presented below. For each question, please consider including in your response concerns, possible obstacles, existing programs, and suggested solutions to guide the Commission in their deliberations.

I. Coordinated Research and Development to Increase Knowledge of Complementary and Alternative Medicine Practices and Interventions

(A) What can be done to expand the current research environment so that practices and interventions that lie outside conventional science are adequately and appropriately addressed?

(B) What types of incentives are needed to stimulate the research of CAM practices and interventions by the public and private sectors?

(C) How can we more effectively integrate the CAM and conventional research communities to stimulate and coordinate research?

II. Guidance for Access to, Delivery of, and Reimbursement for Complementary and Alternative Medicine Practices and Interventions

(A) Do you have ready access to CAM practices and interventions?

(B) How can access to safe and effective CAM practices and interventions be improved?

(C) What types of CAM practices and interventions should be reimbursable through federal programs or other health care coverage systems?

III. Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine

(A) How can uniform standards of education, training, licensure and certification be applied to all CAM practitioners?

(B) What training and education should be required of all health care providers to assure access to safe and effective CAM practices and interventions?

(C) What sources of funds exist for the education and training of CAM practitioners?

(D) Are performance standards or practice guidelines needed to ensure the public will have access to the full range of safe and effective CAM practices and interventions?

IV. Delivery of Reliable and Useful Information on Complementary and Alternative Medicine to Health Care Professionals and the Public

(A) How can useful, reliable, and updated information about CAM practices and interventions be made more accessible? How would you like to receive such information?

(B) As a consumer, what kinds of information about CAM practices and interventions are most needed and important to you?

(C) As a health care provider, what kinds of information about CAM practices and interventions are most needed and important to you?

The Town Hall Meeting is open to the public and opportunities for oral comments and written statements by the public will be provided.

Name of Committee:	The White House Commission on Complementary and Alternative Medicine Policy
Date and Time	September 8, 2000; 8:30 a.m. - 6:00 p.m.
Place:	Holiday Inn Golden Gateway Hotel; 1500 Van Ness Avenue San Francisco, CA 94109
Contact Persons:	Stephen C. Groft, Pharm. D., Executive Director, or Michele Chang, MPH, Executive Secretary; 6701 Rockledge Drive; Room 1010, MSC-7707; Bethesda, MD 20817-7707; Phone: (301) 435-7592; Fax: (301) 480-1691; E-Mail: WHCCAMP@nih.gov

The President established the White House Commission on Complementary and Alternative Medicine Policy on March 7, 2000 by Executive Order 13147. The mission of the White House Commission on Complementary and Alternative Medicine Policy is to provide a report, through the Secretary of the Department of Health and Human Services, on legislative and administrative recommendations for assuring that public policy maximizes the benefits of complementary and alternative medicine to Americans.

Because of the need to obtain the views of the public on these issues as soon as possible and because of the early deadline for the report required of the Commission, this notice is being provided at the earliest possible time.

Public Participation: The Town Hall meeting is open to the public with attendance limited by the availability of space on a first come, first serve basis. Members of the public who wish to present oral comment may register by calling 1-800-953-3298 or by accessing https://safe2.sba.com/whccamp/index.cfm no later than September 1, 2000.

Oral comments will be limited to five minutes. Individuals who register to speak will be

assigned in the order in which they registered. Due to time constraints, only one representative from each organization will be allotted time for oral testimony. The number of speakers and the time allotted may also be limited by the number of registrants. All requests to register should include the name, address, telephone number, and business or professional affiliation of the interested party, and should indicate the area of interest or question (as described above) to be addressed. Individuals interested in attending the meeting to observe the proceedings but not to provide oral testimony should also register.

Any person attending the meeting who has not registered to speak in advance of the meeting will be allowed to make a brief oral statement at the conclusion of the morning and afternoon sessions, if time permits, and at the chairperson's discretion.

Individuals unable to attend the meeting, or any interested parties, may send written comments by mail, fax, or electronically to the staff office of the Commission for inclusion in the public record. When mailing or faxing written comments provide, if possible, an electronic version on diskette.

Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact the Commission staff at the address or telephone number listed no later than September 1, 2000 .

