Revised Outline for WHCCAMP Report

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Report of the White House Commission on Complementary and Alternative Medicine Policy

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Value of this Information / Agenda Item to the report

- Hearing discussion of Commissioners
- Heavy Agenda — Question — what does the agency
- Commissioners to do & the report. what do you need to know
info for report + recommendations

11 Oct 00

Preliminary Agenda for 4-5 Dec 00 Meeting on Access and Delivery

DAY ONE: Monday, 4 Dec 20000

7:30-9:00 am Breakfast [Commissioners: "Getting to Know You."]

9:15 am Welcome and Introductions
Dr. James Gordon

Inquiry the Report

Session I: Overview CAM Utilization Survey Data
[Emphasis on Access & Delivery]
Dr. James Gordon
Panel Discussion

Education of Commissioners
Insight — + Knowledge
what do Commissioners need to Know + make a Recommendation on the Report?

Session II: Making the Case For CAM Access and Delivery
[Format: Each panel of program speaker(s) & patient/client speaker]

"Good Insurance & Good Access" Panel
Panel Discussion

"Bad/No Insurance & Good Access through Research or Pilot Program" Panel
Panel Discussion

~~N.B., Could add "Bad/No Insurance & Poor/No Access" Panel~~

Session III: Making the Case Against CAM Access and Delivery
[Potential speakers identified by Dr. Wallace Sampson]
Panel Discussion

more important

Session IV.
Systems of Delivery [Integration or CAM Separatism?]
[What worked & why/why not?]

Have models / Programs that didn't work — didn't work / models

Private Sector Panel
[e.g., academic health/medical centers, community hospital-based, free-standing for-profit practice-based]
Panel Discussion

Public Sector Panel
Panel Discussion

Ten Wisneski

Federal Sector Panel
SAMSHA
HRSA (Director of Bureau Primary Health Care, Director of HIV/AIDS Bureau, and possibly Director of the Maternal Child Health Bureau)
PHS Office on Women's Health (Dr. Wanda K. Jones)
DOD (Acting Assistant Secretary for Health, Health Affairs)
Panel Discussion

Private Foundations: Novel Systems of Care
[e.g., George Foundation, Robert Wood Johnson, and …]
Panel Discussion

Session V. Commissioners' Discussion

Groft, Steve (NCCAM)

From: Greene, Anita (NCCAM)
Sent: Tuesday, October 10, 2000 10:11 AM
To: Straus, Stephen (NCCAM); Groft, Steve (NCCAM)
Cc: Hussey, Doug (NCCAM); LeBlanc, Stephen (NCCAM)
Subject: White House Commission Media

Listed are 2 press accounts of the recent White House Commission Mtg. held in D.C. last week:

1. Monday, October 09, 2000 [Alternative Medicine]: **Time to Separate Quack**

From Credible: White House Commission Strives to Spur Research on Complementary and [Alternative Medicine]

By Ori Twersky

WebMD Washington Correspondent

Reviewed by Dr. Michael W. Smith

Oct. 6, 2000 (Washington) -- Can acupuncture help relieve arthritis pain? Is meditation a good means of avoiding heart disease? Are dietary supplements a legitimate alternative to conventional medications? How can we know for sure that any alternative therapy is truly effective or safe? A White House commission is set to address these and many other questions about [complementary and alternative medicine]. The goal? To help initiate some desperately needed clinical research.

Over the last decade, Americans' fascination with [complementary and alternative medicine] literally has exploded, giving rise to an estimated $5 billion-a-year dietary supplement industry alone. While experts believe as many as half of all Americans use at least one form of alternative therapy to treat everything from arthritis to cancer, a number of unanswered questions remain regarding the true value of these non-conventional alternatives to traditional medicine due to an overall lack of clinical research.

Now, some of these answers finally may be around the corner. A White House-appointed commission will review complementary and alternative therapies and look at how these therapies can be tested, how conventional doctors can be trained to use them, and how these therapies can be integrated safely into conventional medicine.

Created by an executive order in March, the commission Thursday inaugurated this process by addressing what is perhaps one of the more perplexing questions: How can these alternative therapies be tested and their effectiveness determined?

"Research is crucial. We need answers," James Gordon, MD, chair of the presidential commission, tells WebMD.

But establishing research agendas for some alternative therapies will be problematic.

"It is possible to apply strict scientific methods to test a number of these alternatives," says Jeffery White, MD, a director at the [National Institutes of Health]'s National Cancer Institute. But testing some alternatives, such as acupuncture and meditation, will be complicated, adds Leanna Standish, PhD, director of research at Bastyr University in Kenmore, Wash., a university devoted to researching and teaching alternative practices.

In the case of acupuncture and meditation, it will be difficult to come to a universal conclusion on the effectiveness of these alternative therapies because how they are administered varies so widely from one practitioner to another. Universal treatment guidelines are a cornerstone of conventional medicine, but in the case of alternative therapies, standardizing the treatment will not always be possible, Standish says.

In terms of creating clinical trials, there will be additional obstacles to overcome, Floyd Leaders, founder and CEO of Botanical Enterprises, a maker of dietary supplements, tells WebMD. Even when the therapy can be standardized, as in the case of dietary supplements, testing whether a product prevents a medical condition is almost impossible, he says. "How can you determine whether the condition was prevented without following the individual their entire life?" Leaders asks.

Getting experienced researchers involved in tests of complementary and alternative therapies also may be a problem, White says. Right now, experienced clinical researchers are somewhat reluctant to participate in these types of trials because alternative therapies are still not considered legitimate medicine, he says.

One way to address this obstacle is to schedule workshops to bring these researchers in contact with practitioners of

alternative therapies so that they can educate each other about their respective fields, White suggests.

In the meantime, the [NIH] already is funding some research into alternative therapies for conditions such as cancer, White says. But the [NIH] has had a difficult time launching new research initiatives into alternative therapies because a large number of the proposals it receives are for trials that are not always appropriately designed, he says.

The good news is that "interest is very high on all levels," Gordon says. Not only does the commission enjoy bipartisan support from Congress, but it also benefits from the public's own growing interest in alternative therapies, he says. "It is one of these situations where everyone stands to benefit," he tells WebMD.

The next step of the commission will be to hold additional public meetings to address remaining issues, such as how can alternative therapies co-exist with conventional medicine. It also plans to hold town hall meetings across the country to gauge the public's opinion. An interim report is scheduled for next summer, but the commission's final recommendations probably will not be known until March 2002, when the commission faces its final deadline.

2. New types of care gaining favor

Lee Bowman Scripps Howard News Service

WASHINGTON

With at least 50 percent of Americans doing something to enhance their health that's outside the bounds of traditional health care, doctors and policy makers are rapidly making room for "[complementary medicine]."

Gone are the days when acupuncture, herbal remedies or massage therapy could be dismissed by conventional health professionals as "[alternative" medical] care sought out by patients disaffected from the medical system. It is estimated that 700 million visits were made to alternative caregivers last year, 200 million more visits than were made to family physicians.

The reality is, most patients get some of both, and the realization has come to providers that they better learn about what can work together and what might counteract other treatment or do outright harm to patients.

"Within five or 10 years, complementary therapies will be 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. James Gordon, chairman of a new White House Commission on [Complementary and Alternative Medicine] Policy.

The commission held its first information-gathering session here this week, getting updates on the state of research into alternative therapies.

Gordon, who also is founder and director of the Center for Mind-Body Medicine at Georgetown University, and a former research psychiatrist, said he has become "a believer as far as [complementary and alternative medicine] is concerned," as he's seen unconventional treatments help people with maladies ranging from asthma to attention deficit disorder over the past 35 years.

"Our goal is to try and figure out how to bring the benefit of these therapies to all people in America," Gordon said.

Some of the alternative health care techniques already have become so widely accepted that it's easy to forget they were once controversial, said Dr. Dean Ornish, another member of the commission and a professor of medicine at the University of California-San Francisco.

Ornish was the first to prove that heart disease can be reversed by changing diet and lifestyle, yet it has taken him decades to convince insurance companies to pay for wellness programs that might provide an alternative to some of the $30 billion a year spent for heart surgery and drugs.

"I naively thought that good science would be enough to effect change, but there's a need to push for changes in reimbursement and policy, too," Ornish said.

Still other interventions elude confirmation by the kind of controlled clinical trials demanded of new drugs or diagnostic tools, but researchers are still trying.

Take distant healing - the attempt of someone to mentally or spiritually influence the health of someone without physically touching them.

"It looks as though conscious intervention can affect biology," said Dr. Leanna Standish, a naturopathic physician and director of research at Seattle's Bastyr University.

Anita Greene, M.A.
Press Communications Program Officer

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Kingsbury, Doris (NCCAM)

Subject: Preliminary Draft

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Commissioners:
Please find attached the preliminary agenda for the Dec 4-5th meeting on Access and Delivery of CAM. We are confirmed for a one-hour telephone conference call on Thursday, Oct 12, 12:30 p.m. EST. Please call in at 1-800-545-4387 and reference call M31111 to be connected.

The charge of the Work Group before each meeting is to help develop the agenda and identify speakers. At this time, we would ask you to review the preliminary agenda, formulate discussion questions for the conference call, and begin to think about appropriate speakers. Since this first call is only one hour, we will focus on discussion and consensus on the proposed agenda and goals for the Dec 4-5 meeting.

Our second call is scheduled for Wednesday, Oct 18, 2:00-3:30 EST (1.5 hours). Please note this on your calendars. Please call in at 1-800-545-4387 and reference call M19801 to be connected.

Thanks! Should you have any questions about the call or the agenda that you would like to discuss before Thursday's call, please contact Joe Kaczmarczyk at 301-435-6197.

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11 Oct 00

DRAFT

Preliminary Agenda for 4-5 Dec 00 Meeting on Access and Delivery

DAY ONE: Monday, December 4, 2000 7:30 am - 5:30 pm
DAY TWO: Tuesday, December 5, 2000 8:30 am - 4:00 pm

7:30-9:00 am Breakfast [Commissioners: "Getting to Know You."]

9:15 am Welcome and Introductions
Dr. James Gordon

Session I: Overview CAM Utilization Survey Data
[Emphasis on Access & Delivery]
Dr. James Gordon
Panel Discussion

Session II: Making the Case For CAM Access and Delivery
[Format: Each example will consist of a program speaker & a patient/client speaker on topic areas such as cancer, HIV/AIDS, & addiction]

"Adequate Insurance & Access" Panel
Panel Discussion

"Inadequate Insurance & Situational Access [through Research or Pilot Program]" Panel

Panel Discussion

Session III: Making the Case Against CAM Access and Delivery
[Potential speakers identified by Dr. Wallace Sampson]
Panel Discussion

[Systems of Delivery sessions on CAM Integration or CAM Separatism: Should or shouldn't CAM be integrated... and lesson learned: What worked & why/why not?]

