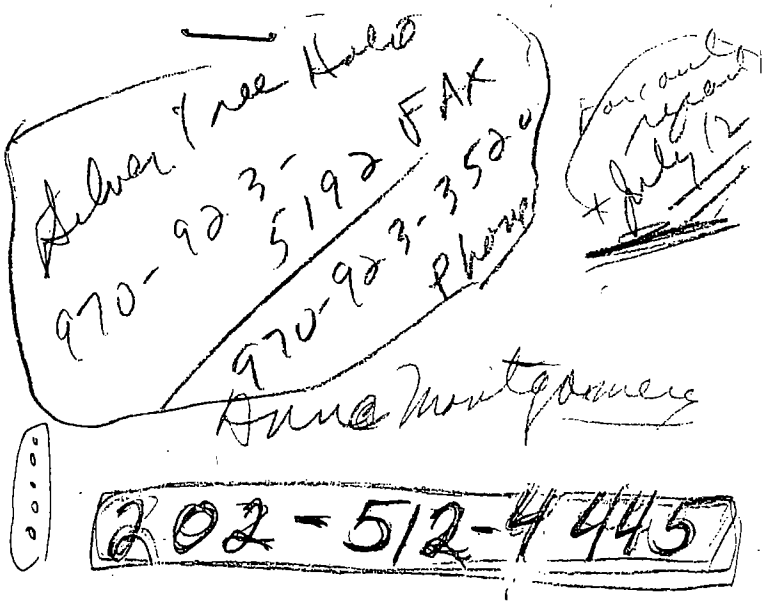
Tom Andrews
202-721-0111

PHOTOCOPY
PRESERVATION


Silverthree Hotel
970-923-5192 FAX
970-923-3500 Phone
Duncan Montgomery
202-512-4445

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

SEP 28 2001

The Honorable Richard Cheney
President of the Senate
Washington, DC 20510

Dear Mr. President:

Enclosed for your information is the Interim Progress Report submitted by the White House Commission on Complementary and Alternative Medicine (CAM) Policy. Executive Order 13147 requires a Final Report to be submitted to the President prior to March 7, 2002. The Final Report will provide administrative and legislative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine.

This report provides a brief overview of the Commission and its activities. It also discusses the Commission's progress to date in developing recommendations and reflects the diverse perspectives heard from advocates, critics and other expert witnesses.

Sincerely,

Tommy G. Thompson

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

SEP 28 2001

The Honorable Dennis Hastert
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

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Washington, DC 20510

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Sincerely,

Tommy G. Thompson

Enclosure

Groft, Stephen (NCCAM)

From: EastWestQi@aol.com
Sent: Wednesday, July 18, 2001 3:35 AM
To: Groft, Stephen (NCCAM)
Subject: Interim Report comments....

Dear Steve,

I would agree with Dean Ornish's note with the addition of these:

1. A statement that there are numerous definitions for CAM and give NCCAM's operational definition and a couple of others as an example.
3. There is a need to define "evidence-based".
4. The only real consensus from the people who testified and the commissioners is for the establishment of a center: To act as a clearinghouse and to continue work and also to further carry out the recommendations of WHCCAMP. Recommendations will be forthcoming with the final report. Definitely a statement that denotes the tremendous diversity of opinions, practices which are put under the whole umbrella of CAM in light of over a thousand testimonies that has been heard. And give a brief page on the range of organizations and institutions and individuals who testified to assure them that this process involved have been a very diversified groups.

There are so many unresolved issues.

I think the staff have been a wonderful ongoing supportive group. Thanks.

Loving Qi,
Effie

Founder and President, East West Academy of Healing Arts (EWAHA)
American Qigong Association (AQA) /World Qigong Federation (WQF)
530 Bush Street, Suite 202
San Francisco, CA 94108
tel: 415-788-2227 fax: 415-788-2242
email: eastwestqi@aol.com
website: eastwestqi.com

Steve,

I have had a chance to read the DRAFT interim report. Excellent job Steve
A couple minor suggestions.

1. In the second paragraph it should be interest and "use" (not just "in the use" CAM).
2. Under "National Surveys" the word "appreciatetive" is a good one although Ernst has shown that patients are actually more satisfied with visits to CAM practitioners than conventional practitioners.
3. I would split up the sentences on the prinicples. It all runs together as written. Didn't we have 10?
4. In the the paragraph that starts "Speakers before the Commission identified various types of CAM research programs..... there should be an "and" not "of" between cost-effectiveness and heath services research.
5. I have a list (can't locate right now) of government reports to connect too. Will send for the final report.
6. I would emphasize "health promotion" as a word in the wellness section by adding it a in a few places where you list, "self-care, wellness, and prevention, etc.".
7. I am collecting some of he generic writings we did while at the OAM that address CAM issues to be used as deemed appropriate and with modifications for the final report. They have never been published but represent hours of word smithing. Some of them might be useful for you and Jim.

Good job and good luck. Hope you get some time off after this is turned in.

Wayne

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: Dr James Gordon **FAX:** 970-923-5192

Total Pages including cover: ____

Comments:

Revised Version. We still have Access + Delivery to complete.

Have a good week.

Steve

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

Stephen C. Groft, Pharm.D.
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6701 Rockledge Drive
Rockledge II, Room 1010, Mail Stop 7707
Bethesda, Maryland 20817
Telephone: 301-435-7592 -- Facsimile: 301-480-1691

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

Phone 410-997-3770 x 614

Total Pages including cover: 3

Comments:

I will call tomorrow to discuss.

