

White House Commission on Complementary and Alternative Medicine Policy
October 4-6, 2001
Neuroscience Building
Bethesda, MD

DRAFT PRELIMINARY AGENDA

August 2, 2001 (5:19pm)

Thursday, October 4

8:30

8:30 – 10:30 (2 hrs)

Session I. Definition of CAM

Staff Lead: Jim Swyers

10:30 – 10:45 (15 min)

BREAK

10:45 – 12:15 (1.5 hr)

Session II. Information Development and Dissemination

Staff Lead: Corinne Axelrod

12:15 – 1:30 (75 min)

LUNCH

1:30 – 3:30 (2 hrs)

Session III. Coordination of CAM Research

Staff Lead: Gerry Pollen

3:30 – 3:45 (15 min)

BREAK

3:45 – 5:45 (2 hrs)

Session IV. Education and Training of Health Care Practitioners in CAM

Staff Lead: Joe Kaczmarczyk

6:00 Adjourn

Friday, October 5

8:00 – 10:15 (1.45 hrs)

Session V, Part I. Access to and Delivery of CAM

Staff Lead: Michele Chang

10:15 – 10:30 (15 min)

BREAK

10:30 – 12:15 (1.45 hrs)

Session V, Part II. Coverage and Reimbursement

Staff Lead: Maureen Miller

12:15 – 1:30 (75 min)

LUNCH

1:30 – 3:15 (2 hrs)

Session VI. CAM in Wellness, Self-Care, Health Promotion and Disease Prevention

Staff Lead: Corinne Axelrod

3:15 – 3:30 (15 min)

BREAK

3:30 – 4:45 (1.15 hrs)

Session VII. Coordinating and Centralizing Federal CAM Efforts

Staff Lead: Joe Kaczmarczyk

4:45 – 5:00 (15 min)

BREAK

5:00 – 6:00 (1 hr)

Public Comments

6:00 ADJOURN

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Saturday, October 6

8:30 – 12:30

- Review of draft recommendations (8:30 – 10:30)
- Final Report process (10:30 – 11:30)
- Open Discussion (Commissioners) (11:30 – 12:30)

HARD OUT by 12:30

WHCCAMP Work Groups for October 4-6 Meeting (August 2, 2001 (2:18pm))

A. Coordination of CAM Research

Staff Lead: Gerry Pollen

1. George Bernier
2. Effie Chow
3. Veronica Gutierrez
4. Bill Fair
5. Wayne Jonas
6. Tieraona Low Dog
7. Dean Ornish

B. Information Development and Dissemination

Staff Lead: Corinne Axelrod

1. David Bresler
2. Tom Chappell
3. George DeVries
4. Tieraona Low Dog
5. Julia Scott

C. Access to and Delivery of CAM

Staff Lead: Michele Chang

1. George Bernier
2. George DeVries
3. Joe Fins
4. Linnea Larson
5. Conchita Paz
6. Joe Pizzorno
7. Buford Rolin
8. Julia Scott

D. Coverage and Reimbursement

Staff Lead: Maureen Miller

1. George DeVries
2. Joe Fins
3. Linnea Larson
4. Conchita Paz
5. Dean Ornish
6. Ming Tian

E. Education and Training of Health Care Practitioners in CAM

Staff Lead: Joe Kaczmarczyk

1. George Bernier
2. David Bresler
3. Joe Fins
4. Joe Pizzorno
5. Buford Rolin
6. Donald Warren

F. Coordinating and Centralizing Federal CAM Efforts

Staff Lead: Joe Kaczmarczyk

1. Veronica Gutierrez
2. Wayne Jonas
3. Donald Warren
4. Effie Chow

G. CAM in Wellness, Self-Care, Health Promotion and Disease Prevention

Staff Lead: Corinne Axelrod

1. Bill Fair
2. Dean Ornish
3. Julia Scott
4. Ming Tian

H. Definition of CAM and Guiding Principles

Staff Lead: Jim Swyers

1. Tom Chappell
2. Effie Chow
3. Wayne Jonas
4. Charlotte Kerr
5. Conchita Paz
6. Joe Pizzorno
7. Veronica Gutierrez

Groft, Stephen (WHCCAMP)

From: Flowers, Susan (NCCAM)
Sent: Monday, August 20, 2001 3:04 PM
To: Groft, Stephen (WHCCAMP); 'James S. Gordon, MD'
Subject: Correspondence from Dr. Stephen E. Straus

Dear Jim and Steve:

Several of my staff members attended the last meeting of the Commission and noted that we at NCCAM are already undertaking or planning activities that address some of the issues raised by the Commissioners. Below is a summary of such activities, to provide you the most up-to-the minute information on the Center's progress. We thought this might be useful to Steve as he prepares his impending presentation to our Advisory Council.