Session IV: Systems of Delivery: Private Sector Panel
Free-standing for-profit practice-based
[Suggestion: Len Wisneski, MD]
Community hospital-based CAM center/clinic
Academic health/medical center
[Suggestion: David Eisenberg, MD- service delivery research]
[Suggestion: Sam Benjamin, MD- unsuccessful program]
Managed Care Organizations [Two representative examples]
American Association of Health Plans (AAHP)
Panel Discussion

Session V: Systems of Delivery: State & Local Government Panel
King County Natural Medicine Clinic, Kent, WA
Country Doc Community Health Center, Seattle, WA
Washington State Insurance Commissioner
Minnesota Complementary and Alternative Health Care Freedom of Access Act [unlicensed CAM practitioners]
Minnesota Natural Health Coalition
Ohio House Bill 90 [licensed physicians integrating CAM]
Panel Discussion

Session VI: Systems of Delivery: Federal Sector Panel
SAMSHA
HRSA
(Suggestion: Director of Bureau Primary Health Care, Director of HIV/AIDS Bureau, and possibly Director of the Maternal Child Health Bureau)
PHS Office on Women's Health
(Suggestion: Dr. Wanda K. Jones)
OPM (Federal Employees' Health Benefits Program)
DOD
Suggestion: (Acting Assistant Secretary for Health, Health Affairs)
Panel Discussion

Session VII: Private Foundations and Novel Systems of CAM Delivery Panel
[e.g., George Foundation, Robert Wood Johnson, National Integrative Medicine Council (NIMC), and ...]
Panel Discussion

Session VIII. Commissioners' Discussion of Access to and Delivery of CAM Practices and Products

WORKING DRAFT 29 SEP 00
ACCESS, DELIVERY, AND REIMBURSEMENT

I. Current reimbursement environment
   A. Overview of conventional health care system reimbursement
   B. Overview of CAM reimbursement
   C. Overview of HCFA perspective on reimbursement

II. Reimbursement Options
   A. 3 panels:
      1. Maintain current reimbursement
      2. Adapt current reimbursement systems to include CAM
      3. Create a new reimbursement system
   B. Questions for each panel:
      1. Why are you advocating or not advocating change?
      2. What are the policy implications of what you're proposing?

III. Consumer perspective
   A. Survey data (Einsenberg, Astin, Dross & Rosenheck, etc.)
   B. Organized labor (AFL-CIO)
   C. Organizations representing "Special Populations" such as women, pregnant women, children, HIV/AIDS, cancer, old/very old, Native Americans/Alaskan Natives, Native Hawaiians, recent immigrants, Traditional populations, poor/medically underserved, persons with disabilities, ...
   D. Questions:
      1. Why do you want to use CAM practices and products?
      2. For what do you want to use CAM practices and products?
      3. When and how do you decide to use CAM practices and products?
      4. Do you need to see a practitioner to use CAM practices and products? If not, when don't you need to see a CAM practitioner? How do you decide when not to see a CAM practitioner?
      5. What are some examples of CAM practices and products that are working?
      6. Do you have access to all of the CAM practices and products you want? If not, what are the barriers [for example, financial, transportation/geographic, child/elder care, cultural, linguistic] and what can be done to remove those barriers?
      7. Who pays for the CAM practices and products you use?
      8. Do you have difficulty paying for CAM practices and products? If so, what do you think should be done about it and what policy changes should be made?

IV. Provider perspective
   A. Conventional physicians
   B. CAM practitioners
   C. Integrative physicians
   D. Questions:
      1. Why do you or why don't you want to include CAM practices and products in your practice?
      2. For what indications should CAM practices and products be used clinically?
      3. How do you decide which CAM practice or product to use or recommend?
      4. Who should provide CAM practices and products?
      5. How do you determine to which CAM practitioner to refer patients?
      6. Where and how should CAM practices and products be provided?
      7. What is the role of CAM in self-care?
      8. What barriers have you experienced in providing CAM practices and products? How have you overcome those barriers? What policy changes would you recommend to facilitate provision/delivery of CAM practices and products?

V. Payors and Purchasers
   A. Conventional health care only
   B. CAM only
   C. Integrative
   D. Benefits managers trade association
   E. Organized Labor
   F. OPM (FEHBP)
   G. AAHP
   H. George Foundation
   I. Questions:
      1. Why should you pay or why should you not pay for CAM practices and products?
      2. For which indications should you be paying for CAM practices and products? How do you decide for which CAM practices and products you will pay?
      3. For which CAM practices and products should you be paying? How do you decide for which CAM practices and products you will pay?
      4. Who should be providing CAM practices and products for which you will pay? How do you decide who should be providing CAM practices and products for which you will pay?
      5. What is the role of CAM practices and products in self-care? Should you pay for CAM practices and products for self-care? If

so, for which practices and products and which conditions should you pay? On what bases should you make those decisions?

6. What is the role of CAM practices and products in managed care?
7. Where and how should CAM practices and products be provided? How do you decide where and how CAM practices and products for which you will pay should be provided?
8. What problems or barriers have you encountered? What should be done about them? What policy changes should be made from your perspective as a payor or purchaser?

VI. Lessons learned from integrative delivery systems (Pre-conception to end-of-life)

A. Private sector

1. Academic health/medical center-based
2. Community hospital-based
3. Free-standing for-profit practice-based
4. Questions:
   a. Why and how did you decide to integrate CAM practices and products with conventional health care?
   b. For which indications do you provide CAM practices and products? Who made that decision? On what basis was that decision made?
   c. Which CAM practices and products do you provide? Who determined which CAM practices and products you provide? On what basis was that decision made?
   d. Who provides CAM practices and products in your organization? On what basis was that decision made? How are your CAM providers selected? Do you use any unlicensed CAM practitioners? If so, why and how are they used?
   e. Where and how are your CAM practices and products provided? How was that determined?
   f. Who pays for the CAM practices and products you provide?
   g. Have any of the users of your CAM practices and products experienced difficulty with access to or payment for CAM practices and products? If so, please specify the difficulty and how it was resolved or should be resolved?
   h. What have you done to make the delivery of CAM practices and products culturally and linguistically appropriate for your CAM users?
   i. Do you provide all of the CAM practices and products you would like to offer? If not, what would you like to add and why? Likewise, do you provide all of the CAM practices and products that your CAM users want? If not, why?

j. What is the role of self-care in the CAM practices and products that you provide?
k. What is the role of CAM practices and products in managed care?
l. What are the lessons that you have learned in dealing with CAM practices and products? What is the single most important lesson that you have learned?
m. From you perspective, what policy changes do you think should be made?

B. Public sector
1. Kent Natural Medicine Clinic
2. Country Doc Community Health Center
3. Winslow, AZ IHS
4. Native Hawaiian Traditional healing
5. Questions: As above

C. Federal
1. HRSA
2. VA
3. DOD
4. SAMSHA
5. IHS
6. Questions:
a. Has your Agency determined the utilization of CAM practices and products in its target populations? If so, how were the utilization data obtained and what did those data show? If not, why?
b. What CAM practices and products does your Agency provide or support? How, why, and by whom were those CAM practices and products selected?
c. Where, how, and by whom are CAM practices and products provided? Who determined this? On what basis was this decided?
d. Is the delivery of CAM practices and products to your target populations integrated with conventional health care? If so, why and to what extent? Where, how, and by whom was this accomplished?
e. What has your Agency done to make the delivery of CAM practices and products culturally and linguistically appropriate for your target populations?
f. Who pays for the CAM practices and products used by your Agency's target populations?
g. Do your target populations have access to all of the CAM practices and products they want? If not, why?
h. Does your Agency provide or support all of the CAM practices and products it would like to offer? If not, why?

i. In dealing CAM practices and products, what are the lessons that your Agency has learned? What is the single most important lesson that your Agency has learned?

VII. Quality of Services and Delivery

A. Consumer/Purchaser perspective

1. Questions:
   a. What is "quality" in terms of CAM practices and products? Should it be measure? If so, how?
   b. Who should be providing CAM practices and products and what credentials should these individuals have?
   c. Where and how should CAM practices and products be provided to assure quality?
   d. What should consumers be told about costs, safety, effectiveness, and time for effectiveness to be evident of CAM practices and products?
   e. How can quality of CAM practices and products be assured if these practices and products are used as self-care?
   f. What should be done to minimize the risks of drug-herb and herb-herb interactions?
   g. If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?
   h. What policy changes should be made to assure the quality of CAM practices and products?

B. Provider perspective

1. Conventional only
2. CAM only
3. Integrative
4. Questions:
   a. How should "quality" in terms of CAM practices and products be defined? Who should define it? How do cost, safety, and effectiveness relate to quality of CAM practices and products?
   b. Should the quality of CAM practices and products be measured? If so, how and by whom?
   c. To assure quality of CAM practices and products, who should provide CAM practices and products?
   d. What credentials should providers of CAM practices and products possess to assure quality?
   e. Where and how should CAM practices and products be provided to assure quality?

f. What should consumers be told about costs, safety, effectiveness, and time for effectiveness to be evident of CAM practices and products?
g. What should be done to minimize the risks of drug-herb and herb-herb interactions?
h. What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider/referring physician or provider?
i. If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?
j. What policy changes should be made to assure the quality of CAM practices and products?

C. Payors perspective
1. Questions:
a. As above

D. Malpractice implications
1. Conventional provider
a. Questions:
1.) What are the malpractice implications of **not** discussing, offering, or referring a patient for CAM practices and products?
2.) What is the liability of referring a patient to a CAM practitioner who then has an adverse outcome?
3.) What policy changes should be made to reduce malpractice liability associated with referral for CAM practices and products?
2. CAM practitioner
a. Questions:
1.) What is the liability of providing CAM practices and products?
2.) What policy changes should be made to reduce malpractice liability associated with CAM practices and products?
3. Integrative provider
a. Questions:
1.) What is the liability of integrating CAM practices and products with conventional health care?
2.) What policy changes should be made to reduce malpractice liability associated with CAM practices and products when integrated with conventional health care?

E. Federal perspective
    1. Federal Trade Commission
        a. Questions:
            1.) What should consumers be told about the safety, effectiveness, and time necessary for effectiveness to be evident of CAM practices and products?
            2.) What should be done to minimize the risks of drug-herb and herb-herb interactions?
            3.) If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?
            4.) What policy changes should be made to assure the quality of CAM practices and products
    2. AHRQ
        a. Questions:
            1.) How should "quality" in terms of CAM practices and products be defined? Who should define it? How do cost, safety, and effectiveness fit
            2.) Should the quality of CAM practices and products be measured? If so, how and by whom?
            3.) To assure quality of CAM practices and products, who should provide CAM practices and products?
            4.) What credentials should providers of CAM practices and products possess to assure quality?
            5.) Where and how should CAM practices and products be provided to assure quality?
            6.) What should consumers be told about costs, safety, effectiveness, and time for effectiveness to be evident of CAM practices and products?
            7.) What should be done to minimize the risks of drug-herb or herb-herb interactions?
            8.) What information should a conventional health care provider communicate to a CAM practitioner? What information should a CAM practitioner communicate to a conventional provider/referring physician or provider?
            9.) If a consumer has a concern or grievance about the quality of CAM practices and products, what mechanism is available to address the consumer's concern or grievance? If none exists, what mechanism should be established for consumers of CAM practices and products?