Steve

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

Groft, Stephen (NCCAM)

From: Linnea Larson [linnealarson@mac.com]
Sent: Thursday, July 19, 2001 7:10 PM
To: Groft, Stephen (NCCAM); 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; Thomas Chappell; Tieraona Low Dog; Veronica Gutierrez; Wayne Jonas; William Fair; Xiaoming Tian
Cc: Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); Jim Swyers; Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Re: Urgent Request for Consideration of Draft Interim Progress Report

on 7/20/01 6:01 AM, Groft, Stephen (NCCAM) at grofts@od31em1.od.nih.gov wrote:

> Thank you for taking the time to review the Commission's Draft Interim
> Progress Report and sending us your comments. Some shared their comments
> with other Commissioners. (Please note you can always do this by pressing
> the "Respond to All" button) We have reviewed all of the comments we've
> received up to this time. As could be expected, we have a diversity of
> opinions on how to proceed with no clear consensus. Now, we need your
> guidance.
>
> The majority of you responded quite favorably to the general structure and
> content of the Report and offered specific suggestions on how to improve it.
> Several Commissioners expressed concern, however, that the Commission
> recommendations in the most recent draft went too far too fast. There were
> two major concerns here. 1) Though we did arrive at a consensus on many of
> the recommendations in the July 2-3rd meeting, the Commission, more
> discussion and specificity are needed before we put recommendations forward
> as "Commission Recommendations" and/or that we would be better served by
> waiting until the Final Report to make our recommendations.
>
> 2) There were two areas - Access and Delivery and the Creation of a
> Coordinating Office at DHHS - which we did not, because of our discussion on
> "guiding principles", have a chance to review as a whole Commission in the
> meeting. Therefore recommendations should not be presented in these areas.
> Also, there were a number of conflicting comments on the discussion of the
> major issues
>
> Because we believe it is essential for the Commission to move ahead with
> consensus, we're now asking each of you to consider three possible options
> that we can all agree to for the Interim Report. They're listed below,
> along with the advantages and disadvantages for each. We want you to
> consider them and let us know what you think. Steve will be calling each of
> you between now and close of business Friday, July 20th, to discuss them
> with you. We are hoping to submit the final Interim report to Secretary
> Thompson by the middle of next week.
>
> 1) The "Basic Facts" Version with no recommendations or discussion of issues
> identified by the public. A less is better approach.
>
> Advantages: No controversy, ease in preparation, ease of clearance.
> Disadvantages: No information will be provided to the public, Congress and
> the Administration for action. This approach will raise questions about
> what the Commission has been doing with the public's money for the last 12
> months. There will be a very limited basis on which to have discussions
> with Congress or the Administration about the Commission's work, possible
> legislation, or Administrative change. This will inhibit the engagement of
> the public in debate about any of the issues before the Commission.
> Stakeholders may be disappointed by the lack of information

>
> This represents the position of a few Commissioners, but does not
> represent the position of the vast majority of Commissioners.
>
> 2) "Middle-of-the-Road" approach. Identification and discussion of the
> issues as raised by the public in each of the areas we've covered as we've
> presented in the Draft, taking your comments into account. This would focus
> on what we've heard from the public, but the Commission itself would make no
> recommendations at this time, deferring them to the Final Report.
>
> Advantages: little controversy and criticism of report; ease of clearance;
> suggests direction of Commission's thoughts; will generate public discussion
> on the issues; will provide a sense of the Commission's work and its scope
> to the public; will offer a platform to begin discussions of possible
> legislation and administrative recommendations; would offer the public an
> opportunity to provide input; will shield the Commission from potential
> criticism at this time; will leave to the Final Report the force of our
> recommendations. This represents a position which may be the easiest for
> Commissioners who are unsure about many recommendations to concur with.
>
> Disadvantages: May slow the Commission's momentum: without firm Commission
> positions or recommendations, efforts at formulating legislation or
> advancing administrative changes will move more slowly; does not provide our
> supporters in Congress with specific proposals on which to build legislation
> in this session of Congress; will likely cause confusion and consternation
> in stakeholders who have been actively engaged in the Commission process.
> This position may be particularly distressing to those present at July 2-3
> meeting or the many to whom reports of that meeting are circulating. Why
> they will wonder if we reached consensus about recommendations, are we now
> withdrawing them?
>
> This represents the position of a majority of Commissioners that we heard
> from.
>
> 3) "Modified Version of the July 12th Draft" recently circulated on which
> Commissioners have made comments. The modifications would include
> recommendations in the report but would delete any recommendations about
> Access and Delivery and the Central Office, because of lack of full
> Commission discussion.
>
> Advantages: Makes the Commission's work and its considered thought on
> matters presented clear to Congress, the Administration and the
> stakeholders; provides a clear basis for legislative and administrative
> recommendations now and for moving the process ahead in this session of
> Congress; adheres to public actions in July 2-3rd meeting; fulfills our
> commitment to Congress; will gain significant public attention. Represents
> the position we publicly agreed on at the July 2-3 meeting.
>
> Disadvantages: May indeed be a premature representation of the Commission's
> collective positions; general recommendations will be made before specific
> implementation has been worked out; may put the Commission in high profile
> and exposed position; may provoke criticism from those who are opposed to
> recommendations; may focus too much attention on the Interim as opposed to
> the Final Report at a time when we're not prepared to discuss in detail the
> recommendations; Clearance process may be more difficult; may move too
> quickly for several Commissioners.
>
> This position represents the view of several Commissioners, but again not a
> majority of the Commission members.
>
>Dear Steve,

Thank you for your email concerning the interim report.

Before I respond to your request for my opinion about this reports contents I want to express my concern about the process we have followed in approaching this matter. The fact that we find ourselves considering three quite divergent report descriptions one week after the report was to have been issued is testament to the need for this Commission to establish a

clear plan supported by procedural rules for the completion of its work. Without these, and without leadership that respects them we can only expect to find ourselves in similar confusion when our final report is due next March.

In the interest of ensuring both an orderly decision making process and a report of policy recommendations of the highest possible caliber, I intend to propose a plan and procedures for completing our work within the next two weeks. I am sure that whatever I propose can be improved by the thoughts of both staff and others on the Commission, and I hope that will occur. I am asking you now for your support in arranging whatever communications are necessary to formally adopt a plan and procedures as soon as possible.

As to the immediate question of the contents of the Commissions interim report, I have previously expressed my support for the "bare bones" approach originally recommended by Dean Ornish. However, in the interest of consensus, if the only addition to that "bare bones" approach is a careful and informative summary we have received on each of the four topics we are charged to investigate, I will support your proposed "middle of the road" approach.

There are three reasons to reject option three at this time:
(1) the recommendations we are asked to make in the four subject areas enumerated in the Executive Order are highly interactive. It is therefor a mistake to propose public policy changes in any topic area until we have developed a consistent set of recommendations in all topic areas.
(2) recommendations for Executive branch or Congressional consideration should be formulated as specific proposals for changes in federal statutes, regulations, or program policies. Generally speaking the recommendations we have discussed have not been put in this form. We should therefor wait until our recommendations have been properly formulated before we issue them.
(3) Mr. Tom Andrews advised us at our July 2-3 meeting to be cognizant of the health policy issues pending in the Congress as we deliberate to formulate health policy recommendations. The Commission has received no input of any kind on this subject. I cannot, therefor, understand your reference to "our supporters" in the Congress. Who are they? And, who might our opponents be? What issues concern "our supporters" in the Congress? What are the legislative politics that surround those issues? What are the positions of the Bush administration on those issues and others that touch on our area of responsibility? Indeed, what are the positions of this Commission on the issues that concern "our supporters" and the Bush administration?