- 1) As did the Commissioners, NCCAM noted a role for industry. Therefore, we convened an Industry-NCCAM colloquium on May 14th to explore opportunities for collaboration. The meeting was planned jointly with members of the dietary supplement industry. We are work working now with the planning committee to prepare a summary that will be posted on the meeting Web site. We will notify you when it is posted. In the meantime, you may access a full description of the goals and agenda of the colloquium at <http://nccam.nih.gov/colloquium/>
- 2) Similarly, we plan within the year to explore opportunities to collaborate with foundations.
- 3) Bill Fair, citing the model used to advance the field of prostate cancer research, noted the need to attract outstanding conventional biomedical researchers to apply their knowledge and expertise to the conduct of CAM research. To this end, we will advertise our Program Announcements and Requests for Applications extensively among relevant societies. In addition, we hope to begin a series of informal meetings with leaders in e.g, molecular biology and genetics, individuals who are experts in the leading edge technologies, and influential members of the fields of neurobiology, immunology, endocrinology, physics, etc.
- 4) Finally, we hope to organize a workshop on Clinical Research Methodology, including topics such as methodological and ethical issues related to design of clinical trials to test single agents, complex mixtures, and complete alternative medical systems; and the role of qualitative research.

Best regards,

Steve

Senators Propose Legislation for Dietary Supplement Insurance Coverage

Senators Tom Harkin (D-Iowa) and Orrin Hatch (R-Utah) introduced a bill on August 2 to encourage health insurance coverage of dietary supplements, medical foods, and foods for special dietary use. The "Dietary Supplement Tax Fairness Act of 2001" proposes that dietary supplements be treated as medical expenses in the same manner currently applied to prescription drugs. The legislation would also allow the cost of these items to be tax deductible for employers and excluded from taxable income for employees.

The proposed bill also includes an incentive for strengthening the FDA's quality oversight of these products. Dietary supplements would only receive the improved tax treatment if they comply with good manufacturing practices prescribed by the FDA. The bill notes the testimonies received by the White House Commission on Complementary and Alternative Medicine concerning the demand for increased insurance coverage of products. The bill (which appears in the August 2 *Congressional Record*) can be accessed at <http://www.access.gpo.gov>.

References

Congressional Record. 107th Cong., 1st sess., 2001. Vol. 147(11): S8709-S8770.

;

By Mr. HARKIN (for himself and Mr. Hatch):

S. 1330. A bill to amend the Internal Revenue Code of 1986 to provide that amounts paid for foods for special **dietary** use, **dietary** supplements, or medical foods shall be treated as medical expenses; to the Committee on Finance.

Mr. HARKIN. Madam President, today I am introducing legislation, the **Dietary Supplement Tax Fairness Act**, on behalf of myself and my distinguished colleague Senator Hatch. This legislation will make the cost of **dietary** supplements, medical foods, and foods for special **dietary** when offered as a health insurance plan **tax** deductible for employers and excluded from taxable income for employees. Unfortunately, today the **tax** code provides this sensible **tax** treatment for these products only if they are prescribed drugs.

Our current policy is unfair and is failing to take full advantage of the potential to improve health and hold down health care costs through preventive health care practices available to consumers. Many Americans are using these healthcare products to improve their health and to stay healthy and would like to be able to have access to these products in the form of an insurance benefit. Insurance companies and employers responding to this consumer demand have been frustrated by being unable to offer a benefit like this in a manner consistent with other health care practices which receive favorable consideration in the Internal Revenue Code. The White House Commission on Complementary and Alternative Health Care Policy has consistently heard in testimony of the need for greater insurance coverage of products like the ones in my legislation. Bringing the code up to date to recognize and allow for this important need for wellness and health promotion is an important step forward to overall sound healthcare policy.