10.) What policy changes should be made to assure the quality of CAM practices and products?

3. National Practitioners Data Bank
   a. Questions:
      1.) Should all CAM practitioners irrespective of whether or not they are physicians be included in the NPDB? Why or why not? If so, how should this accomplished?
      2.) Should entities and individuals providing CAM practices and products provided in the Federal environment be covered under Federal Torts Act (FTCA)?
      3.) What policy changes should be made to assure the quality of CAM practices and products

F. Licensure/Certification [National] considerations
   1. Unlicensed CAM practitioners
      a. Minnesota legislation
      b. Native Hawaiian and Native American Traditional healers
      c. Practitioners licensed by some but not all states such as NDs and LACs
   2. Licensed CAM practitioners
   3. Licensed health providers practicing CAM
      a. All providers other than physicians (RN, NP, CNM, PA, PT, RD, Nutritionists, RPh/PharmD, ...)
      b. Physicians (primarily MDs)
         1.) Texas guidelines for integration
         2.) Arizona State Board Homeopathy
         3.) Medical Acupuncture Board Certification
         4.) DOs, DCs, NDs need to be considered as well, especially in States with separate Boards
   3. Questions:
      a. Should there be national standards, licensure, or certification to provide CAM practices and products? If so, who should establish them?
      b. What is the role of the unlicensed CAM practitioner such as the Traditional Healer?
      c. Should there be practice condition-specific or modality-specific practice guidelines? If so, who should develop them and how should they be implemented?
      d. What policy changes should be made to assure the quality of CAM practices and products?

G. Turfism/differential rates of reimbursement
   1. Example: Acupuncture

    a. Reimbursed differently for LACs and physicians
2. Questions:
    a. How should issues of "turfism" be resolved?
    b. Should there be universal/standardized or differential reimbursement rates for a given CAM practice or product? If so, who should establish these reimbursement rates and policies?
    c. What policy changes should be made to assure the quality of CAM practices and products?

WORKING DRAFT 10 Oct 00
ACCESS, DELIVERY, AND REIMBURSEMENT

I. Current reimbursement environment
   A. Overview of conventional health care system reimbursement
   B. Overview of CAM reimbursement
   C. Overview of HCFA perspective on reimbursement

II. Reimbursement Options
   A. 3 panels:
      1. Maintain current reimbursement
      2. Adapt current reimbursement systems to include CAM
      3. Create a new reimbursement system

III. Consumer perspective
   A. Survey data (Eisenberg, Astin, Dross & Rosenstock, etc.)
   B. Organized labor (AFL-CIO)
   C. Organizations representing "Special Populations" such as women, pregnant women, children, HIV/AIDS, cancer, old/very old, Native Americans/Alaskan Natives, Native Hawaiians, recent immigrants, Traditional populations, poor/medically underserved, persons with disabilities, …

IV. Provider perspective
   A. Conventional physicians
   B. CAM practitioners
   C. Integrative physicians

V. Payors and Purchasers
   A. Conventional health care only
   B. CAM only
   C. Integrative
   D. Benefits managers trade association
   E. Organized Labor
   F. OPM-(FEHBP)
   G. AAHP
   H. George Foundation

VI. Lessons learned from integrative delivery systems (Pre-conception to end-of-life)
   A. Private sector
      1. Academic health/medical center-based
      2. Community hospital-based
      3. Free-standing for-profit practice-based
   B. Public sector
      1. Kent Natural Medicine Clinic
      2. Country Doc Community Health Center
      3. Winslow, AZ IHS
      4. Native Hawaiian Traditional healing

C. Federal
    1. HRSA
    2. VA [Recommend deleting because of 4-5 Oct 00 testimony]
    3. DOD
    4. SAMSHA
    5. IHS [Recommend deleting because of 4-5 Oct 00 testimony]

VII. Quality of Services and Delivery Access

A. Consumer/Purchaser perspective
B. Provider perspective
    1. Conventional only
    2. CAM only
    3. Integrative
C. Payors perspective
D. Malpractice implications
    1. Conventional provider
    2. CAM practitioner
    3. Integrative provider
E. Federal perspective
    1. Federal Trade Commission
    2. AHRQ
    3. National Practitioners Data Bank
F. Licensure/Certification [National] considerations
    1. Unlicensed CAM practitioners
        a. Minnesota legislation
        b. Native Hawaiian and Native American Traditional healers
        c. Practitioners licensed by some but not all states such as NDs and LACs
    2. Licensed CAM practitioners
    3. Licensed health providers practicing CAM
        a. All providers other than physicians (RN, NP, CNM, PA, PT, RD, Nutritionists, RPh/PharmD, ...)
        b. Physicians (primarily MDs)
            1.) Texas guidelines for integration
            2.) Arizona State Board Homeopathy
            3.) Medical Acupuncture Board Certification
            4.) DOs, DCs, NDs need to be considered as well, especially in States with separate Boards
G. Turfism/differential rates of reimbursement
    1. Example: Acupuncture
        a. Reimbursed differently for LACs and physicians

Tiziana
Joe Fine
George DeVries
Conchita P

12 Oct 00

DRAFT

Preliminary Agenda for 4-5 Dec 00 Meeting on Access and Delivery

DAY ONE: Monday, December 4, 2000 7:30 am – 5:30 pm
DAY TWO: Tuesday, December 5, 2000 8:30 am – 4:00 pm

7:30-9:00 am — Breakfast [Commissioners: "Getting to Know You."]

9:15 am — Welcome and Introductions
Dr. James Gordon

Session I: Overview CAM Utilization Survey Data [Emphasis on Access & Delivery]
Dr. James Gordon
Panel Discussion

Session II: Making the Case For CAM Access and Delivery
~~[Format: Each example will consist of a program speaker & a patient/client speaker on topic areas such as cancer, HIV/AIDS, & addiction]~~

~~"Adequate Insurance & Access" Panel~~
~~Panel Discussion~~

~~"Inadequate Insurance & Situational Access [through Research or Pilot Program]" Panel~~
~~Panel Discussion~~

Overview of CAM therapies with sufficient evidence for integration and demonstrated cost-effectiveness
Dr. Ken Pellitier

Cost-Effectiveness of Mind-Body approaches
Dr. David Sobel (Kaiser-Permanente)

Effectiveness of selected CAM modalities and programs
Massage Therapy—Tiffany Fields
Chiropractic—Ian Colter
Dean Ornish's Program – Somebody other than Dr. Ornish
Acupuncture

Joint overview to go to all speakers
demographics
dollars spent
{Disease Based
Life-Cycle Based}
What therapies people use
how extensively are they used

Call K.P. to determine best method of cost effectiveness

Barre Cassileth

Disease-specific examples of effectiveness of CAM therapies
[2-3 illnesses (e.g., cancer, HIV/AIDS, addiction) with a program representative and a patient/client speaking about each condition.]
Need suggested conditions and speakers.

Panel Discussion

Session III: Making the Case Against CAM Access and Delivery
[Potential speakers identified by Dr. Wallace Sampson]
Panel Discussion

[Systems of Delivery sessions on CAM Integration or CAM Separatism: Should or shouldn't CAM be integrated... and lesson learned: What worked & why/why not?]

George DeVries
Oxford Health Plan

Session IV: Systems of Delivery: Private Sector Panel
Free-standing for-profit practice-based
[Suggestion: Len Wisneski, MD]
Community hospital-based CAM center/clinic
Academic health/medical center
[Suggestion: David Eisenberg, MD- service delivery research or Woodson Merrill, MD]
[Suggestion: Sam Benjamin, MD- unsuccessful program]
Managed Care Organizations [Two representative examples]
American Association of Health Plans (AAHP)
Panel Discussion

What the service or why they are offered

Session V: Systems of Delivery: State & Local Government Panel
King County Natural Medicine Clinic, Kent, WA
Country Doc Community Health Center, Seattle, WA
Washington State Insurance Commissioner
Minnesota Complementary and Alternative Health Care Freedom of Access Act [unlicensed CAM practitioners]
Minnesota Natural Health Coalition
Ohio House Bill 90 [licensed physicians integrating CAM]
Panel Discussion

Appropriate regulations

Session VI: Systems of Delivery: Federal Sector Panel
SAMSHA
HRSA
(Suggestion: Director of Bureau Primary Health Care, Director of HIV/AIDS Bureau, and possibly Director of the Maternal Child Health Bureau)
PHS Office on Women's Health
(Suggestion: Dr. Wanda K. Jones)
OPM (Federal Employees' Health Benefits Program)

DOD

Suggestion: (Acting Assistant Secretary for Health, Health Affairs)

Panel Discussion

Session VII: Private Foundations and Novel Systems of CAM Delivery Panel
[e.g., George Foundation, Robert Wood Johnson, National Integrative Medicine Council (NIMC), Fetzer, and ... 1-2 more]
Panel Discussion

Session VIII. Commissioners' Discussion of Access to and Delivery of CAM Practices and Products

DRAFT

(1)

Oct 5-6, 2000

Steve Straus 435-5042
Susan Flowers

IC Public Liaison
→ COPR

C.R. 20B - NIH ⇒ Slides

✱ NIH ~~Statement Setting Research Priorities~~ → obtain copy

More Central role for NIH director in Priority Setting

– Public Liaison Office - Constituency – COPR

Groups must (1) Inform (3) Challenge (5) Respect to NCCAM

(2) Advocate (4) Discuss – to Broaden Input

Use all Mechanism – available through

COPR Offices, town Hall Meetings,

crafting a good proposal

Models from IC ~~that~~ have been aggressive in implementing Recommendations – check with Anne Thomas

✱ Office of Behavioral – OBSSR → April Mtg

Basic vs ~~Applied~~ Clinical vs Developments

– Real importance is to provide public funds to study those products that are not patentable or that would not be studied by Industry

NIH – Remarkably Successful Agency – must take care of it

↑ Budget for AHRQ + CDC, etc

Sune 6348

– ~~N~~CCAM – not considered separately from other intervention

+C. Promotional Health vs Treatment of Disease

★ Adequacy of IRB Reviewers to look at CAM

Obstacles – Skepticism /
Emphasis on Wellness / Gov

1

634F

FOSA

12

- Good well written anecdotal reports - perceptive, well described
- Ambulatory Medicine
- Joe Pizzorno - Key Recommendations

NHSC - Exclude

Remove Exclusionary Language

Consensus Development Conference on CAM Research Methodology

Fund CAM Academic Health Centers
- CAM centers

Need High Level Champions to move Process along

3 year process - Harvard Alumni

dual
Dialogue training + Education

Key to Integration

Energy Therapists - not trained as researchers

Cooperative efforts of NCCAM + ORWH
funding Interdisciplinary Research

Do we need a program, similar program, Ph.D program, Ph.D.