As always I want you to know how appreciative I am for the sincere, hard work of the staff and of my fellow Commissioners in attempting to make our work together as useful as it can be.

Respectfully,

Linnea

Groft, Stephen (NCCAM)

From: DeanOrnish@aol.com
Sent: Friday, July 20, 2001 11:21 AM
To: Groft, Stephen (NCCAM); tierney334@yahoo.com; cmapaz@totacc.com; Bresler@aol.com; drwarren@artelco.com; EastWestQi@aol.com; gbernier@utmb.edu; georged@ashn.com; jsgordon@mindspring.com; drpizzorno@qwest.net; jjfins@mail.med.cornell.edu; Jrsct6@cs.com; linnealarson@mac.com; Tom@toms-of-maine.com; Lowdogmd@aol.com; Veronicapgdc@aol.com; wjonas@usuhs.mil; DrFair@haelth.com; MingTian@aol.com
Cc: Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); jpswyers@starpower.net; Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Re: Urgent Request for Consideration of Draft Interim Progress Report

In a message dated 7/19/01 3:03:15 PM Pacific Daylight Time, grofts@od31em1.od.nih.gov writes:

<< Thank you for taking the time to review the Commission's Draft Interim Progress Report and sending us your comments. Some shared their comments with other Commissioners. (Please note you can always do this by pressing the "Respond to All" button) We have reviewed all of the comments we've received up to this time. As could be expected, we have a diversity of opinions on how to proceed with no clear consensus. Now, we need your guidance.

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Disadvantages: May slow the Commission's momentum: without firm Commission positions or recommendations, efforts at formulating legislation or advancing administrative changes will move more slowly; does not provide our supporters in Congress with specific proposals on which to build legislation in this session of Congress; will likely cause confusion and consternation in stakeholders who have been actively engaged in the Commission process. This position may be particularly distressing to those present at July 2-3 meeting or the many to whom reports of that meeting are circulating. Why they will wonder if we reached consensus about recommendations, are we now withdrawing them?

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Disadvantages: May indeed be a premature representation of the Commission's collective positions; general recommendations will be made before specific implementation has been worked out; may put the Commission in high profile and exposed position; may provoke criticism from those who are opposed to recommendations; may focus too much attention on the Interim as opposed to the Final Report at a time when we're not prepared to discuss in detail the recommendations; Clearance process may be more difficult; may move too quickly for several Commissioners.

This position represents the view of several Commissioners, but again not a majority of the Commission members.

We encourage you to tell us within the next day and a half how you feel about these options and talk with Steve about them. Steve will be in touch with you tomorrow or as soon as you are available for a phone call. Please initiate the call to Steve if you have a few spare moments either tonight (home 301-424-1273) or tomorrow. After these discussions, we will complete the re-draft of the report and send it out to you again.

Steve can be reached on 1-866-373-1124 (Toll Free) or 301-435-6199 (Direct Line).

Thank you for your consideration.

Jim Gordon and Steve Groft
>>
Thank you for the summary. I appreciate so much your thoughtful comments and all the hard work that has gone into the July 12th draft.

I will restate and expand upon the concerns I expressed in my prior e-mail. I do not feel the same sense of urgency that some are expressing. If the ideas are valid, they will still be valid in the next sesssion of Congress. However, once opinion is mobilized against us, it will be very difficult to undo that.

We must not be naive in underestimating the depth and intensity of opposition to many of the ideas that are expressed in the July 12th draft. Most of these ideas may not seem very radical to many of the Commissioners, but I have spent the past seven years trying to persuade Medicare that it was less radical to ask people to eat vegetables, walk, meditate, and quit smoking than to place unproven radioactive stents in coronary arteries or saw open their chests. It took my colleagues and I more than seven years before HCFA finally agreed to move forward with a demonstration project-- and that was with the strong personal support of the White House, 12 U.S. Senators, and 15 members of the House across the political spectrum, from President Clinton to Newt Gingrich, from Charles Rangel to Dan Burton. Perhaps I am too colored by those experiences, but it has left me more respectful of how difficult it is to effect change in the government and how easy it is to be derailed.

It is a real role reversal for me to be counseling patience, as my nature is to want to do everything right away. However, I have learned from making many mistakes in the past, especially with the government, that lasting change often involves taking the time to build consensus, being able to discuss issues thoroughly and anticipate criticisms fully, and avoiding giving easy targets to one's opponents. If there is concern among any stakeholders that we are moving too slow for them, then we can help them understand the wisdom of moving a little more slowly than they might like. Slow but steady wins the race, and this race is a marathon.

What is the hurry? If I'm wrong, not much has been lost, as legislation is an ongoing process. However, there is a real risk of moving too quickly before we're completely ready. Even strong advocates in the House and Senate (and there may not be as many as one might hope, at least at this stage) may wilt if enough powerful interests are mobilized against CAM before we are completely ready to defend the positions that we take, even if we are only echoing ideas that were presented to us. I am no stranger to controversy, but I have learned that it is usually best to wait until the army is fully prepared and of one mind before going into battle. As you know, there is wisdom in patience, in waiting for the right moment.

Given the divergence of opinions and perspectives and backgrounds, I recommend option 1: we issue an interim report that is based solely on factual information--e.g., here are the members, here is when we met, we heard oral testimony from x people, written testimony from y more, a divergence of opinions and recommendations (we could include some of these as examples as long as we don't give any indication of what we think of them), here are some of the issues that are under consideration (without making any recommendations on these issues at this time). The report may be only a few pages long, which is fine for now.

It is now apparent that there are a number of basic issues that we have not worked out among ourselves. There are legitimate differences of opinion, and many are passionately felt on different sides. Clearly, these are not going to be resolved within the next few days. These issues deserve thoughtful discussion; it is good that they are being raised now. For example, are we going to take an advocacy position or a more neutral one? Do we need to

reach consensus or are we going to have separate dissenting opinions? What do we think about the many specific issues that have not yet been resolved?