I want to emphasize the importance our legislation places on quality. Consumers need and deserve to know that the products they are buying are of a high quality and consistency. With that in mind, the **Dietary Supplement Health and Education Act of 1994** called on the Food and Drug Administration, FDA, to develop and implement Good Manufacturing Practice Standards, GMPs, for **dietary** supplements. Senator Hatch and I have repeatedly pushed the FDA to produce and implement these important consumer protections. After seven years, draft GMPs were published in the Federal Register but have not been finalized. I am hopeful that these final standards will be put in place without further delay. The legislation we are introducing requires that **dietary supplement** and other products meet good manufacturing practice standards in order to receive the improved **tax** treatment. This will offer a strong incentive to maintain and improve quality.

I urge my colleagues to review this legislation and I hope they will join us in support and join us in our effort to win its passage. I ask unanimous consent that the text of the bill be printed in the Record.

There being no objection, the bill was ordered to be printed in the Record, as follows:

S. 1330

Be it enacted by the **Senate** and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This **Act** shall be known as the ``**Dietary Supplement Tax Fairness Act of 2001**.''

SECTION 2. FINDINGS.

The Congress finds that--

- (1) the inclusion of foods for special **dietary** use, **dietary**

supplements, and medical foods in the deduction for medical expenses does not subject such items to regulation as drugs,

(2) the Internal Revenue Code **of** 1986 treats such items as allowable for the medical expense deduction, but only if such items are prescribed drugs,

(3) such items have been shown through research and historical use to be a valuable benefit to human health, in particular disease prevention and overall good health, and

(4) children with inborn errors **of** metabolism, metabolic disorders, and autism, and all individuals with diabetes, autoimmune disorders, and chronic inflammatory conditions, frequently require daily **dietary** interventions as well as medical interventions to manage their conditions and such **dietary** interventions often become a significant economic burden on such individuals.

SEC. 3. AMOUNTS PAID FOR FOODS FOR SPECIAL **DIETARY** USE,
DIETARY SUPPLEMENTS, OR MEDICAL FOODS TREATED
AS MEDICAL EXPENSES.

(a) In General.--Paragraph (1) **of** section 213(d) **of** the Internal Revenue Code **of** 1986 (relating to medical, dental, etc., expenses) is amended by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively, and by inserting after subparagraph (B) the following new subparagraph:

“(C) for foods for special **dietary** use, **dietary** supplements (as defined in section 201 **of** the Federal Food, Drug, and Cosmetic **Act**), and medical foods,”.

(b) Special Rule for Insurance Covering Foods for Special **Dietary** Use, **Dietary** Supplements, and Medical Foods.--Subsection (d) **of** section 213 **of** the Internal Revenue Code **of** 1986 (relating to medical, dental, etc., expenses) is amended by adding at the end the following new paragraph:

“(12) Special rule for insurance covering foods for special **dietary** use, **dietary** supplements, and medical foods.--Amounts paid for insurance covering foods and supplements referred to in paragraph (1)(C) shall be treated as described in paragraph (1)(E) only if such foods and supplements comply with applicable good manufacturing practices prescribed by the Food and Drug Administration or with other comparable standards.”.

(c) Conforming Amendments.--

(1) Subparagraph (E) **of** section 213(d)(1) **of** the Internal Revenue Code **of** 1986, as redesignated by subsection (a), is amended by striking “subparagraphs (A) and (B)” and inserting “subparagraphs (A), (B), and (C)”.

(2) The last sentence **of** section 213(d)(1) **of** such Code is amended by striking “subparagraph (D)” and inserting “subparagraph (E)”.

(3) Paragraph (6) **of** section 213(d) **of** such Code is amended--

(A) by striking “and (C)” and inserting “(C), and (D)”, and

(B) by striking “paragraph (1)(D)” in subparagraph (A) and inserting “paragraph (1)(E)”.

(4) Paragraph (7) **of** section 213(d) **of** such Code is amended by striking “and (C)” and inserting “(C), and (D)”.

(5) Sections 72(t)(2)(D)(i)(III) and 7702B(a)(4) **of** such Code are each amended by striking “section 213(d)(1)(D)” and inserting “section 213(d)(1)(E)”.