But more $ in Program

le agm
Jim
Degen
Jim

Know how to bring benefits to CAM ~~intervention~~ to all in the US,
what kind of info can we provide to public?

Stationary

Caucus

Written comments/

Public comment

Philip Skinner - Global Physiology
Performance enhancing drugs
IOC - Gene Upshaw NFL Players Assn
Healthy Sports
Content of Herbs + Dietary ~~Supplement~~
Sports Medicine

Richard Povel - "Soul in the Biofield"

Conflict Resolution / Building of Trust
Leonard Marker Conflict

How to expand Research - ~~Medical School~~
Child learning / End of life / Dannie Brinkley

Feb 23 Alb

March 12 Minneapolis

Feb 23 - Alb
March 12 Minneapolis - Pittsburg
Chicago
NY

(3)

(4)

Strategic Plan for NCCAM | Steve Straus |
- Involvement in Research

Research Agenda - Hierarchy of Evidence + -
- Infrastructure - Centers Program + -
- Public Health Priorities -
- Leverage $ to = IC Center/Research -
(15) Centers 2 Specialized Centers for CA Research - advisor Dodd JHG

5 PC/R&D Studies Ohene Stephen Dax

Duke St John's Wort NIMH
Bone Community Shark Cartilage NCI
Ginkgo Biloba Dementia NIA
acupuncture Osteoarth
Glucosamine/Chondroitin NIAMS

Key Principle
- Same Design + Outcomes Measurement Where Possible 2nd/Rx
Flexibility in Study Design
- CAM - Studies will require skill CAM Practitioner

Cancer, Pain, Ageing, Dementia, Arthritis John Stubbs Karen Sulm > Nick Gonzalez

How do we help NCCAM - ① Patience ② Cont. NCCAM - Encourage & Supported / Science as a Process
Support Basic & Clinical Research
Encourage Industry, Pat advocacy

Structure / Function
Types of Claims

(5)

Regulation

FDA

3:45

Janet Woodcock

Botanicals Drug Products - Guidance - Non Binding Advice
How to Study them & then get through Approval Process
Botanical - Predicated on use as People Eat them & Some Characterization
- FDA Available to Talk to
- Controlled Clinical Trials
☆ Combination Products ~~Action~~ Requirements
Draft - Proposed Issue for Botanicals.
☆ Additional Resources as Required
Botanicals will go to OTC
Approval - Standards of (S+E) - If approved as a drug
Need to Characterize Botanical well, Chemistry Standards
Non-plants
PDUFA - Opportunity for Fee Waiver

Small Business Assistance
Adverse Effects - Combination - Drug Interactions
MEDWATCH -

☆ Call FDA to see if they Need Anything or Info
"Can't come" to Connect Cultural from
If a Dietary Supplement + Marketed as a Dietary Supplement
as Approved as a drug
Incentives ~~may~~ are needed

Devices 510K Afear

90% of marketed Devices Do not have ~~standard~~ & have gone through No approval process

300-400 IDE

PMA - 60-100 Each year - Small Subset of Devices

"Device Advice" - to help classify & determine What status there would be

CAM - NonCAM devices - No difference

Cu Bracelets, Magnets - Class I Exempt devices ~~that require~~ no Pre Market Approval Clearance

Claims for Diseases

FTC Approach

~~Approved Device for Unapproved Use~~ - ~~now~~ Regulated by FTC

Least burdensome path to market approach

~~Joe Levitt~~ - Food Center

~~Christine Lewis~~ Office of Nutrition, Labeling & Dietary Supplement

Responsibility under the law

25 FR notices to Implement DSHEA

Slides 5

- ↑ Interest in Level Playing Field - Enforcement

Adverse Event Reporting System

Safety

Labeling

Boundary (between a drug which is a substance)

Enforcement

Research Tie

development CAMP Adverse Event Reporting System

Thank you to Jane Henney
Forthcoming + Open
Major Misperception Discussion

* DSHEA = / mistake – Low Maintenance – Did do
No Consideration for adequate staff

Science Base – NCCAM / ODS
NAS/ – Retrospective Review
DSHEA – was a program – (authorized not appropriated)
Small # of people – Could fall in a priority list and
a dedicated program is available

Novel Review – Class 3 – "de Novo" Process

Vision – Denver – Reasonable Science –
Safety is there – Evidence of Efficacy –
and Reasonable Claims that there is high
likelihood of efficacy

Common Adverse Events

Joe L. come back + talk about Food
food
What is safety expectation for Food supplement

Dr Pizzorno - Reinforce State Medical Board Responsibility & Role

Need Good Solid information about CAM Intervention
e.g. Chelation and degree of efficacy.
Accountability, evidence, Scientific Rigor, Health
Care Mgt. Division
Research Project - IRB
No Consent Form, No Knowledge of Research Project
Federation - will develop guidelines or policies to evaluate
CAM Therapies

Floyd Godwin
money - Mindset / Taken New Chemical Entity - Paradigm overlap
Not Enough (Botanical Guidance) on Botanicals
"Never offer a New Medical Use" - FDA not enough
personnel to respond to the need.
Previous Experience = Botanical, should count
"Proprietary Property Rights" - Need to make Profit
Regulation / Regulatory Exclusivity (3)
DSHEA - Inhibit Research
the process defining the product

Rod McCaleb
Should not have market exclusivity
Status of Natural Products Research in US - Total Value last Yr
Total Expenses data (Safety data from Europe)
Phytomedicine information
Merge of Information from the Specialized Collections of
data - Cooperation + Collaboration of Govt

From Sandor

Cost of developing a nutraceutical
- Dietary Supplements - Info Center
5-10,000 out of 250,000 have been studied or screened ~~extensively~~
Labor Intensive & unproductive method to ~~proceed~~
Can move product into a Phase II ~~stage~~

Content of ~~Bottle~~
What is in the Bottle is really ~~the~~
- DSHEA - 100% of product must be clear on labeled
- Industry - 3rd Party testing + Re-testing
INA - ~~Institute~~ of ~~Neutraceutical~~ Analyses
- Need FDA Enforcement ~~Activities~~
- Need more FDA Enforcement
Methods Analytical Board
Need Quality Control in Supplement & Quality

AOAC USP
IP INC

CNN - Bernard

Rick Levy - ~~Contact~~ - Formal Professional ~~Societies~~ practitioner Am. ~~Associations~~

(18)

↑ Funding for CCAM ↗

HCFA - Reimbursement for Cl. Trials

Deanna Chambers - Friends of Health - Circle Poem

Markham Poem - Coordinate Research -

Max Lloyd - we are trying to solve ours

~~Leny~~

~~Brennan~~ Linseed Oil + Yogurt

Ned Hartfield - Life Will - ~~Body Heart Mind~~

World Peace Flame + Light during meeting - Techniques

Boyd Landry, - CAN - Coalition for Natural Health

3 Stages of Life - Youth Middle Age, Hey You Are looking pretty Good Today

People should have Access to therapy

Practitioners should be able to use

Natural & ~~Holistic~~ Health (may not be able to

Boards + Medical License   Force Adherence into

Call to Act upon Discrimination + Licensure Training

Richard Powell - Grouping Segment - Turns into Singular Therapy

Thomas - Migraine Headache - ~~Treatment~~

Medical

Health Related Q of Life Instrument

Validated Rating Scale

Unlicensed Healers - Traditional Healers

(15)

Lack of Q. Funding for Review
Obstacles – Policy & Procedures
Homeopathic / Request for MD
Inclusion II – [illegible] HIV/AIDS
CAM Review at IRB – Hepatitis C – Bastyr
"Conceptual Block"
Practice Based Outcomes Research – NCI – 30 contact
Only 4 were submitted [Need trust]
needs funding; Needs support; Needs Publicity
cost $35–$75,000
Pilot NCI funded
CAM Center – CAM Practitioners – CAM Funders
Consortium Development

[illegible] – Outcome Research
BCS analysis
[illegible]
Cost-Benefit / cost Effectiveness / Choice of a
Comparison Group

Researcher-Mentoring Program for CAM Practitioners
HIAA – Complementary & Alternative Medicine
are they capturing info
CQI – Continuous Quality Improvement –
(NCQA) – Assessment Body for Managed Care FS-12
NCCAM Supported Centers – could Participate
in Best Case Series Effort
VA
Albuquerque – Protocol Design Team

More Hot Water + tea Bags
all Day for Conversion

Lubean Religious Freedom Act
Expatriation — Moral Leadership
(Genocide - in the world)

Cultural Perspective of Research

Paul Ortega

Timothy Miller,
Birth of the Byzantine Hospitals in the Byzantine Empire

Medical Care From Ancient Times

Cliff Prudhett / NIOMS / Leaves

VA.COM

Could we get copies of the guidance for Industry on Botanical Drug Products that came out from FDA in August?

Send out

R. Reed

Tom Chappell

Groft, Stephen (NCCAM)

To: Commissioners E-mail
Cc: Anne/Rita For Tieraona (E-mail); Carolyn Gillett (E-mail); Chris Wennerstrom; Joan Matthews (E-mail); Louise Johnson (E-mail); Marjorie for Ornish (E-mail); Tierney Lancaster (E-mail); Tracy Wiens (E-mail)
Subject: (1) Request for Draft Recommendations and (2) Review of Draft Outline of Report

Note To Commissioners:

Draft Recommendations

It is time to think of recommendations that you would like to include in the Interim Report to the White House and to Congress and the format and content of the Final Report. The release of the Interim Report is still scheduled for July 15. I would like to ask you to provide by next Friday, **February 16**, the 4 or 5 recommendations that you think are essential to be included in the report. (Please don't limit yourself to this limit if you would like to provide more.) I will summarize your recommendations and have a draft available for you to review prior to the February 22-23 meeting. We also need this information to enable us to complete our planning for the remaining meetings . It will also help us determine the areas where a consensus is developing. We will not discuss these recommendations at the open session of the meeting. I will not attribute any recommendation to a particular Commission member. Please focus on policy recommendations to the White House and to the Congress. We are trying to stay away from recommendations related to individual practices or products in the recommendations, although they may be used as examples in the report.

Draft Outline of the Final Report

have also attached at **Draft Outline** of the Report. Again, this will change considerably as we move forward. I would like to ask you to review the **Draft** and suggest areas of discussion we should add, delete, or change the emphasis. As I mentioned at our last meeting, please make the changes you feel are needed to address the issues you feel are important. This was initially constructed in December before we had the New York City Town Hall (Otherwise known as the NY CAMarathon) and before we initiated planning for the February and March meetings. Please send your comments to me or simply make the changes in the document and send back to me.

Thank you for your consideration and I look forward to seeing you on the 22nd. It will be a very busy meeting once again but I thinkyou will see the results of your participation in the planning sessions for the working groups. We have received some very good responses to our requests for information on traininf, education, licensing, credentialing and accountability.