We can use the time in our remaining meetings to discuss these issues among ourselves rather than hearing more testimony. We have had relatively little time to do so. We can work on drafts of the report via e-mail in-between meetings, and we can schedule telephone conference calls as needed. We can try to find common ground and build consensus with each other. Nothing is more likely to undermine moving the field forward than having dissenting opinions on an interim report. Especially at this vulnerable stage, we all need to feel completely comfortable with what is issued.

The interim report can be used to build consensus with the general public and legislators and avoid giving ammunition to critics at a vulnerable time. I understand that there may be opportunities for legislation in this session, but nothing will make this legislation more vulnerable than mobilizing critics with an interim report that provides easy targets for them. An interim report that takes an advocacy position may mobilize powerful forces that will make it much more difficult to advance the field.

I know that a lot of work has been put into drafting this interim report, so my suggestion may arouse a certain amount of frustration. However, none of this work will not be lost or wasted, as it will form the basis for the next round of discussions as we move forward together.

I would value your thoughts and comments. I remain deeply grateful for the privilege of working together. On a personal note, getting to spend time together has been very meaningful for me.

Thanks for taking the time to read this. With best wishes and warm regards,

Dean Ornish

Groft, Stephen (NCCAM)

From: Groft, Stephen (NCCAM)
Sent: Friday, July 20, 2001 12:48 PM
To: 'Bresler@aol.com'
Subject: RE: Urgent Request for Consideration of Draft Interim Progress Report

David,

Thank you for the selection and I will be back in touch hopefully this evening.

Steve

-----Original Message-----
From: Bresler@aol.com [mailto:Bresler@aol.com]
Sent: Friday, July 20, 2001 11:59 AM
To: Groft, Stephen (NCCAM); DeanOrnish@aol.com; tierney334@yahoo.com; cmapaz@totacc.com; drwarren@artelco.com; EastWestQi@aol.com; gbernier@utmb.edu; georged@ashn.com; jsgordon@mindspring.com; drpizzorno@qwest.net; jjfins@mail.med.cornell.edu; Jrsct6@cs.com; linnealarson@mac.com; Tom@toms-of-maine.com; Lowdogmd@aol.com; Veronicapgdc@aol.com; wjonas@usuhs.mil; DrFair@haelth.com; MingTian@aol.com
Cc: Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); jpswyers@starpower.net; Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Re: Urgent Request for Consideration of Draft Interim Progress Report

Dear Staff and Commissioners:

I, too, greatly appreciate all the work that the staff put into the draft of the Interim Report, and all the efforts that everyone is making to come to a concensus. I think that all the current conversations about procedures and content are healthy, helpful, and necessary, and should be encouraged to continue.

However, we need to make a quick decision about what to do regarding our interim report, and once again, I find Dean's logic difficult to argue with. Like most doctors, I daily make decisions based upon an assessment of potential benefits vs. risks. I see little to be gained at this point by letting any cats out of the bag, and great potential danger to the wide acceptance of our final report by giving various lobbyists early ammunition to begin firing against us. As Dean states so well, this is a marathon, not a sprint.

Based on my early research at UCLA, it was clear to me over thirty years ago that acupuncture was an effective and useful treatment modality, and despite at least 5,000 years of continuous practice in the Orient, it's taken decades for it be accepted into general medical practice in the US. There is often a "speed of going more slowly", and I believe that we can best help move the acceptance of CAM forward by taking the time needed to resolve the conflicting issues among Commissioners (via email and conference calls), to get more input about framing our recommendations to Congress, as Dean suggests, and to reach a strong concensus of the Commissioners for specific legislative action. Until we have our act completely together, I think we should hold our cards as close as possible to our chests.

Therefore, I also vote for #1.

David E. Bresler, PhD, LAc
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30765 Pacific Coast Hwy

Malibu, CA 90265
310-589-9333
310-589-9523 FAX
Bresler@aol.com

Groft, Stephen (NCCAM)

From: DeanOrnish@aol.com
Sent: Saturday, July 21, 2001 6:35 AM
To: Groft, Stephen (NCCAM)
Cc: jsgordon@mindspring.com
Subject: reply

In a message dated 7/20/01 10:12:31 AM Pacific Daylight Time, grofts@od31em1.od.nih.gov writes:

<< Dean,

Thank you for your comments and guidance. Your experience indicates the value of establishing a neutral position at this time with no revelation of the direction or content of the Commission's recommendations. My reading, and please correct me if I interpreted your comments, is that we move to a Heavier #1 with added comments from the public or a Light # 2 with fewer conclusions.

Again, thanks for the suggestions.

Steve >>

Dear Steve,

Thanks for your note. I really appreciate your efforts.

I'm open to the possibility of including some comments from the public as long as it's absolutely clear that we are not yet taking a position on any of these. In the last e-mail, the "middle of the road approach" stated that one of the advantages was that it "suggests direction of Commission's thoughts." This is precisely what I believe we would be wise to avoid until we have reached clear consensus on our thoughts and are fully prepared to defend these positions. Also, I think we need to do the kind of work that Tom Andrews described before mobilizing opposition.

I considered the option that our interim report could say something along the lines of, "We listened to oral testimony from over 1,000 people and received written testimony from 2,000 [or whatever the numbers are]. People testified from a wide range of backgrounds [give examples]. We heard very diverse recommendations from those who testified. For example, testimony about licensure ranged across a wide spectrum from those who said that only licensed physicians should be allowed to use CAM modalities in their practices to those who testified that anyone should be allowed to practice any CAM modality with any patient as long as they disclosed their qualifications and experience. We will carefully consider all testimony before making our recommendations in the final report."

However, even this makes me a little uncomfortable since it may provoke opposition from those who are concerned that we would even be considering extreme points of view on either end of the spectrum. As a result, they may feel the need to do a "pre-emptive strike" and begin mobilizing opposition in hopes of influencing our recommendations in the final report. Of course, all testimony is designed to influence our recommendations, but people testifying is different than beginning to actively mobilize opposition. I agree with David Bresler when he wrote, "I see little to be gained at this point by letting any cats out of the bag, and great potential danger to the wide acceptance of our final report by giving various lobbyists early ammunition to begin firing against us."

Anyway, I would appreciate the opportunity to discuss this with you by telephone. I'm available most of today (Saturday) or Sunday at 415/332-3456 or 415/990-1081. It will be a little harder to reach me on Monday as I'm

going to LA on Sunday afternoon and returning Monday afternoon. I'm also available most of Tuesday.