(d) Effective Date.--The amendments made by this section shall apply to taxable years beginning after the date **of** the

Groft, Stephen (WHCCAMP)

From: Chang, Michele (WHCCAMP)
Sent: Tuesday, August 07, 2001 2:10 PM
To: Bill Fair (E-mail); Conchita Paz (E-mail); David Bresler (E-mail); Dean Ornish (E-mail); Donald Warren (E-mail); Effie Chow (E-mail); George Bernier (E-mail); George DeVries (E-mail); Jim Gordon (E-mail); Joe Fins (E-mail); Joe Pizzorno; Julia Scott (E-mail); Linnea Larson; Tieraona Low Dog (E-mail); Tom Chappell (E-mail); Veronica Gutierrez (E-mail); Wayne Jonas (E-mail); Wayne Jonas2 (E-mail); Xiaoming Tian (E-mail)
Cc: Anne/Rita For Tieraona (E-mail); Carolyn Gillett (E-mail); Chris Wennerstrom; Joan Matthews (E-mail); Marjorie for Ornish (E-mail); Tracy Wiens (E-mail); Axelrod, Corinne (WHCCAMP); Fisher, Ken (WHCCAMP); Gerry Pollen (E-mail); Jim Swyers (E-mail); Joe Kaczmarczyk (E-mail); Kingsbury, Doris (WHCCAMP); Miller, Maureen (WHCCAMP); Steve Groft (E-mail)
Subject: WHCCAMP Work Groups

Commissioners:

Thank you for nominating the following facilitators for work groups. Where possible, co-facilitators have been selected to share and ease responsibilities of tasks.

NOTE: Meanwhile, Kate Groft continues her arduous task of scheduling our first conference call (1.5 hrs) with the 8 work groups, all of which we hope to conduct by August 17. With the overlap between work groups and differences in time zones, Kate's task is Herculean at best. Your continued flexibility and willingness to work with Kate to find mutually possible schedules is critical. You can reach her most easily through Michele at 301-435-6232, or by fax 301-480-1691.

A. Coordination of CAM Research

Staff Lead: *Gerry Pollen*

Co-facilitators: Wayne Jonas, Dean Ornish

B. Information Development and Dissemination

Staff Lead: *Corinne Axelrod (Maureen Miller substitute until 8/20)*

Co-facilitators: David Bresler, Tieraona Low Dog

C. Access to and Delivery of CAM

Staff Lead: *Michele Chang*

Co-facilitators: Joe Fins, Linnea Larson

1D. Coverage and Reimbursement

Staff Lead: *Maureen Miller*

Facilitator: George DeVries

E. Education and Training of Health Care Practitioners in CAM

Staff Lead: *Joe Kaczmarczyk*

Co-facilitators: George Bernier, Joe Pizzorno

F. Coordinating and Centralizing Federal CAM Efforts

Staff Lead: *Joe Kaczmarczyk*

Facilitator: Donald Warren

G. CAM in Wellness, Self-Care, Health Promotion and Disease Prevention

Staff Lead: *Corinne Axelrod (Michele Chang substitute until 8/20)*

Facilitator: Dean Ornish

H. Definition of CAM and Guiding Principles

Staff Lead: Jim Swyers

Co-facilitators: Tom Chappell, Wayne Jonas

If you have any questions concerning this list, please contact Dr. Joe at 301-435-6197, or Michele at 301-435-6232.

Thank you for your efforts!

James S. Gordon, MD
Chair

Joseph M. Kaczmarczyk, DO, MPH
Acting Executive Director

Groft, Stephen (WHCCAMP)

From: Stone, Robin (HHS/OS)
Sent: Monday, August 06, 2001 8:36 AM
To: Groft, Stephen (WHCCAMP)
Subject: RE: Interim Progress Report - White House Commission on Complementary and Alternative Medicine Policy

Morning Steve

You transmit the report yourself to Secty. Thompson and the Senators. We would also like a report to put in you committee's file.