Steve Groft

ReportOutlineWHC
CAMP.2801.doc

DRAFT OUTLINE

Report of the White House Commission on Complementary and Alternative Medicine Policy

Letters of transmittal
- The President
- Congress
  - President of the Senate
  - Speaker of the House

Secretary Department of Health and Human Services
Prologue - Chairman's Summary - 1 page vision
Acknowledgements
Commission Members
Commission Staff
Working Groups (Planning)

Executive Summary (10 pages)
Conclusions
Recommendations (a) Administrative Actions
(b) Legislative Proposals

Table of Contents

(B) Public Input to Identify Research Opportunities
(C) Interface Between CAM Research and Regulatory Agencies
  (1) Practice-Based Research
  (2) CAM Research and Experimental
  (3) Research in the Regulatory Framework
  (4) Facilitating CAM Research and Regulatory Challenges
(A) The Need to Coordinate CAM Research and Development Efforts
  (1) Collaborative Efforts
  (2) Research Areas in Need of Coordinated Efforts
  (3) Underutilized Coordinating Bodies
  (4) Evaluation of Interventions by non-traditional Research methods

(A) Support for Research
  (1) Basic Research
  (2) Clinical Research
  (3) Health Services Research
  (4) Epidemiological/Follow-up Long Term Studies
  (5) Existing Sources of Funding
  (6) Research Opportunities In Waiting
  (7) The Research Community; Perceptions and Realities of Support for CAM Research
  (8) Peer Review of CAM Research Proposals

Part V. Gaining Access to the Delivery of CAM Interventions and Products **(Dr. Joe Kaczmarczyk)**
(A) The Availability of CAM Interventions and Products
(B) Concerns About Liability
(C) CAM Delivery Systems
  (1) Private Sector
    (a) Private Practice Based
    (b) Community Hospitals
    (c) Academic Health Centers
    (d) Managed Care Organizations
  (1) State and Local Government Supported
    Washington
    Minnesota
    Ohio
  (2) Federal Sector Activities

(A) Cost Effectiveness of CAM Interventions

Part VI. Reimbursement for CAM Interventions and Products **(Maureen Miller) (to be expanded after meeting)**
(A) Financing CAM Interventions, Services and Products
(B) Medical Insurance Industry, Criteria for Reimbursement
(C) Eligibility Requirements for Medical and Medicare
(D) Reimbursement/coverage in the Managed Care Setting
(E) Gaps in Reimbursement and Coverage

PartVII. The Education and Training of CAM Researchers and Health Care Practitioners **(Dr. Joe Kaczmarczyk) (to be expanded after meeting)**
(A) Attracting and Retaining CAM Research Investigators

(B) Research Training and Career Development of CAM Practitioners
(C) Emerging CAM Professions
(D) Introducing CAM Intervention Theory to the Research Community and to Healthcare Practitioners
(1) Undergraduate Education
(2) Graduate Education
(3) Continuing Education of Health Care Providers
(E) Licensure, Certification and Credentialing of CAM Practitioners

Part VIII. Development and Delivery of Information on CAM Interventions and Products **(Corinne Axelrod) (to be expanded after meeting)**
(A) The need for Information
(1) Public
(2) Patients
(3) Health Care Providers
(4) CAM Practitioners
(A) Sources of Information
(1) Public Sector
(2) Private Sectors
(A) Access to Information
(1) Media, (a) TV (b) Press (i) Professional (ii) Public
(2) Internet

Part IX. A Vision for the Future
(A) Building the Scientific Basis of Understanding CAM Interventions
(B) Overcoming the Bias against CAM Practices
(C) Increasing Public Awareness of Safe and Effective Interventions
(D) Ensuring Access and Delivery of CAM Intervention and Products
(E) Providing Access to Culturally Specific Interventions in a Native population
(F) Eliminating Financial Barriers to Interventions
(G) Reducing Regulatory and Legal Constraints
(H) Aiming Towards Parity in Research , Training, and Education of CAM Practitioners and Researchers
(I) Providing Adequate Reimbursement for Services Provided

Part X. (A) Conclusions
(B) References
(C) Glossary
(D) Appendices

Appendix A
(1) Expanded List of Commission Members
(2) List of Commission Meetings
(3) Location of Town Hall Meetings
(4) Questions Addressed at Town Hall
(5) Participants at Town Hall Meetings
(6) Invited Participants at the Commission Meetings

Appendix B
(1) Executive Order 13147 and Amendment
(2) Appropriation Language Suggesting Creation of Commission

(2) Charter of the WHCCAMP

Appendix C

Implementation of Recommendations (Suggested Responsibility - President, Congress Secretary DHHS, Federal Agencies, Private Sector, Not-for-Profit Foundations and Organizations

(E) List of tables and figures

(F) Index

Robert Stroup
63 5-3777
Marlene Jefferson
63 5-2102

Information Items - Public

1. Change of Format to this meeting - The Commission continues to Evolve - Early On - Information Gathering / Listening mode we will continue to do this but we now must think about recommendations for the Interim Report in July & then the Final Report due in less than a year from now

What you hear today and tomorrow may or may not be the final recommendations whispers are starting to be heard that the Commission will be recommending certain actions There will be the first meeting that the Commission will begin to formulate draft recommendations

(2) In the change of format we will rely upon working group discussions to help form the information received from nearly 100 ~~org~~ CAM and Conventional Medical Organizations. There will be more on this later We will place on the walls the working groups and the information submitted by various groups

(3) Submissions received after the background book was mailed out have been mounted at your working area. Our apologies for the size of the 2 volumes It was our intent to double side the printed material We will do so in the future

(4) There will be a Town Hall Meeting on March 16 in the Minneapolis - St Paul area. We are working with a planning group to help focus on submissions related to Minnesota and CAM practices, needs, health needs and CAM Frontiers

(5) The Website is becoming more functional and informative We have added a number of transcripts from the meetings By the middle of next week, we should be caught up on providing Agendas, FR announcements + Transcripts. Most Recent reputation can be done through the website

(6) Public Participation - Limited by time. If Chairman Brad you will [illegible]

Priorities
Strategic
Messages
Techniques
Themes

(A) April (Early) – Congressional Staff Mtg
Late April – Members of Congress
Briefing

Jim
Sandoval

(1) Outline of the Report and Recommendations
Robert Quarles
– Tom Andrews – need to hear from you and your thoughts on the Content & Format of the Report. We need your advice not only here but in formulating basic recommendations. ~~Not done~~ Need to develop a message.

We need ~~to be soon~~ to meet your needs by scheduling appropriate agenda items to discuss at future meetings.

(2) Wellness
Friday at lunch we will have a short discussion of the Wellness issue, scheduled for discussion at the March 26-27 meeting. It is a big bear that we are grappling with. We need some assistance to bring your concerns into focus for discussion during the meeting.

(3) – Change of Administration
No apparent interruption of Commission activities. Information about the Commission has been provided to the Secretary Thompson's staff.

Writing of Report – ~~We look~~ Working Draft approved those involved in various ~~parts~~ issues will remain involved in the review of the document. Steps
(1) Jim Sawyer will write 1st draft
(2) Staff review & working group review
(3) Integrate Sawyer & Edit Draft to Working Group
(4) Out to Full Commission for Review
(5) Discussion at ~~the~~ meeting

(5) Update of Issues – When asked to do so – send in thy form – for COT

FAMA
Next Friday – Invite Chesapeake Alliance
Small Group – Implement Recommendations

4/26/07

634F

①

Denise Clevaugh – Referral
Univ of Minnesota – Interdisciplinary Integrative Review & Training Program

Murray Kaplan – Discussion to meet ē him

Minnesota
- Linnea Larson
- Joe Pegoen
- Wayne Dyner

George deVries
Jim Gordon
Tom Andrew

Office?
Yogurt?
Pamphlet
Brad

Form Working Group of Implementation Plan
- Ford Chappell
- David Brooks ◇ Jim Gordon
- George deVries — Linnea Larson
- Charlotte Kerr ◇
- Susan Dinick

Dianne Miller
Mary Jo Kreitzer

Create Interactive Website

Call Liang Loot

☆ Group of people to Review Report
- Bigwell
- W. Cohen
- David Eisenberg
- Brian Berman

Call Robin Slater Re: Room 800 / Reservations
Ind Office Setty

Sandy Bart Interim Report / Final Report
Further Review

Thank you Notes — Jim Signature

Lodging rate
Independence
Berkley

Marc Henrich
Pedro Russell — Hon P.R. / Pediatric Surg
Institute of Politics

CA
Amputee
Cuban

Foreign Countries – Cuba – Tony Martinez – Hamm
Bamford

Reimbursemab

Freedom of Choice
Help keeps
Education for self care

March 14 – Implementation Plan / Permanent Office
White House
Domestic Policy

Secretary / Administrative Rec
Permanent Office
Advisory Group – Outside of Govt

Good / Solid – Data

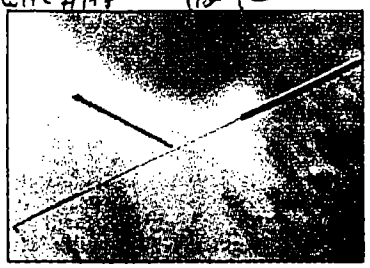
2/27/01 Joe Fuu 1A

636 G

Feldenkrais George Kurtz
C.P. Stroke Patients ASP
Experiential Base Theory follow

NEWSDAY (NASSAU EDITION)
LONG ISLAND, NY
TUESDAY 463,406
JAN 16 2001

MEDICINE



Controversial Effort To Pinpoint Legitimate Alternative Treatments

C5

Test of the Unconventional

But federal panel on integrating remedies draws debate

THE ASSOCIATED PRESS

Newsday File Photo / Alan Rai

Some of the nation's hospitals now offer alternative remedies like acupuncture.

THE 55-YEAR-OLD refused surgery for sinus cancer and instead bought on the Internet unregulated pills touted to fight tumors. Four months later, he was dead — not from his still-present cancer but from liver and kidney failure that an autopsy blames on those pills.

An estimated four in 10 Americans use some form of alternative medicine, from acupuncture or hypnosis to herbs or Internet-touted wonder remedies. Some may work; in fact, some of the nation's best-known hospitals have begun offering certain remedies. But others can be quackery or outright dangerous. How is a patient to know the difference?

A new presidential commission is traveling the country on a two-year quest to determine how to help doctors and consumers sort out what works, what doesn't and what's too risky, and to integrate alternative remedies that do prove effective into mainstream health care.

It's an ambitious effort, funded with $2 million in taxpayer dollars, to breach the medicine wars and recommend to Congress a national policy on alternative therapies. But it's drawing fire from some critics who complain that the White House Commission on Complementary and Alternative Medicine Policy is packed with proponents of the unconventional.