I look forward to our discussion. Many thanks, as always.

Dean

MEMORANDUM OF CALL

Previous editions usable

TO: Steve

☐ YOU WERE CALLED BY— ☐ YOU WERE VISITED BY—

Charlotte Kerr

OF (Organization)

Mail Deadline — Teaching toe

☐ PLEASE PHONE ▶ *(Enter area code, if necessary)* ☐ DSN

410-997-3770

☐ WILL CALL AGAIN ☐ IS WAITING TO SEE YOU

☐ RETURNED YOUR CALL ☐ WISHES AN APPOINTMENT

MESSAGE

Format [Deans]

ext 614

Basic issue

passionate positions

"Trust" & Preliminary Suggestions

Support

RECEIVED BY | DATE | TIME

NSN 7540-00-634-4018
50363-111
UNICOR FPI-SST

OPTIONAL FORM 363 (Rev. 7-94)
General Services Administration

Space — Repository for

CAM

Caveat

Statements

Trust

Consumer

Move them on

& highlight

the definition

Transformation

PHOTOCOPY PRESERVATION

Steve,

I have had a chance to read the DRAFT interim report. Excellent job Steve
A couple minor suggestions.

1. In the second paragraph it should be interest and "use" (not just "in the use" CAM).
2. Under "National Surveys" the word "appreciatetive" is a good one although Ernst has shown that patients are actually more satisfied with visits to CAM practitioners than conventional practitioners.
3. I would split up the sentences on the prinicples. It all runs together as written. Didn't we have 10?
4. In the the paragraph that starts "Speakers before the Commission identified various types of CAM research programs..... there should be an "and" not "of" between cost-effectiveness and heath services research.
5. I have a list (can't locate right now) of government reports to connect too. Will send for the final report.
6. I would emphasize "health promotion" as a word in the wellness section by adding it a in a few places where you list, "self-care, wellness, and prevention, etc.".
7. I am collecting some of he generic writings we did while at the OAM that address CAM issues to be used as deemed appropriate and with modifications for the final report. They have never been published but represent hours of word smithing. Some of them might be useful for you and Jim.

Good job and good luck. Hope you get some time off after this is turned in.

Wayne

Groft, Stephen (NCCAM)

From: EastWestQi@aol.com
Sent: Monday, July 09, 2001 8:33 AM
To: Groft, Stephen (NCCAM)
Cc: Chang, Michele (NCCAM)
Subject: Re: Review of Interim Draft Progress Report and Core Values of the Co mmission

Dear Steve,

Thank you for your information. It was a very stimulating meeting and thank you for your expert guidance at all times. Also thanks to Michele and your whole staff for such wonderful and efficient support work.

I am in Ottawa and having some great days.

First some general comments re interim report:

1) I think the interim report is evolving well.
2) Could the introductory include:
a) will the list of the 1000 testimonies be attached as appendix? and I would also suggest that of the 1000 testimonies, give a small sample of the breadth of who/what agencies testified giving some examples of the most conservative prestigeous institutions/people, to Cam people/institutions to the opposition speakers that we have had. This will give the Secretary, President, and Congress a comfortable sense that the most conservatives and respected are very much included in giving input to our considerations.
b) a few statements be made about the history of the evolution of CAM including the persecutory times in the 1970's where the practitioners of acupuncture, homeopathy, holistic health, were actually jailed, even into the 80's and 90's and how it has positively evolved to acceptance at this time in history but yet still now some doctors (example NY testimonies) are still being persecuted.....why the recommendation for protection. It can be made as gentle as you think it is needed, but for the real education of those who will read the report, I think that part of history should be included.
c) that this CAM has a strong energy concept focus....(It may be included into a statement of our Core Value ..eg..in number 5. The emphasis on the care of the whole person (mind, PHYSICAL AND ENERGETIC body, and spirit). Health is more than just the absence of disease.

The following is related specifically to the text.

1) I know that there will be editing for incomplete sentences and grammar.
2) Can there be elaboration on the one statement sentences?
3) Use only positive expressions even in negative situations....eg
* All those who are in accredited schools who are learning in the health profession, whether CAM or conventional, should have access to federally backed student loans. There are still unresolved issues in the area of loan forgiveness. There is also some disagreement about licensed versus unlicensed.
Say instead..... THE COMPLEXITY OF THE ISSUES OF LOAN FORGIVENESS AND LICENSURING REQUIRES MORE EXTENSIVE EXPLORATION AND DISCUSSION WITH PROPER AUTHORITIES TO MAKE ANY SUBSTANTIAL RECOMMENDATIONS.

There may be other things, and I will immediately convey them to you when it comes up, Steve, but I hope that the above is helpful. I look forward to receiving the next correspondence. I am in Ottawa until Wed early morning, travelling in the am and back to San Francisco on Wed. pm. So that you will knowwhere to reach me in this urgent time. My phone number here is 613-234-6369. I can always have access to my regular email.

Thanks again.

Loving Qi and warmest regards,

Effie

PS....Can you please have your office forward to me the list of Medical Universities and their curriculum for CAM? Marilyn Schlitz is also asking for that information.
Thanks....

Founder and President, East West Academy of Healing Arts (EWAHA)
A 501(c)3 non-profit organization dedicated to integrating holistic Complementary and Alternative Medicine (CAM) and Modern Western Medicine (MWM) with a special focus on Traditional Chinese Medicine (TCM) and Qigong .
We foster practice of excellence in educational, clinical, and research activities with concepts of body, mind, and spirit bringing the best of health care for all people. Our clients with serious and minor conditions usually experience good results where all else may have previously failed.