Dated: _____

_____

LaVerne Y. Stringfield
Director, Office of Federal Advisory Committee Policy

White House Commission on Complementary and Alternative Medicine Policy

ROSTER

CHAIRPERSON

James S. Gordon, M.D.
Director
The Center for Mind-Body Medicine
2934 Macomb Street, N.W.
Washington, D.C. 20008

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001. list	White House Commission on Complementary and Alternative Medicine Policy Roster (partial) (1 page)	09/25/2000	b(6)

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White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

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FOLDER TITLE:
WHCCAMP Meeting #2, October 5-6, 2000

2011-0568-S
kc831

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[091]

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September 25, 2000

DRAFT Coordinated Research Meeting Agenda
October 5, 2000 (Italicized names are confirmed)

7:30 a.m.	Registration	
8:30	Welcome and Introductions	*Dr. James S. Gordon*, Chair
8:45	**Session I: Research Priorities and Public Input**	
	Institute of Medicine IOM Report on Priority Setting and Public Input at NIH	TBA *Dr. Leon Rosenberg*
	Discussion	
9:30	**Session II: Federal (NIH) Support for CAM Research**	
	National Cancer Institute	*Dr. Jeffrey White*
	National Heart, Lung, and Blood Institute	*Dr. Claude Lenfant*
	National Institute of General Medical Sciences	*Dr. Marvin Cassman*
	National Institute of Arthritis and Musculoskeletal and Skin Diseases	*Dr. Steven Hausman*
	Office of the Director/Office of Dietary Supplements	*Dr. Paul Coates*
	Discussion	
10:45	**BREAK**	
11:00	**Session III: Academic Centers and Support for CAM Research**	
	University of Pennsylvania	*Dr. Alfred Fishman*
	Harvard University	*Dr. Daniel Federman*
	U of Texas/Johns Hopkins	TBA
	Bastyr University	*Dr. Joseph Pizzorno*
	Palmer College of Chiropractic	*Dr. William Meeker*
	Discussion	
12:15 p.m.	**LUNCH**	
1:30	Public Comment	

2:15 **Session IV: Research Support and Collaborations**

National Center on Complementary and and Alternative Medicine	*Dr. Stephen E. Straus*

Discussion

2:55 **BREAK**

3:10 **Session V: Facilitating CAM Research and Regulatory Challenges**

Center for Drug Evaluation and Research	*Dr. Janet Woodcock*
Center for Devices and Radiological Health	*Dr. David W. Feigal*
Center for Food Safety and Applied Nutrition	Dr. Joseph A. Levitt

Discussion

4:10 **Session VI: Research in the Regulatory Framework**

Botanical Enterprises, Inc	*Dr. Floyd Leaders*
CAM Dietary Supplements Company	TBA
CAM Medical Devices Company	TBA
Federation of State Medical Boards	*Dr. James R. Winn*

Discussion

5:10 **BREAK**

5:20 **Session VII: Outcomes Research Part I– The Interface Between CAM Research and Regulatory Agencies**

Private Practice	*Nicholas Gonzalez*
National Cancer Institute	*Dr. Jeffrey White*
Private Practice	*Dr. Ann McCombs*
	Dr. Devi Nambudripad

5:50-6:10 **Discussion**

DRAFT Coordinated Research Meeting Agenda
October 6, 2000

8:30-9:30	**Session VIII: World View**	
	Discussion on CAM World View	Full Commission
	Session IX: Not-for-Profit Sector Support for CAM Research	
9:30-9:40	Fetzer Foundation	Inouye/Wiletzky/Sluyder
9:40-9:50	Templeton Foundation	Dr. John M. Templeton, Jr.
9:50-10:00	Robert Wood Johnson	Dr. Ruby Hearn
10:00-10:10	Bill and Melinda Gates Foundation	Stonesifer/Perkin
10:10-10:20	Rockefeller Foundation	TBA
10:20-10:30	American Cancer Society	Ms. Teri Andes accepted
10:30-10:50	**Discussion**	
10:50-11:05	**BREAK**	
	Session X: Private Sector Support for CAM Research	
11:05-11:15	Pharmaceutical Research Manufacturers of America	Dr. Alan Holmer
11:15-11:25	Advanced Medical Technology Association	Dr. James Benson
11:25-11:35	Johnson and Johnson	Dr. Debra Bowen
11:35-11:45	Pfizer, Inc.	Dr. Jasfat Bindra
11:45-11:55	American Botanical Council	Dr. Marc Blumenthal accepted
11:55-12:05	Council for Responsible Nutrition	Dr. Annette Dickenson accepted
12:05-12:25	**Discussion**	
12:25-1:30	**LUNCH**	
1:30-2:30	Public Comment	