That doesn't mean they champion all alternative remedies, insists commission chairman Dr. James Gordon, a psychiatrist whose Center for Mind / Body Medicine in Washington often works with local doctors.

"What I'm interested in is what works for people . . . what has the fewest harmful side effects," said Gordon, who offers everything from well-tested acupuncture to the admittedly "far-out, strange treatment" of putting a rheumatoid arthritis sufferer on a weeklong watermelon-only diet.

"We want to protect the public health," said Dr. Joseph Fins of New York-Presbyterian Hospital, one of three commissioners who doesn't practice or promote alternative therapies. "There is a healthy amount of skepticism." And doctors reluctant to learn about alternatives "need to appreciate that there is this other parallel universe out there," Fins said: Millions of Americans using remedies without their physicians' knowledge and without unbiased information about safety and effectiveness.

Sometimes those choices prove fatal. Last month, doctors reported in the journal Annals of Internal Medicine about the 55-year-old who died from hydrazine sulfate, a controversial, unregulated chemical. While such severe toxicity seems rare, National Cancer Institute studies say hydrazine sulfate doesn't fight cancer, begging the question of how many patients would use it if they saw the NCI's report.

Other studies suggest certain treatments may work but are risky if used the wrong way.

The herb St. John's wort, widely used for mild depression, can dull the effectiveness of birth control pills and of drugs for cancer, AIDS and organ transplants. Patients aside, how many U.S. doctors are trained enough about alternative remedies to know that?

However, some top hospitals have begun offering certain unconventional remedies as "complementary therapy," add-ons to traditional medicine, when studies show they help.

Boston's Beth Israel Deaconness Hospital, for instance, recently reported that patients suffer significantly less pain during surgery by using self-hypnotic relaxation. The University of California at Los Angeles employs acupuncturists to treat children's pain.

But there is little science behind other alternative remedies. The National Institutes of Health is spending tens of millions of dollars this year testing some of them.

Proof may be years away, but the White House commission is charged with determining how to ensure doctors and patients learn the available evidence — and if something works, how to pay for it.

Don't expect a push to pay for alternative remedies before getting Medicare to pay for proven disease-fighting medications, cautioned Fins. Will other commissioners agree? The panel's first draft report to Congress is due in July.

Associated Press Placement

Publication	Date	Circulation
Asbury Park Sunday Press (Neptune, NJ)	1/14	159,472
Bayside Times (NY City Market Area)	1/11	4,908
Branson Tri-Lakes Daily News (Branson, MO)	1/13	12,149
Bristol Press (Bristol, CT)	1/9	20,420
Brooklyn Daily Eagle & Daily Bulletin (New York, NY)	1/11	16,088
Bryan Times (Bryan, OH)	1/18	11,194
Cecil Whig (Elkton, MD)	1/15	14,006
Chillicothe Gazette (Chillicothe, OH)	1/30	16,380
Citizen (Auburn, NY)	1/30	15,697
Citizen Tribune (Morristown, TN)	1/10	19,043
Commercial-News (Danville, IL)	1/10	20,529
Cortland Standard (Cortland Standard)	1/16	11,668
Courier-Post (Cherry Hill, NJ)	1/24	86,632
Daily American Republic (Poplar Bluff, MO)	1/15	13,613
Daily Chief-Union (Upper Sandusy, OH)	1/9	4,219
Daily Citizen (Beaver Dam, WI)	1/9	11,173
Daily Democrat (Woodland, CA)	1/10	10,818
Daily Gazette (Schenectady, NY)	1/9	59,172
Daily Mail (Olney, IL)	1/9	17,416
Daily Sentinel-Star (Grenada, MS)	1/10	5,049
Daily Sparks Tribune (Sparks, NV)	1/9	6,540
Dayton Daily News (Dayton, OH)	1/9	152,308
Dodge City Daily Globe (Dodge City, KS)	1/9	8,611
Dominion Post (Morgantown, WV)	1/10	19,907
Eagle-Tribune (Lawrence, MA)	1/10	55,912
Elk City Daily News (Elk City, OK)	1/10	5,740
Evening Times (Little Falls, NY)	1/12	8,668
Flushing Times (Bayside, NY)	1/11	1,603
Herald (New Britain, CT)	1/11	22,756
Herald News (Passaic, NJ)	1/9	39,690
Herald-Citizen (Cookeville, TN)	1/10	11,038
Intelligencer (Wheeling, WV)	1/9	23,864
Jamaica Times (Bayside, NY)	1/11	3,138
Kenton Times (Kenton, OH)	1/13	8,500
Laurelton Times (Bayside, NY)	1/11	1,738
Leader (Corning, NY)	1/9	15,907
Lebanon Democrat (Wilson County News Lebanon, TN)	1/10	8,552
Litchfield News-Herald (Litchfield, IL)	1/9	5,880
Marysville Journal Tribune (Maryville, OH)	1/9	5,925
Morris Daily Herald (Morris, IL)	1/15	7,449
Muscatine Journal (Muscatine, IA)	1/10	8,459
News (New Castle, PA)	1/15	18,855
News Capital & Democrat (MC Alester, OK)	1/14	12,280
Newsday (Nassau Edition, Long Island, NY)	1/16	575,595
North County Times (Encinitas-Solana Beach Edit., Oceans	1/9	89,754
North County Times (Escondido, CA)	1/9	39,273
North County Times (Escondido, CA)	1/9	39,273
North County Times (Oceanside Edition)	1/9	89,754

North County Times (Oceanside, CA)	1/9	89,754
Okmulgee Daily News (Okmulgee, OK)	1/1	4,797
Oxford Eagle (Oxford, MS)	1/9	6,000
Pampa News (Pampa, TX)	1/29	6,614
Parkersburg News (Parkersburg, WV)	1/9	23,403
Patriot Ledger (Quincy, MA)	1/8	83,683
Post-Journal (Jamestown, NY)	1/9	25,421
Record Searchlight (Redding, CA)	1/9	38,438
Record-Herald (Wash. Court House, OH)	1/11	5,800
Register Citizen (Torrington, CT)	1/9	16,306
Review Times (Fostoria, OH)	1/18	7,291
Sapulpa Daily Herald (Sapulpa, OK)	1/16	7,020
Shawnee News-Star (Shawnee, OK)	1/9	11,758
Sidney Daily News (Sidney, OH)	1/10	13,379
Tiffin Advertiser-Tribune (Tiffin,OH)	1/9	10,827
Times (Gainsville, GA)	1/9	23,485
Times Bulletin (Van Wert, OH)	1/1	6,276
Times West Virginian (Fairmont, WV)	1/9	15,104
Town Talk (Alexandria, VA)	1/10	199,805
Vinita Daily Journal (Vinita, OK)	1/10	4,200
Wapakoneta Daily News (Wapakoneta, OH)	1/10	4,729
Wayne Daily Independent (Wayne Daily Independent)	1/9	4,307
Wheeling News-Register (Wheeling, WV)	1/1	22,406
Total Circulation*		**2,447,418**

*Based on clippings received as of 2/22/01

FEDERATION OF STATE MEDICAL BOARDS

SPECIAL COMMITTEE ON QUESTIONABLE AND DECEPTIVE HEALTH CARE PRACTICES

CHARGE TO THE COMMITTEE

- To research, review and evaluate the current status of questionable health care treatments, procedures and/or promotions, which may be unsafe and thereby considered a risk to the public's health, safety and welfare.

- To research, review and evaluate the current status of questionable health care treatments, procedures and/or promotions, which may be worthless and thereby likely to deceive or defraud the public.

- To develop strategies for recommendation to state medical boards for the regulation and discipline of physicians who engage in unsafe and/or deceptive practices.

- To develop strategies for recommendation to state medical boards for educating licensees, the public and state legislators on issues surrounding health care fraud and practices which may be potentially harmful and/or deceptive.

- To develop guidelines for state medical boards to use in educating and regulating physicians who use complementary and alternative medicine in their practices.

Amended – April 2000

Groft, Stephen (NCCAM)

From: Maureen M. Miller [maureen.miller@starpower.net]
Sent: Wednesday, February 21, 2001 2:40 PM
To: Groft, Stephen (NCCAM); Chang, Michele (NCCAM)
Subject: Dr. Gordon's question

fsmbcommittee.doc

Steve and Michele -- At the last staff meeting with Dr. Gordon, he raised the issue that integrative physicians are being treated differently (i.e., more harshly, or targeted more for action) than straight conventional practitioners. After discussions with Joe and Gerry, it was decided that I would follow up on the matter.

FSMB Policy Actions
After reviewing the transcript on this matter --from Winn's previous appearance -- I spoke with Pat McCarty, Winn's assistant at the Federation of State Medical Boards. She was not helpful, other than sending me to Bruce Levy, MD, JD who has been active at the state board level and now with FSMB. He also headed the Special Committee on Health Care Fraud that came up with the 1997 Committee report on Questionable and Deceptive Health Care Practices. Note: this committee of the FSMB was renamed in 1999 to the Special Committee on Questionable and Deceptive Health Care Practices. (The '97 report is on the FSMB web site, and I now have it printed.)

Joe (our Joe) tells me that this report is out of date, which is validated by the fact that Doctor/Lawyer Levy is heading up a new effort by the aforementioned Special Committee to come up with current information, strategies and guidelines for dealing with treatments, procedures, and/or promotions that are deceptive, fraudulent, and potentially harmful to the public's health and welfare. The official charge is attached. Dr. Levy has brought together national experts, including integrative physicians. FSMB would not release the names of the committee members, but I happen to speak to one as a result of some Break Out Group 3 followup -- Dr. Russ Greenfield, a grad of the Andrew Weil program. Russ spoke highly of Levy and the committee's work to date. The committee has met once and meets again in March. The committee is in the process of again changing its name.

This committee's work should be completed in a year to 18 months. Their report will go to the Board of Governors, possibly in February of 2002 at the earliest, and -- if approved by the Board -- it will go to the FSMB House Assembly in April 2002. If approved by the House Assembly, the report will become FSMB model guidelines -- and then each State will consider whether to adopt the guidelines as issued, adopt the guidelines with modifications, or to not adopt. If the FSMB Board of Governors does not approve the committee report, it will likely send it back for further work.

Levy is very aware of the public's role in use of CAM -- of the growing interest of patients to participate in their own health care, to make their own choices, and to take their own actions toward caring for themselves. He seemed not only knowledgeable but balanced, a view supported by Dr. Greenfield.

Data on State Actions Against Physicians

At the fall meeting, there was discussion of FSMB providing data on the number of CAM/integrative physicians who have undergone state medical

board review/action. I spoke with David Hooper who does the FSMB data system. FSMB does not code state actions by physician type/specialty and therefore such data is not available. Levy and Hooper feel the numbers are small. (But are they relatively small? . . .. .)

Let me know if you think anything else should be done. Maureen

See Tab 30 under Discussion Group ~~H~~ I for DRAFT Executive Summary to be discussed by Dr. Fishman

Plenary Speaker - Look Under Group

Tom C.