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San Francisco, CA 94108
415-788-2227 tel.
415-788-2242 fax.
email: <A HREF="eastwestqi.com">eastwestqi@aol.com</A>
Website: <A HREF="eastwestqi.com">eastwestqi.com</A>

From: Dr Xiaoming Tian
Academy of Acupuncture & Chinese Medicine
Wildwood Medical Center
10401 Old Georgetown Road, #102 & #104
Bethesda, Maryland 20814
Tel : (301) 530-5308
Fax: (301) 564-5808

To: Dr Steve Groft July 16, 01
Ms Michele Chang (301) 480-1691

Note: I suggest add something like "some other patients are beneficial from CAM treatments after they fail to respond to conventional medicine. So CAM is used as an alternative treatment choices to meet patient's need" —

To page 2, after the 8th line from bottom "whole person" I because CAM is complementary & also alternative Medicine such as

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Tel : (301) 530-5308
Fax: (301) 564-5808

Using P.T. to beat sciatica may not work, or taking celebrex / Vioxx may not improve, however patient decides to use acupuncture tx, & his/her sciatica was completely gone, we could call "alternative", it is not "complementary"

Many thanks

Ming

2 pages

Geraldine B. Pollen, M.A.
Senior Program Analyst
TEL: 301-435-6233
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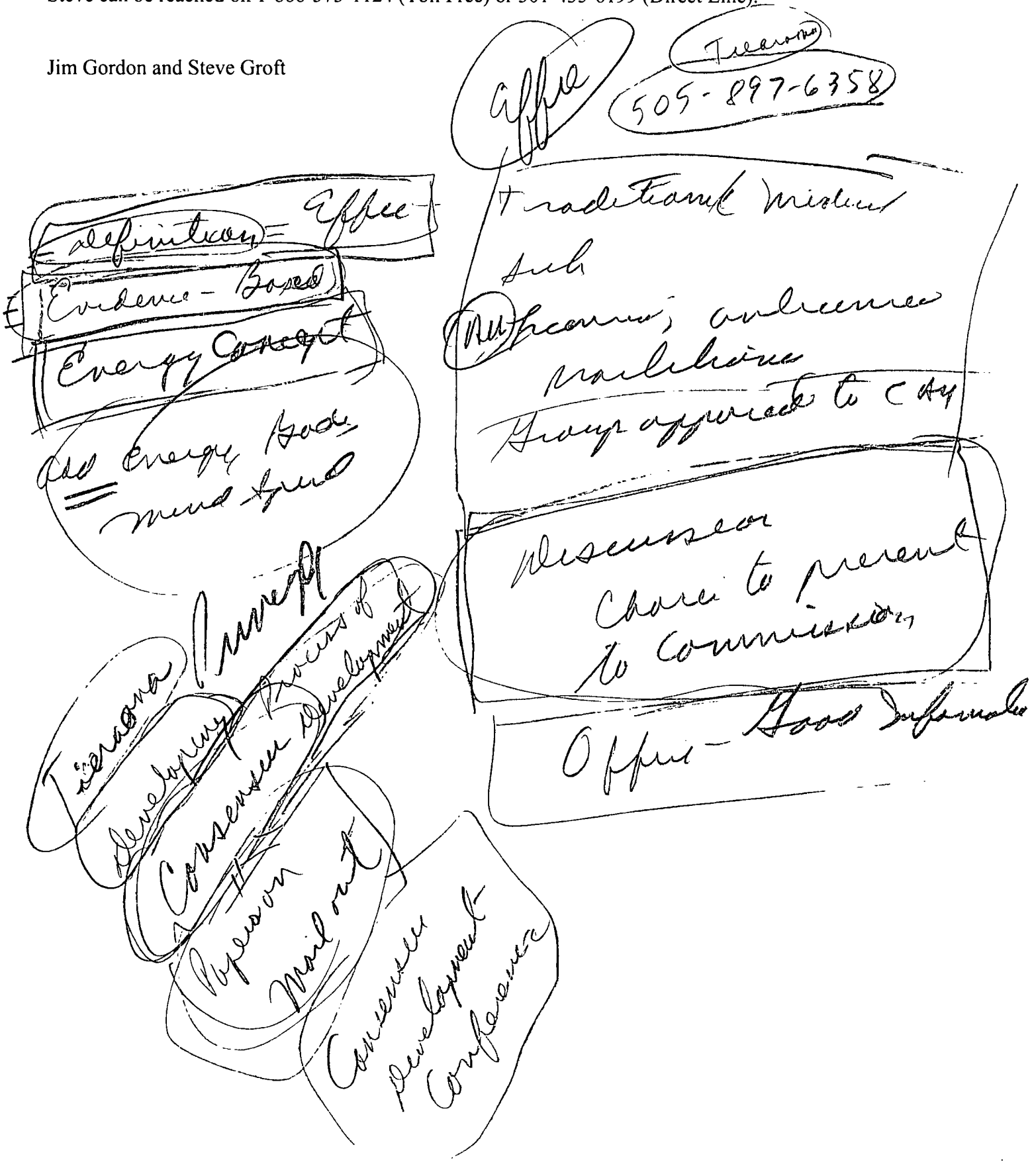
Jim Swyers
Writer-Editor
E-MAIL: jpswyers@starpower.net

about them. After these discussions, we will complete the re-draft of the report and send it out to you again.

Steve can be reached on 1-866-373-1124 (Toll Free) or 301-435-6199 (Direct Line).

Jim Gordon and Steve Groft



6/17/01 State Issues & Office Georgetown
Report Comments

If they both mentioned before we eliminate Rec.

②

- Eliminate Recommendations
- Suggestions from Public
- ~~Chairman's Report~~ =
- Ex Director's Report =
- Commissioner's Report =
- Disagree

Working Groups
- move forward

Village Voice
(KAM.

Commission word
- More Time
- Ownership

Jim (World View)
Vision Section -
Can Select other - do it yourself

Loss of Time

Neutral Stance / Reality
Sense of Frustration & not adequately Review Time, Voice not being heard

Survey of Commissioners of Options

Jim Sawyers /
= Introduction
- Hx

Zen Path to our Goals → Jim Prepare World Vision

Jim Sawyer - Managing Editor

(Status Advocacy vs Neutral
Commission members → Professional Neutral -
advocacy

PH + S
Report
Recommendations

International - Status -

Discontent - Can Not make leaps - Resign

Groft, Stephen (NCCAM)

From: Veronicapgdc@aol.com

Sent: Monday, July 16, 2001 12:23 PM

To: Groft, Stephen (NCCAM)

Subject: July 12th draft

Dear Steve,
I've just reread the draft after having the opportunity to read the comments of Linnea, Joe, and Dean.

I agree that the July meeting left quite a bit undecided; however, there was strong agreement on the ten principals. So, my first suggestion is that we present them with "bullets" and not let them run into each other the way that the present draft allows.

Secondly, my ongoing concern, as expressed at each meeting has to do with vocabulary. We are not going to be able to change the paradigm to health while using such terms as defined in my dictionary as:
MODALITY: (Medical) "rare"-The employment of, or the method of employment of, as therapeutic agent. (I counted the use of this word four times.)
vs.
APPROACH-To begin dealing with.