Session XI: Interface Between CAM Research and Regulatory Agencies (continued)

Outcomes Research: Institution-Based

2:30-2:40	Center fo Disease Control and Prevention	Dr. Elaine Cramer accepted
2:40-2:50	Bastyr University	Dr. Leanna Standish accepted
2:50-3:00	Kaiser Permanente	Dr. David Lawrence
3:00-3:10	Association of Schools of Public Health	TBA
3:10-3:30	**Discussion**	

Session XII: Federal Agency Support for CAM Research

3:30-3:40	NSF	TBA
3:40-3:50	CDC	TBA
3:50-4:00	DoD	TBA
4:00-4:10	VA	TBA
4:10-4:20	IHS	Dr Michael Trujillo accepted
4:20-4:40	**Discussion**	
4:40-5:00	Wrap-up and Adjournment	

Sept 27, 2000 Release

October 5-6, Meeting

What began as a small grass-roots movement of Americans exploring alternatives to conventional medical care such as acupuncture and herbalism has blossomed into a highly significant trend in modern medical science.

Seven out of ten cancer patients use some form of alternative medicines (according to a recent study in the Journal of Clinical Oncology). In the last decade there has been an estimated 50 percent increase in the number of times Americans visit alternative medical practitioners (according to a 1998 study in the Journal of the American Medical Association). In total, Americans made over seven hundred million such visits last year, two hundred million more than the number of visits to primary care physicians.

Over two-thirds of medical schools in the United States now offer at least a course in complementary and alternative medicine (CAM). The budget of the National Center on Complementary and Alternative Medicine at the National Institutes of Health has increased from $2 million in 1992 to a proposed $100 million for FY 2001.

Now, President Clinton has created a special White House commission to report to the President and Congress how U.S. public policy can maximize the benefits of complementary and alternative medicine (CAM) to the American public. The commission is headed by Dr. James Gordon, an internationally recognized expert in CAM therapies and a Georgetown University Medical School professor.

"Within five to ten years complementary therapies will be a part of the care in every major hospital and clinic across the country and our definition of medicine will be far larger than it is today" said Dr. Gordon. "The questions are not 'if' or even 'when' this will happen. The questions that must be answered, and the ones the Commission will address, are how we can find out which of these therapies are truly effective; how clinicians can be trained in using them and the public educated about them; and how therapies that do prove effective will be safely integrated into a truly comprehensive and humane care for all Americans."

Next week the White House Commission will take at look at the latest research in complementary and alternative medicine and how public policy might enhance and apply the findings of this research to modern medical practice. The two-day hearing will be held on Thursday and Friday (Oct. 5 & 6) in Room 800 of the Hubert Humphrey Building, Washington D.C. The hearing will feature leading experts in complementary and alternative medicine as well as officials from the National Institutes of Health, the Food and Drug Administration and other federal agencies.

To help introduce the first stage of the commission's work Dr. Gordon will host a press briefing during the lunch break at next week's hearing (12:30 p.m., Room 634 F). Four medical experts who work at the cutting edge of the alternative medical field will appear with Dr. Gordon. They are Dr. Dean Ornish, a pioneer in treating and reversing heart disease with diet, stress management and group support; Dr. Nicholas Gonzalez, a physician who uses an experimental regimen to slow the progress of pancreatic cancer; Dr. Leanna Standish, a naturopath, research director and developer of innovative CAM programs for HIV positive

patients at Bastyr University; and Dr. Floyd Leaders, CEO of a Maryland based company specializing in plant-based medicines.

Dr. James Gordon -- a Harvard-trained physician and former research psychiatrist at the National Institute of Mental Health. Professor at Georgetown University Medical School, he is the founder and director of the Washington, DC based Center for Mind-Body Medicine. Dr. Gordon can speak of the significance of the commission and scope of its work: "I believe that what the commission is going to do will have a major impact on healthcare for the rest of the century." He can also speak to the need to set aside more research dollars for CAM. Dr. Gordon is an expert in mind body medicine and other CAM therapies such as acupuncture, nutrition, herbal remedies and musculoskeletal manipulation. He is co-author of the recently released book, Comprehensive Cancer Care: Integrating Complementary and Alternative Therapies, and author of Manifesto for a New Medicine.