WHAT, FOR WHOM, HOW, WHEN

Policy ~~?~~ STRATEGIC INITIATIVES

(1) Strengthen the "discovery process" for CAM products and services (safety and efficacy)

(2) Improve access to emerging knowledge of CAM

(3) Organize new knowledge into learning systems, both formal and practice

(4) Publish policies and standards/practices for:
- professional education, examination, credentialing, licensing, and operating ~~ethics~~

for each profession

(5) Create a continuous watchdog/feedback system monitoring ~~malpractice~~

(6) create a CAM regulatory office to provide for standards for accreditation and operating CAM: equal rights, equal access, equal accountability

Questions: what should be left to the marketplace?
What should be the role of the gov't.

Proposed Schedule and Review Process for WHCCAMP Report:

Tentative Schedule:

March 2nd: Jim finishes first draft of Parts I-III (Groft/Gordon review)

March 30th: Jim finishes first draft of Education and Training (Joe K. review)

April 27th: Jim finishes first draft of Development and Delivery of CAM Information (Corinne A. review)

May 18th: Jim finishes first draft of Reimbursement for CAM (Maureen M. review)

June 1st: Jim finishes first draft of Coordination of CAM Research (Geri P. review)

June 15th: Jim finishes first draft Gaining Access to the Delivery of CAM (Joe K. Review)

June 20th: Jim finishes first draft of Interim report (staff review)

June 22th: Jim finishes second draft of Interim Report (Commission review)

June 23rd-July 1st: Jim Swyers on vacation

July 2nd-3rd: Commission meeting to discuss/refine Interim Report

July 6th: Jim Swyers finishes revisions to Interim Report (staff review)

July 11th: Jim Swyers finishes any final staff edits to interim report

July 12th: Commission submits interim report to Congress

July 27th: Jim finishes first draft of Vision for the Future

July 27th to August 24th: Jim Swyers finishes revisions and edits to Sections 1-9: (full commission review?)

September 28th: Jim finishes first drafts of remaining sections (Conclusions, references, glossary, and appendices). (staff review)

October 4-5th: Commission meeting to review progress on final report

October 19th: Jim Swyers finishes revisions to full report and assembles for Public Comment Review

Submit for Public Comment

November 16th: Jim Swyers incorporates public comment/Commission/staff revisions

November 19th-December 7th: Jim Swyers prepares Full Report for desktop publishing

December 10th –December 28th: Report layout and formatting

January 5th, 2001: Submit report for publishing

Proposed Review Process:

Step 1: Jim Swyers meets with the appropriate WHCCAMP staff to discuss the general outline and content areas of each section; also to gather the appropriate background materials.

Step 2: Jim Swyers develops first rough draft and submits it to appropriate WHCCAMP staff for detailed review.

Step 3: Jim Swyers incorporates edits/comments/ suggestions from WHCCAMP staff and then resubmits report section for second review, if needed.

Step 4: Jim Swyers incorporates final edits.

Step 5: WHCCAMP staff submit report section to appropriate Commission members for review.

Step 6: Jim Swyers incorporates Commissioners' comments into report section (submit to full Commission?).

Step 8: Jim Swyers incorporates final comments from Commissioners.

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Groft, Stephen (NCCAM)

From: Groft, Stephen (NCCAM)
Sent: Friday, February 09, 2001 4:00 PM
To: Buford Rolin; Conchita M. Paz; David Bresler; Dean Ornish; Donald Warren; Effie Chow; George Bernier; George DeVries; James Gordon; Joe Pizzorno; Joseph Fins; Julia Scott; Linnea Larson; Thomas Chappell; Tieraona Low Dog; Veronica Gutierrez; Wayne Jonas; William Fair; Xiaoming Tian
Cc: Chang, Michele (NCCAM); Pollen, Geraldine (NCCAM); Kaczmarczyk, Joseph (NCCAM); Axelrod, Corinne (NCCAM); Kingsbury, Doris (NCCAM); Albrecht, Joan (NCCAM)
Subject: (1) Request for Draft Recommendations and (2) Review of Draft Outline of Report

Note To Commissioners:

Draft Recommendations

It is time to think of recommendations that you would like to include in the Interim Report to the White House and to Congress and the format and content of the Final Report. The release of the Interim Report is still scheduled for July 15. I would like to ask you to provide by next Friday, **February 16**, the 4 or 5 recommendations that you think are essential to be included in the report. (Please don't limit yourself to this limit if you would like to provide more.) I will summarize your recommendations and have a draft available for you to review prior to the February 22-23 meeting. We also need this information to enable us to complete our planning for the remaining meetings . It will also help us determine the areas where a consensus is developing. We will not discuss these recommendations at the open session of the meeting. I will not attribute any recommendation to a particular Commission member. Please focus on policy recommendations to the White House and to the Congress. We are trying to stay away from recommendations related to individual practices or products in the recommendations, although they may be used as examples in the report.

Draft Outline of the Final Report

have also attached at **Draft Outline** of the Report. Again, this will change considerably as we move forward. I would like to ask you to review the **Draft** and suggest areas of discussion we should add, delete, or change the emphasis. As I mentioned at our last meeting, please make the changes you feel are needed to address the issues you feel are important. This was initially constructed in December before we had the New York City Town Hall (Otherwise known as the NY CAMarathon) and before we initiated planning for the February and March meetings. Please send your comments to me or simply make the changes in the document and send back to me.

Thank you for your consideration and I look forward to seeing you on the 22nd. It will be a very busy meeting once again but I thinkyou will see the results of your participation in the planning sessions for the working groups. We have received some very good responses to our requests for information on traininf, education, licensing, credentialing and accountability. I can be reached on 301-435-6199 if you would like to discuss in greater detail.

Steve Groft

ReportOutlineWHC
CAMP.2801.doc

DRAFT OUTLINE

Report of the White House Commission on Complementary and Alternative Medicine Policy

Letters of transmittal

Stephen C. Groft, Pharm.D.
WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY
6701 Rockledge Drive
Rockledge II, Room 1010, Mail Stop 7707
Bethesda, Maryland 20817
Telephone: 301-435-7592 -- Facsimile: 301-480-1691

TO: Charlotte Kerr **FAX: 410-964-3544**

Total Pages including cover: 6

Comments:

(If there is any problem with this facsimile, please call Doris Kingsbury at 301-435-7592)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of H
Bethesda, Maryland 20

DATE: February 6, 2001

TO: EPMC Members

FROM: Deputy Director for Extramural Research, NIH
Director, Office of Federal Advisory Committee Policy

SUBJECT: Policy Announcement 2001-02: Use of Electronic Communications by NIH Federal Advisory Committees

Background: Communicating electronically is becoming a common practice. This means of communication could be a convenient and efficient mechanism or tool for Federal advisory committee members and Federal staff involved in advisory committee activities. Conducting peer review meetings using web-based systems is also becoming more commonplace. This policy announcement is established to clarify the extent to which communicating electronically can be used by Federal advisory committees.

Policy Statement for National Advisory Councils, Program Advisory Committees, and Boards of Scientific Counselors' Use of E-mail Systems and Web-based Systems: Federal advisory committee members may use Institute/Center (IC) e-mail and web-based systems such as chat rooms to gather information or conduct research for an NIH chartered advisory committee, to analyze relevant issues and facts, or to draft proposed position papers for deliberation by the full advisory committee. Web-based systems may not be used to convene meetings that would normally be open to the public. Chat room exchanges may not include discussions of committee business that would normally be addressed during a meeting.

Discussion: Under the provisions of the Federal Advisory Committee Act (FACA), 5 U.S. Code, Appendix 2, and the Government in the Sunshine Act, 5 U.S. Code, section 552b, Executive Branch agencies of the Federal Government are required to allow the public access to advisory committee meetings unless an exemption under the Government in the Sunshine Act is authorized.

Federal advisory committee members may use an IC web-based system or chat room for the purpose of conducting non-FACA activities. These activities include gathering information or conducting research for a chartered advisory committee, analyzing relevant issues and facts, or

drafting proposed position papers for deliberation by the advisory committee. Federal advisory committee members may not use an IC chat room to:

- deliberate in preparation for a vote or to vote on any matter.

- participate in chat room exchanges for the purpose of deliberating on the substantive matters upon which the committee provides advice and recommendations.

- take any action that is for deliberation by the full committee at a meeting that meets the public notice and public participation requirements of the FACA.

It is important for IC staff and advisory committee members using an IC web-based system or chat room to remember that:

- relevant issues and facts gathered in the chat room must be fully discussed by the full committee in open session before advice is given to a Federal official.

- the public must be kept informed of all issues being deliberated by a chartered Federal advisory committee.

Policy Statement for Initial/Integrated Review Groups and Special Emphasis Panels' Use of Web-based Systems: NIH Federal advisory committee members may use web-based systems to conduct closed peer review meetings on an IC's Internet. NIH peer review meetings held to review grant applications and contract proposals are generally closed to the public under the provisions of 5 U.S. Code, section 552b (c)(4) and (c)(6). Exemption (c)(4) is used because grant applications or contact proposals and their discussions could disclose confidential trade secrets or commercial property such as patentable material. Exemption (c)(6) is used since disclosure of personal information concerning individuals associated with the grant application or contract proposal could constitute a clearly unwarranted invasion of personal privacy.

Discussion: Totally closed web-based peer review meetings are subject to the FACA and as such must adhere to the laws, regulations and NIH policies governing the management of all Federal advisory committees. Primary requirements are:

- notice of all meetings must be published in the Federal Register.
- NIH staff must fulfill reporting and record keeping requirements mandated by the FACA.
- members must complete appropriate NIH conflict of interest certifications or financial disclosure reports.
- a Federal official must attend all meetings and approve the agenda.
- minutes must be kept of all meetings and certified by the Chair according to NIH committee management practices and policies.

General Information: Detailed information on NIH Federal advisory committee record keeping policies and specific guidance related to electronic communication can be found in NIH manual chapter 1743, Keeping and Destroying Records, section 1100 G (Federal Advisory Committee Records). Electronic documents which are made available to or prepared for or by an advisory committee are subject to the Freedom of Information Act (FOIA), 5 U.S. Code, section 552 and the FACA. These documents must be made available for public inspection and copying upon request unless exempt under FOIA. Documents such as e-mail communications and exchanges created by participants in chat rooms or web-based meetings are bound by these laws. ICs are also responsible for ensuring the security and confidentiality of reviews and discussions held electronically.

This policy is effective immediately. Issues related to this policy should be referred to the Office of Extramural Programs, OER, OD, 435-2768 or the Office of Federal Advisory Committee Policy, OD, 496-2123.

/s/
Wendy Baldwin, Ph.D.