The word modality is used several times in this draft and can easily be changed to a word (like approach) that better reflects the full spectrum of CAM.

THERAPY-"Treatment of disease or any physical or mental disorder by medical or physical means, usually excluding surgery; sometimes used in compounds (hydrotherapy).

MEDICAL NECESSITY
Not a good basis to determine appropriateness of care. Chiropractors, and I imagine others, can testify to the insurmountable barriers this term has created.

Under the discussion of Consumer Choice and Safe Access to CAM Practices and Products, there is no discussion of creating the Federal umbrella for legitimate researchers to protect them from State Board disciplinary actions.

Under D. The Education and Training of Health Care Practitioners in CAM, paragraph 3, reference is made for the "need to educate CAM practitioners in the basics of conventional medicine so that they can recognize the limits of their clinical expertise and make appropriate referrals to conventional physicians and other health care providers." Boy, if there was ever a need to "recognize the limits" of anything, it is the limits of drugs and surgery, especially as we move the focus from diagnosis and treatment to health and wellness. At least that reference should reciprocate the responsibility for referral both ways.

Thank you for the opportunity to comment at this stage.

Veronica

Axelrod, Corinne (NCCAM)

From: Groft, Stephen (NCCAM)
Sent: Monday, July 16, 2001 2:49 PM
To: Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); Jim Swyers; Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: FW: Draft Interim Progress Report

-----Original Message-----
From: Lowdogmd@aol.com [mailto:Lowdogmd@aol.com]
Sent: Monday, July 16, 2001 12:51 PM
To: Groft, Stephen (NCCAM)
Subject: Re: Draft Interim Progress Report

Steve,

The study was published in the New England Journal - here is an emailed article from Reuter's that references it. Thank you for taking the time to talk with me this morning. I would like to summarize my comments about the interim report that we discussed this morning:

1) Access and delivery - I do not believe that we have consensus on the recommendations at this point and do not feel that we should include any in this report.

2) Wellness - I believe that it is premature to make recommendations on the use of CAM for preventing illness and maintaining health. At this time there is no evidence that acupuncture prevents any disease or that chiropractic increases health and well-being. I do not believe that we have consensus on these recommendations and do not believe we should include any in this report.

3) Special Office (Section E) - While I agree in principle, the Commission has not had the opportunity to discuss this in detail and reach consensus about the recommendations being made.

I also think that in addition to Eisenberg's study we should include some of the recent studies that have shown that 6.5 - 10% of the population visit CAM practitioners. (NEJM article referenced below; 1997 Medical Expenditure Panel Survey (MEPS) which 24, 676 people responded to and found that 6.5% of Americans used both conventional and "unconventional" medical servies and that 1.8% used only "unconventional therapies, etc.).

I felt that the initial sections A and B were well written and represent

the
consensus of the group thus far. Keep up the good work.

Tieraona

From Reuters Health:
Healthcare use little changed in 40 years
By Karen Pallarito
NEW YORK, Jun 28 (Reuters Health) - Despite tremendous upheaval in the financing and delivery of healthcare in the US, Americans' use of health services has changed little since John F. Kennedy was president, a new study finds.
Each month, an estimated 800 of every 1,000 American men, women and children experience health-related symptoms, according to national survey data. Of these, 217 visit a physician, 13 visit an emergency room and eight are hospitalized, researchers report in the June 28th issue of The New England Journal of Medicine.
"That certainly surprised us," said study co-author Dr. David Lanier of the Agency for Healthcare Research and Quality in Rockville, Maryland. "We expected huge changes when we first began the study."
The report updates a 1961 study of the "ecology" of healthcare. The original study estimated that in a population of 1,000 adults, 750 reported an illness each month, 250 consulted a physician and nine were hospitalized.
Why so little change? The authors suggest that people's use of healthcare services depends more on their own preferences than on changes in the way healthcare system is organized.
Another possibility is that various developments in healthcare have offset increased use. "For example," they write, "an increase in the proportion of older persons with chronic disease may have resulted in more office visits and hospital stays, but cost containment by hospitals and the shifting of care to outpatient departments and patients' homes may have moderated these effects."
The study indicates that, despite the tremendous changes in healthcare delivery since 1961, basic human nature about whether to seek care and where to seek it has not changed that much, Lanier said in an interview.
One slight change is the proliferation of healthcare settings. The study found that 65 out of 1,000 people visited a complementary or alternative care provider each month, and 14 received home healthcare services.

Groft, Stephen (NCCAM)

To: EastWestQi@aol.com
Subject: RE: FW: re Interim Report - For Your Information

Effie,
I think our discussion was that there was an Inadequate opportunity to discuss all parts of the report to draw conclusions and establish recommendations

-----Original Message-----
From: EastWestQi@aol.com [mailto:EastWestQi@aol.com]
Sent: Monday, July 16, 2001 10:29 AM
To: Groft, Stephen (NCCAM)
Subject: Re: FW: re Interim Report - For Your Information

In a message dated 7/16/2001 6:13:30 AM Pacific Daylight Time,
grofts@od31em1.od.nih.gov writes:

<< I feel that we have had an adequate opportunity to discuss the report as a whole deliberative body and that without additional discussion we will not be able to properly fulfill our mandate. >>

DEAR STEVE,

THIS SENTENCE PERHAPS HAS AN ERROR IN IT AND NEEDS CLARIFICATION PLEASE TO MAKE SENSE? DOES HE MEAN "INADEQUATE OPPORTUNITY" ??? I CANNOT ASSUME IT.

THANKS,
EFFIE

Founder and President, East West Academy of Healing Arts (EWAHA)
American Qigong Association (AQA)/World Qigong Federation (WQF)
530 Bush Street, Suite 202
San Francisco, CA 94108
tel: 415-788-2227 fax: 415-788-2242
email: eastwestqi@aol.com
website: eastwestqi.com

Groft, Stephen (NCCAM)

From: linnealarson [linnealarson@mac.com]
Sent: Sunday, July 15, 2001 9:34 PM
To: Groft, Stephen (NCCAM)
Cc: WHC@falcon.mail.pas.earthlink.net
Subject: Reactivate the working groups

Dear Steve,

Although I loathe offering advice which I cannot follow myself I suggest that the commissioners form working groups immediately to provide assistance to you and the staff in rewriting the interim report if the commissioners agree to the proposal Dean made in his earlier email.