Dr. Dean Ornish -- a clinical professor of medicine at the University of California (San Francisco) and a member of the White House Commission on CAM Policy. Dr. Ornish can speak of his own pioneering research into the positive effects of a calibrated diet and low-stress lifestyle. He was the first to establish that heart disease is reversible through changes in diet and stress. A best-selling author, he was recognized by Life magazine as "one of the 50 most influential members of his generation."

Dr. Nicholas J. Gonzalez -- a New York-based physician and a panel member at the White House Commission hearing. Dr. Gonzalez can speak of his treatment of pancreatic cancer with a nutritional regimen of large doses of vitamins, enzymes and diet restrictions. Dr. Gonzalez's treatment has won a five-year, $1.4 million research grant from the National Institutes of Health, in partnership with the National Center for Complementary and Alternative Medicine.

Dr. Leanna Standish -- a trained practitioner of alternative treatments and a panel member at the White House Commission hearing. Dr. Standish, a naturopath, is director of research at the Seattle-based Bastyr University where she has developed innovative and highly effective CAM programs for HIV positive patients. She has become well versed in the regulatory issues of CAM research, including the role of the Food and Drug administration

Dr. Floyd Leaders -- a panel member at the White House Commission hearing. He is CEO of Botanical Enterprises Inc., a Maryland-based company specializing in plant-based dietary supplements and plant-based drugs.

Dean Ornish: 415-332-2525-222
Nick Gonzalez: 212-213-3337
Floyd Leters: 301-840-3930

Leanna Standish: 425-602-3166

SPEAKERS FOR OCTOBER 5 & 6

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August 4, 2000

Steve and Michele,

Attached are the pages of the July 14 meeting transcript that turned up th term, world view. The July 13 transcript found no references to that term.

The first two references appear to be associated with access to CAM services.

After that we get into Tom Chappell's fifth category idea.

Finally, we have Jim Gordon suggesting that time be set aside at the next meeting for discussion on the concept (probably an ongoing topic). He also suggests that the world view be part of the introduction to the report rather than a fifth category.

As I interpret the remarks of Jim, Effie Chow, Bill Fair and others, the focus seems to be on:

> the individual as a self aware partner in his or her own health and health care;
>
> health and healing as art as well as science, requiring a "healing partnership," which the physician alone has little time for; and
>
> access to a full choice of reliable health promotion and health care options for informed decision making.

Steve,

What I typed above is what I found on the pages that included references to world view, but the world view really comes out when reading the notes and full transcript. It's a concept that I think I can begin to (or at least try to) sketch out next week.

* Okay. Great. Then let's move on to Number 2, which -- Steve, you word it as Guidance for Appropriate Access to and Delivery of Complementary and Alternative Medicine. And this -- it sounds small, but this is really huge. This is what issues do we need to address to understand how both the practices and the world view of CAM can be integrated into health care for everybody.

So it's a big topic and we can start anywhere anyone would like with this topic.

You're stunned?

MR. GROFT: Let me just go over a few things about the microphones. When you want to speak, just press the button on the right. And when you're finished, turn it off. If there are six microphones that are on at one time we'll get a ding-dong and everything will just shut off.

So before you speak, just press the button and the red light will come on in front of you and the orange light on the microphone. Okay?

DR. GORDON: Please, George.

MR. DEVRIES: So, Dr. Gordon, when you're talking about access, access to and delivery of complementary and alternative medicine, maybe you can help us, give us some more definition.

Are we talking coverage under insured benefit programs; coverages by pairs; recommendations in terms of licensure, scope of practice; how members will access these services; are they under the indirect/direct supervision of a medical physician or are they not.

Just trying to understand what you're looking for there.

DR. GORDON: The answer is yes. That's part of it. Or, looked at another way, if I'm going to my primary care doctor, if I'm looking around my community, if I'm going to a community mental health center, if I'm going to a hospital, what should I expect. What does CAM, the techniques, the approach, the world view that we discussed yesterday, how can we as a Commission -- what do we need to know to make recommendations to say to Congress we feel that Medicare patients should have -- and Medicaid patients -- should have access to this.