/s/
LaVerne Stringfield

cc:
Dr. Kirschstein
Dr. Maddox
IC Directors
RPC
CMOC
eRA Committee
OD Senior Staff
POPOF
GMAC

Groft, Stephen (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Thursday, March 01, 2001 3:23 PM
To: Groft, Stephen (NCCAM)
Subject: FW: Policy Issuance

Steve: Do we need to review and discuss vis-a-vis our plans to do closed web-based review of the final report with commissioners?

-----Original Message-----
From: Stoneberger, Amanda (NICHD)
Sent: Tuesday, February 27, 2001 9:59 AM
To: Pine, Martha (NIGMS); Groft, Stephen (NCCAM); Chang, Michele (NCCAM); Gorman, Jennifer (OD); Thomas, Anne (OD)
Cc: Galloway, Esther (NIGMS); Lee, Sally (NIGMS); Plummer, Mary (NICHD)
Subject: FW: Policy Issuance

FYI...

Mandy

-----Original Message-----
From: Middendorf, Nancy (OD)
Sent: Tuesday, February 20, 2001 3:00 PM
To: Amanda Stoneberger; Andrea Collins; Antonette Neal; Arlene Simmons; Bonnie Kaps; Brenda Caldwell; Camilla Holland; Carol Robinson; Carol Scibek; Caroline Grabner; Carolyn Baum; Cheryl Fee; Cikena Reid; Claudia Goad; Denise Manouelian; Esther Galloway; Gloria Duvall; Ida Nestorio; Jane Ades; Janet Craigie; Janet Gregory; Janice Ramsden; Karen Oden; Kathryn Valeda; Kerry Peasland; Kim Brinson; Kimberly Caraballo; Kina Forrest; Leslie Loomis; Linda Quick-Cameron; Marilyn Delores Thomas; Mary Nuss; Mary Plummer; Melvin Carter; Nakita Harris; Rosalind Bailey; Ruth Linn; Sally Lee; Shari Adams; Sherri Park; Virginia Wills; Watkins, Marie <mw34b>; Whelan, Kate <kw10y>; Benfer, Claire <cb75g>; David Clay; Gibson, Sterlyn; LaVerne Stringfield; Melanie Gray; Nina Scott; Payne, Linda; Snouffer, Anna
Subject: Policy Issuance

As discussed at previous CMOC meetings, attached is the approved Policy Announcement 2001-02: Use of Electronic Communications by NIH Federal Advisory Committees.

The document is forwarded in WordPerfect and Microsoft Word.


policy2001-02-ElectronicComm.w...


policy2001-02-ElectronicComm.d...

Nancy Middendorf
Program Analyst
Office of Federal Advisory Committee Policy
NIH/OD/OPC
Building 31, Room 3B59
(301) 402-6326; fax: (301) 402-1567
e-mail: nm11s@nih.gov

Proposed Schedule and Review Process for WHCCAMP Report:

Tentative Schedule:

March 7th: Jim finishes first draft of Parts I-III (Groft/Gordon review)

April 2nd: Jim finishes first draft of Education and Training (Joe K. review)

April 27th: Jim finishes first draft of Development and Delivery of CAM Information (Corinne A. review)

~~May 18th~~ June 15th: Jim finishes first draft of Reimbursement for CAM (Maureen M. review)

June 1st: Jim finishes first draft of Coordination of CAM Research (Geri P. review)

~~June 15th~~ May 18th: Jim finishes first draft Gaining Access to the Delivery of CAM (Joe K. Review)

June 20th: Jim finishes first draft of Interim report (staff review)

June 22th: Jim finishes second draft of Interim Report (Commission review)

June 23rd-July 1st: Jim Swyers on vacation

July 2nd-3rd: Commission meeting to discuss/refine Interim Report

July 6th: Jim Swyers finishes revisions to Interim Report (staff review)

July 11th: Jim Swyers finishes any final staff edits to interim report

July 12th: Commission submits interim report to Congress

July 27th: Jim finishes first draft of Vision for the Future

July 27th to August 24th: Jim Swyers finishes revisions and edits to Sections 1-9: (full commission review?)

September 28th: Jim finishes first drafts of remaining sections (Conclusions, references, glossary, and appendices). (staff review)

October 4-5th: Commission meeting to review progress on final report

October 19th: Jim Swyers finishes revisions to full report and assembles for Public Comment Review

Submit for Public Comment

November 16th: Jim Swyers incorporates public comment/Commission/staff revisions

November 19th-December 7th: Jim Swyers prepares Full Report for desktop publishing

December 10th –December 28th: Report layout and formatting

January 5th, 2001: Submit report for publishing

Proposed Review Process:

Step 1: Jim Swyers meets with the appropriate WHCCAMP staff to discuss the general outline and content areas of each section; also to gather the appropriate background materials.

Step 2: Jim Swyers develops first rough draft and submits it to appropriate WHCCAMP staff for detailed review.

Step 3: Jim Swyers incorporates edits/comments/ suggestions from WHCCAMP staff and then resubmits report section for second review, if needed.

Step 4: Jim Swyers incorporates final edits.

Step 5: WHCCAMP staff submit report section to appropriate Commission members for review.

Step 6: Jim Swyers incorporates Commissioners' comments into report section (submit to full Commission?).

Step 8: Jim Swyers incorporates final comments from Commissioners.

White House Commission on Complementary and Alternative Medicine Policy
Outreach to Health Care Groups

✓Association of American Medical Colleges
Dave Moore
202 828 0400

Association of Schools of Allied Health Professionals
202 293 4848

American Cancer Society
Dan Smith
202 661 5700

✓ National Breast Cancer Coalition
Jennifer Katz, Government Relations Manager
202 296 7477

American Academy of Pediatrics
Graham Newson, Director Department of Federal Affairs
202 347 8600

Health Insurance Association of America
Marianne Miller, Director Federal Regulatory Affairs and Policy Development
202 824 1600

Association of American Health Plans
Julie Goon, Director
202 778-3200

Washington Business Group on Health
Sally Coberly, Director Public Policy
202 408 9320

PhRMA
Barry H. Caldwell, Vice president for Federal Affairs
202 835 3400

American Medical Association
Richard Deem, Government Affairs
202 789 7400

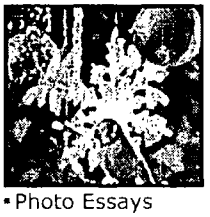
American Nurses Association
Marjorie Vanderbilt, Director of Government Affairs
202 651 7000

Center for Science and the Public Interest
Gail Shearer, Health Care Government Relations Manager
202 332 9110

Consumers Union
Adrienne Hahn, Legislative Counsel
202 462-6262

Public Citizen
Frank Clemente, Congress Watch Director
(202) 588-1000

American Public Health Association
Sarah Lister, Director of Government Relations
202 682 0100



For Immediate Release
Office of the Press Secretary
November 28, 2001

Executive Order: Creation of the President's Council on Bioethics

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Establishment. There is established the President's Council on Bioethics (the "Council").

Sec. 2. Mission.

(a) The Council shall advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology. In connection with its advisory role, the mission of the Council includes the following functions:

(1) to undertake fundamental inquiry into the human and moral significance of developments in biomedical and behavioral science and technology;

(2) to explore specific ethical and policy questions related to these developments;

(3) to provide a forum for a national discussion of bioethical issues;

(4) to facilitate a greater understanding of bioethical issues; and

(5) to explore possibilities for useful international collaboration on bioethical issues.

(b) In support of its mission, the Council may study ethical issues connected with specific technological activities, such as embryo and stem cell research, assisted reproduction, cloning, uses of knowledge and techniques derived from human genetics or the neurosciences, and end of life issues. The Council may also study broader ethical and social issues not tied to a specific technology, such as questions regarding the protection of human subjects in research, the appropriate uses of biomedical technologies, the moral implications of biomedical technologies, and the consequences of limiting scientific research.

(c) The Council shall strive to develop a deep and comprehensive understanding of the issues that it considers. In pursuit of this goal, the Council shall be guided by the need to articulate fully the complex and often competing moral positions on any given issue, rather than by an overriding concern to find consensus. The Council may therefore choose to proceed by offering a variety of views on a particular issue, rather than attempt to reach a single consensus position.

(d) The Council shall not be responsible for the review and approval of specific projects or for devising and overseeing regulations for specific government agencies.

(e) In support of its mission, the Council may accept suggestions of issues for consideration from the heads of other Government agencies and other sources, as it deems appropriate.

(f) In establishing priorities for its activities, the Council shall consider the urgency and gravity of the particular issue; the need for policy guidance and public education on the particular issue; the connection of the bioethical issue to the goal of Federal advancement of science and technology; and the existence of another entity available to deliberate appropriately on the bioethical issue.

Sec. 3. Membership.

(a) The Council shall be composed of not more than 18 members appointed by the President from among indi-viduals who are not officers or employees of the Federal Government. The Council shall include members drawn from the fields of science and medicine, law and government, philosophy and theology, and other areas of the humanities and social sciences.

(b) The President shall designate a member of the Council to serve as Chairperson.

(c) The term of office of a member shall be 2 years, and members shall be eligible for reappointment. Members may continue to serve after the expiration of their terms until the President appoints a successor. A member appointed to fill a vacancy shall serve only for the unexpired term of such vacancy.

Sec. 4. Administration.

(a) Upon the request of the Chairperson, the heads of executive departments and agencies shall, to the extent permitted by law, provide the Council with information it needs for purposes of carrying out its functions.

(b) The Council may conduct inquiries, hold hearings, and establish subcommittees, as necessary.

(c) The Council is authorized to conduct analyses and develop reports or other materials.

(d) Members of the Council may be compensated to the extent permitted by Federal law for their work on the Council. Members may 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), to the extent funds are available.

(e) To the extent permitted by law, and subject to the availability of appropriations, the Department of Health and Human Services shall provide the Council with administrative support and with such funds as may be necessary for the performance of the Council's functions.

(f) The Council shall have a staff headed by an Executive Director, who shall be appointed by the Secretary of Health and Human Services in consultation with the Chairperson. To the extent permitted by law, office space, analytical support, and additional staff support for the Council shall be provided by the Department of Health and Human Services or other executive branch departments and agencies as directed by the President.

Sec. 5. General Provisions.

(a) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.), may apply to the Council, any functions of the President under that Act, except that of reporting to the Congress, shall be performed by the Secretary of Health and Human Services in accordance with the guidelines that have been issued by the Administrator of General Services.

(b) The Council shall terminate 2 years from the date of this order unless extended by the President prior to that date.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

GEORGE W. BUSH

THE WHITE HOUSE,

November 28, 2001.

# # #

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Track about Consensus
Shift to what can you live with

Recommend Action Step Okay as is
Okay with edits
- Rewording - Can we edit to make it acceptable
Not acceptable and need to state Difference of Opinion
People who can't live with it will be given time to state their concern and how they want to change

Lack of Consensus

Sent one more time

Time Schedule

~~Time Changes by Friday March~~
Full Report out by E Mail on Friday
Conference Calls on Thursday - Februm 28
Response back by COB Monday

Jim - Procedure for Review