Thanks Steve

-----Original Message-----

From: Groft, Stephen (WHCCAMP)
Sent: Friday, August 03, 2001 4:33 PM
To: Stone, Robin (HHS/OS)
Subject: Interim Progress Report - White House Commission on Complementary and Alternative Medicine Policy

Robin,

After much debate and numerous drafts, we have arrived at agreement on the content of the Interim Progress Report from the Commission that was requested by Secretary Shalala and Senators Harkin and Mikulski last year at the swearing in ceremony (and that seems like a long time ago). We do need your guidance on the transmittal of this report. Do we send it to you to handle for the Secretary Senator Harkin, Senator Mikulski, and the White House or is it transmitted from us directly to the Secretary, Senator Harkin, Senator Mikulski, and the White House? Any light you can shed on this process would be helpful. Are there others in the department who should review the document prior to the Secretary.

I am on leave next week in the mountains and canyons of Colorado, Utah, and Arizona, but will be checking in when phone is accessible. Dr. Joseph Kaczmarczyk (301-435-6197) is the Acting Executive Director during my absence and Michele Chang is the Executive Secretary (301-435-6232). They both are familiar with the report and can develop whatever you need to accompany the report.

Thank you for your help.

Steve Groft
301-435-6199

<< File: DraftIntReptsg#22725011.rtf >>

Working Groups – Final Report

A. Coordination of CAM Research (Gerry)

1. Guterrez (1)
2. Chow (1)
3. Fair (1)
4. Jonas (2)
5. Low Dog (2)
6. Warren (2)
7. Bernier (3)–already assigned to E, C

B. Information Development and Dissemination (Corinne/Gerry on regs)

1. Low Dog (1)
2. Bresler (2)
3. DeVries (3) – already assigned to D,C
4. Scott (3) – already assigned to G,C
- 5.

C. Access to and Delivery of CAM (Mi)

1. Larson (1)
2. Pizzorno (1)
3. Paz (1)
4. Rolin (1)
5. DeVries (2)
6. Scott (2)
7. Bernier (2)
8. Bresler (3) –already assigned to E, B

D. Coverage and Reimbursement of CAM Practices and Products (Maureen)

1. Tian (1)
2. DeVries (1)
3. Paz (1)
4. Larson (2)
- 5.

E. Education and Training of Health Care Practitioners in CAM (Joe/Gerry)

1. Bernier (1)
2. Bresler (1)
3. Warren (1)
4. Pizzorno (2)
5. Rolin (2)
5. Larson (3) – already assigned to C, D

F. Coordinating and Centralizing Federal CAM Efforts (Joe)

1. Guterrez (2)
2. Jonas (3) – already assigned to H, A
3. Kerr (3) – already assigned to H, G
- 4.
- 5.

G. CAM in Wellness, Self-Care, Health Promotion and Disease Prevention (Corinne)

1. Scott (1)
2. Kerr (2)
3. Tian (2)
4. Guterrez (3) – already assigned to A,F
5. Chow (3) –already assigned to A,H
6. Warren (3) – already assigned to E, A
7. Fair (3) – already assigned to A
8. Rolin (3) – already assigned to C, E

H. Definition Of CAM and Guiding Principles (Mi)

1. Chappell (1)
2. Jonas (1)
3. Kerr (1)
4. Chow (2)
5. Pizzorno (3) – already assigned to C, E
6. Paz (3) – already assigned to D, C

Commissioners pending:

Fair (still pending 2nd choice)
Fins (E?)
Ornish (G, A, D?)
Chappell (for D,G)



Academy for Educational Development

Conference Center

Interim Report July 2-3 Meeting
Review of Recommendations & Specific
Specific Recommendations & Specific
June 18 Master List of Recommendations Broken id

8 Categories - Brief Analysis
Review Draft Chapter

I, II, III

I Introduction

II History of Commission / CAOT

III World View

Review - Interim Report (A)

Interim Report Contents

Hx of Commission

Activities - Subject Items at Meeting

Schedule of Meetings - Regular + Town Hall

+ homes - Office at OS, Full Implementation
of DSHG A/C & G.F.D.A

Recommendations

Relatively Easy Implementation, Not Expensive

Identify Missing Information

Internal Staff Process for Work Groups

— *Order Committee*
nurturing in schools
(Michele Jacobson)
— *Health Centers*

August 3-6:

Staff receive nominations for Work Group Facilitator (WGF). WGFs should be finalized by Monday, August 6.