We feel that part of every patient's care should include X, Y or Z. We feel that insurance coverage should include. We feel that such-and-such practitioners should be part of this setting, that setting or the other setting.

It's a huge area. And what we're trying to

choice. And they don't know that they even have other options.

So I think that if we can combine the science, the credentialing, the quality assurance and the reimbursement, then we're going to find that it will be necessary for patients to be given truly informed decisionmaking which most patients really don't have the access to.

DR. GORDON: Thank you. I think that's very helpful.

Yes. Tom and Joe.

MR. CHAPPELL: The more we talk about our difficulties of fitting the practices and mindset of CAM into existing governmental regulatory thinking, the more it's clear to me that we really, as part of this assignment, need to define our world view and our beliefs as a group. And I'm thinking that that could be a fifth group, a fifth category. We have four categories that we've been asked to express an interest in.

This world view or, that is, the beliefs that we have here really has to precede anything that we ultimately produce. It has to be a precept. Because it's an orientation that is different from a Western orientation.

really doing our task and we happen to be doing it very efficiently, which is nice. So I appreciate it.

Let's move on to number -- yes, Tom?

MR. CHAPPELL: I'm sorry. I just wanted to get clarification of this suggestion of a fifth working piece on beliefs and world view. And since I understand there's a working order to our focus, I believe that this should be the first piece that we work on because the sooner we set up our understanding of how we relate to all of these four topics through a world view or a belief system, the more easily we'll be, the more comfortable we'll be that everything is fitting into that orientation.

So I wonder if we could just put that together.

DR. GORDON: I would make a somewhat different -- just because I have a sense of the logistics of what needs to be done. That we could set aside some time to work on that during the first -- the next meeting, rather than wait. Because I think we can move ahead with some of the research because a lot of that is gathering information.

MR. CHAPPELL: Well, I think that's a wonderful suggestion.

DR. GORDON: And we can set aside time for

discussion about belief and world view at that meeting. Okay?

MR. CHAPPELL: Thank you.

MR. GROFT: And actually, Tom, at that point we may want to build that into the introduction to the report rather than making it a separate issue or something. We have time to discuss exactly how we want to present it but we'll get it put together.

DR. GORDON: And I see also it's very much of an ongoing discussion as well.

Okay. Let's begin then.

Thank you, Tom, for reminding us of that.

*Number 3, the provision to health care professionals of reliable and useful information about complementary and alternative medicine that can be made readily accessible and understandable to the general public. And I would like to add another piece to that, which is the provision of information directly to the general public as well.

So let's begin with discussing once again what we need to know or how we need to be informed in order to make recommendations in this area.

And you'll notice this is slightly different, although not altogether different, from number 4, which has the education and training of health care

how they work. They don't really -- nobody teaches them anything about how the mind works or how the body works really. Health is focused basically on a few diseases or smoking. And I think part of the way I see part of our mission and a lot of the work which I can describe at some other point that we've done has been working with school kids here and in other countries teaching them some things about themselves and encouraging them to learn about themselves.

And I think that we can make those kinds of recommendations as well. My basic point -- and this comes back I suppose to philosophy -- is that if you become aware of your capacity to understand yourself and to take care of yourself, then your view of the options and your view of the standard of care is altogether different than if you think it's just a doctor who knows something about you.

So this world view and this perspective and this philosophy to me seems to me to need to be integrated into the provision of information, too.

Bill?

DR. FAIR: To follow up on that though, I'd like your thoughts. I agree with you completely that the time to get the message out is to children. That's the ideal way. But if you look at the incidence of

10 minute visit is with us for the foreseeable future. You can't be all things to all people, so physicians are going to have to rely more on other practitioners to deliver these things, like massage and acupuncture and so forth. Unless you think otherwise.

DR. GORDON: I don't have -- personally, I don't have, except in very rare instances, the time or the inclination to do massage, even though I've had some training in it. I think the 8 or 10 minute visit is an abomination except for a kid with a little cut.

This brings us back to the whole issue of services. I think we have to challenge that. And fundamentally, again, this is coming back to Effie's point and the point that many of us have made, is that the whole vision of CAM is not of an 8 to 10 minute visit. It's a vision of some kind of what I call healing partnership with people. And I think that's part of our world view. And even though it's a major change, has to happen.

For that to happen, I think that we need to come down on the -- I think we shouldn't accept that particular status quo.