— *Joe Fine - Sociology of CAM -*

August 6-10:

Staff member coordinates with WGF to develop “strawman” document proposing key issues under their working group topic. This may also include a brief rationale statement for each issue, an outline of the current state-of-progress, and a list of obstacles and challenges. If possible, initial draft recommendations may be put forward as well. The strawman document should be e-mailed to work groups no later than August 10, copied to all staff and denoted as:

[Topic/date/SM/staff initials]. (SM=strawman)

August 10-17:

Conference calls should be completed no later than August 17th. If staff send out a report to their work group, it should be denoted as **[Topic/date/CC#/staff initials].** (CCR=conference call report, numbered in sequence).

August 17-24:

Staff meet to consult on their first drafts, particularly the format and style of draft recommendations.

August 24:

1st draft should be e-mailed to work groups, copied to all staff and denoted as:

[Topic/date/#1/staff initials].

August 29:

Comments are due back to staff leads. Staff work on revisions between August 29-31.

August 31:

2nd draft should be e-mailed to work groups, copied to all staff and denoted as:

[Topic/date/#2/staff initials].

September 5:

Comments are due back to staff leads. Staff work on revisions between September 5-10.

September 10-12:

Briefing Book materials are due to Palladian no later than Wednesday, Sept. 12. Electronic versions should be sent to Michele and copied to all staff, denoted as: **[Topic/date/final/staff initials].**

September 17-19:

Briefing Books are due to be sent out by Monday, Sept. 17-18; Staff check in with Commissioners by the 19th.

September 19- October 4:

Commissioners review materials. Staff leads work with WGF to prepare work group reports to the full Commission.

Lifeless
Deadline (Oct)

Facilitators
Group Self Select
Chair

Working Group Members
1-2-3 | Issues
Chair Chair Chair

Options

- Eliminate Recommendation
- State or Symposium from Public testimony
- Draft - Basic just the facts
- Need Report from Commissioners (not looking for sign off)
- Meeting in August

Comments

- More Neutral Position vs Advocacy
- White House Level (High) -
- CAM Advocate - ~~Factor~~ Report what we heard -
- Need to be advocate for Public's Health & Safety, not CAM
- Concern that we need to hear what they are saying
- More time for Review
- No more Speakers

Act

Boyd Landry
- Blindon et al
PAG fills

Action

- Activate Work Group
- J6 World Vision Section - Submit for Discussion Oct
- JS. Interior/IX Review by Commission - Submit for Discussion Oct

October Meeting

- Work Group Reports
 - Identify Issue
 - Develop Recommendation
 - Draft Sections for Review
- Definition of CAM
- Revise Principles

Working Groups

- GP ① Coordination of Record
- CP ② Information Develop + Dissemination
- OK → ③ Access & Delivery (Lien + Certificate)
- CP ④ Coverage & Reimbursement
- SK ⑤ Education + Training
- CP ⑥ Wellness, Self-Care, Pre, Health
- SG ⑦ Coordinating Effort - Central Office
- SG ⑧ Definition + Oversee Principle
- Elect Co-Chair

Definition of CAM
- Principle

Uthra Safer

no met

call

Peter Reneke & Update

(3) (3) Calls + options

middle $\rightarrow$ ~~stop~~ we feel $\rightarrow$ ~~no~~ is the way
to go - bare of comment
way to go
- want to go in sense of
community

need to have
some substance
to talk to people
congruent contributions

Don't Force Recommendations
want to

not prudent to make Recommendations

what
does she
need in

Livned

Jim talk to a

more difficult
due to
inadequate
discussion

Dean Smith

essential elements

e mail Today

Phone calls tomorrow

Friday night / Sat

Response Monday COB

structure September 15

Veronica

not yet

- Final Report

- Wordings

View

Sean Smith

Tom
Principles

* Freedom of access

* How can produce CAs

Any advocacy position
position
Neutralize

5:25 ct
Jan here
9:30

Reached

ITAS

Jim Muthig

Different
Phase

New Roles

19. Summary
Other

Facilitator
handle session

Acknowledgment of
Role + Accomplishment

Central Facilitator
Guidance for Staff
as Bureaucrats

- Objectives
- Communion Participation
- Objectivity

Leader of something
Bigger than anything

Whereas more
powerful from
Communion group
vs. individual
+ support of group

met