DR. FAIR: I'm just saying that the --

DR. GORDON: That doesn't mean we shouldn't refer to massage therapists or acupuncturists or other

of that.

And I still need two checklists over there.

MR. GROFT: We are considering in the future having these actual meetings be live on the internet so we're going to look into the expense of that effort and communicate that out more broadly as well so it will be much more accessible to the public.

DR. GORDON: Anything else?

MR. GROFT: No.

DR. GORDON: So our next step -- there will be a couple of other steps. We will act and get out a communication to all members of Congress, to major health care organizations and associations and citizens groups about the existence of the Commission. We will be sending all of you soon a summary and some ideas about how we're going to proceed. A summary of the meeting and ideas about how we're going to proceed for the next panels on the four topics that we covered, as well as opportunity to talk among ourselves about our overview, our philosophy, the world view of the Commission and of CAM.

We will be planning meetings. We've tentatively -- Dean and Effie and I have tentatively scheduled a town hall meeting in San Francisco on September 8th and we'll be talking. Joe and Bill and I

Media Advisory For:
October 5, 2000

Contact: Helen Szablya, Lisa Magnino
Fenton Communications (202) 822-5200

Press Briefing: Thursday, October 5, 2000 at 12:30 p.m.

New White House Commission on Complementary and Alternative Medicine Policy Launches Public Hearings

Focus on Research

The White House Commission on Complementary and Alternative Medicine Policy will hold public hearings on October 5 and 6. A press briefing will take place on Thursday, October 5 at 12:30 pm. This special White House commission will report to the President and Congress on how U.S. public policy can maximize the benefits of complementary and alternative medicine (CAM) to the American public. The purpose of the hearing is for the White House Commission to take at look at the latest research in complementary and alternative medicine and how public policy might enhance and apply the findings of this research to modern medical practice.

The two-day hearing will be held on Thursday (8:30 a.m. - 6:00 p.m.) and Friday (8:30 a.m. - 5:00 p.m.) - Oct. 5 & 6 in Room 800 of the Hubert Humphrey Building, Washington D.C. The hearing will feature leading experts in complementary and alternative medicine as well as officials from the National Institutes of Health, the Food and Drug Administration and other federal agencies.

The public is encouraged to attend the hearings. Public comment will be heard from 1:30 - 2:15 p.m. on both October 5 and 6.

Press Briefing

Who: Dr. James Gordon, Commission Chair -- a Harvard-trained physician and former research psychiatrist at the National Institute of Mental Health;
Dr. Dean Ornish -- a clinical professor of medicine at the University of California (San Francisco), best-selling author and a member of the White House Commission on CAM Policy;
Dr. Nicholas J. Gonzalez -- a New York-based physician, a pioneer in pancreatic cancer research using alternative therapies and a panel member at the White House Commission hearing
Dr. Leanna Standish -- Director of Research at Bastyr University, a trained practitioner of alternative treatments and a panel member at the White House Commission hearing;
Dr. Floyd Leaders -- CEO of Maryland-based Botanical Enterprises and a panel member at the White House Commission hearing.

When: Thursday, October 5 at 12:30 p.m.

Where: Hubert Humphrey Building, 200 Independence Avenue SW, Room 634 F
Washington DC

Groft, Steve (NCCAM)

From: Tom Andrews [tom@neweconomy.org]
Sent: Friday, September 29, 2000 2:39 PM
To: Groft, Steve (NCCAM)
Cc: helen@fenton.com; jsgordon@mindspring.com
Subject: Media Packet

Steve,

Thanks for being willing to put the materials that we need for the media packet and getting it to us on Monday.

Just to review, we need:

* White House Commission folders (where all of this will go);
* Commission members with brief bios;
* Speakers list for news briefing with bios: Dean Ornish; Nick Gonzalez; Leanna Standish; Floyd Leaders (I will ask Jim for a copy of his);
* Meeting Agenda;
* One or two page description of the Commission including background and mission;
* One or two page fact sheet highlighting important CAM facts that we would like the media to use in describing CAM, e.g. the increase in #s of Americans using CAM;
* One page description of research issues that might include a description of significant and interesting research findings; public policy research questions, etc.

Would you please have these materials delivered to Fenton Communications ATT: Helen Szablya.

Thanks, Steve!
Tom