I hope and trust that what I gave you last week will be useful to you and the staff.

I apologize at not being able to contribute any more at this time.

Regards,

Linnea

Groft, Stephen (NCCAM)

From: linnealarson [linnealarson@mac.com]
Sent: Sunday, July 15, 2001 4:32 AM
To: Groft, Stephen (NCCAM); tierney334@yahoo.com; cmapaz@totacc.com; bresler@aol.com; deanornish@aol.com; drwarren@artelco.com; eastwestqi@aol.com; gbernier@utmb.edu; georged@ashn.com; jsgordon@mindspring.com; drpizzorno@qwest.net; jrsct6@cs.com; Tom@toms-of-maine.com; lowdogmd.@aol.com; Veronicapgdc@aol.com; wjonas@usuhs.mil; DrFair@haelth.com; mingtian@aol.com; linnealarson@mac.com; jjfins@med.cornell.edu
Cc: Chang, Michele (NCCAM); Axelrod, Corinne (NCCAM); Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); gp13b@nih.gov; Fisher, Ken (NCCAM); Miller, Maureen (NCCAM); jpswyers@starpower.net
Subject: July 14 Draft Interim Report

Dear Steve,
    If this document--which ignores the sense of the Commission as well as my written recommendations submitted on July 8, 2001, and does not read like the work of a health policy expert--is going to be issued in its present form, then I will only endorse its submission to the Secretary if it is clearly marked "Chairman's Interim Report".

Respectfully,
Linnea

A copy of this email mailed to Charlotte R. Kerr, RSM

Groft, Stephen (NCCAM)

From: Lowdogmd@aol.com
Sent: Monday, July 16, 2001 11:46 AM
To: Groft, Stephen (NCCAM)
Subject: Re: FW: re Interim Report - For Your Information

Steve,

Just finished a careful read of the interim report and I found it to be pretty darned good! My only issues are still in the areas of access/delivery and wellness. Did Joe further elaborate what his particular concerns were with the report?

Tieraona

Groft, Stephen (NCCAM)

From: James S. Gordon, MD [jgordon@cmbm.org]
Sent: Friday, July 06, 2001 4:33 PM
To: Groft, Stephen (NCCAM); Chang, Michele (NCCAM); tierney334@yahoo.com; cmapaz@totacc.com; bresler@aol.com; deanornish@aol.com; drwarren@artelco.com; eastwestqi@aol.com; gbernier@utmb.edu; georged@ashn.com; drpizzorno@qwest.net; jjfins@mail.med.cornell.edu; jrsct6@cs.com; linnealarson@mac.com; Tom@toms-of-maine.com; lowdogmd@aol.com; Veronicapgdc@aol.com; wjonas@usuhs.mil; DrFair@haelth.com; mingtian@aol.com
Subject: Thank You

I just wanted to drop everyone a note to thank you all for your active, thoughtful and energetic participation in our recent meetings. I feel we took some major steps in assuming ownership of our collective work and in surfacing and working on differences as well as in coming to consensus on some important issues. I particularly appreciated the leadership of those who were willing to take responsibility for the various areas of our report and of the leaders of the small groups on core principles. It was really good to feel us making so much progress in defining the spirit, as well as the dimensions of our work together. I was glad that we were able to rework the schedule so that we could do that.

I know it's often easier to see what needs to happen when we come together, but it would be extremely helpful if each of you would also let me know on an ongoing basis, if there are areas that you think we need to attend to, or if anything comes up that is of concern to you. This will help in planning the October meeting and making sure we've addressed the subjects that are of central concern to you. Once we have the Interim Report out, the staff will send out a preliminary list of topics that we hope to address in October. If there are others, please let us know.

I also wanted to remind everyone about the schedule for the Interim Report. The staff is going to be working on each of the sections in accordance with our discussions at this last meeting, and adding the material some of you agreed to provide and I'm doing a draft of the introductory section. We'll pull all that together, and with Jim Swyers' editorial guidance, do our best to give it a coherent voice. We hope to have that next draft of the Interim Report to you by Monday, July 9th. At that point, we'll ask you to please get all comments back by Wednesday, July 11. We want to make sure that the report is consistent with the spirit of our meeting and that it covers the content on which we have general agreement. Remember (as I'm sure you do) that we'll address areas where we don't have that kind of general agreement in our discussions about and preparation for the Final Report. The whole staff, together with Jim Swyers and me, will meet on Thursday morning, July 12 and incorporate the changes. Steve will write the letters that need to accompany the report and it will be forwarded to Secretary Thompson and to each of you.

If you want to speak to me about any portion of the report, or anything else, please feel free to call at 202-537-6837, or email me.

Jim

Groft, Stephen (NCCAM)

To: DeanOrnish@aol.com
Subject: RE: Draft Interim Progress Report

Dean,

Thank you very much for your comments. This is one option I was considering and we seem to be gaining some support for it. I too feel it is a beginning for where we would like to go in the final report. I will forward a copy of Joe Fins comment. Joe also wanted to reduce the content and the message right now due to the absence of the opportunity to discuss this version, a departure from the previous draft.

The staff also feels that this is a good starting point to initiate discussions with the working groups for each section of the report. They have done a tremendous amount of work to reduce content even to this level. It will be possible to expand with the help of the working groups the sections even more and then discuss in October and December. We could make the October meeting issue oriented, centered around the recommendations and direction the Commission would like to go.

Thank you for the recommendation and your time from a busy schedule. I hope the family is doing well.

Steve

-----Original Message-----
From: DeanOrnish@aol.com [mailto:DeanOrnish@aol.com]
Sent: Sunday, July 15, 2001 11:59 PM
To: Groft, Stephen (NCCAM); tierney334@yahoo.com; cmapaz@totacc.com; Bresler@aol.com; drwarren@artelco.com; EastWestQi@aol.com; gbernier@utmb.edu; georged@ashn.com; jsgordon@mindspring.com; drpizzorno@qwest.net; jjfins@mail.med.cornell.edu; Jrsct6@cs.com; linnealarson@mac.com; Tom@toms-of-maine.com; Lowdogmd@aol.com; Veronicapgdc@aol.com; wjonas@usuhs.mil; DrFair@haelth.com; MingTian@aol.com
Cc: Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); jpswyers@starpower.net; Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Re: Draft Interim Progress Report

In a message dated 7/13/01 2:50:05 PM Pacific Daylight Time, grofts@od31em1.od.nih.gov writes:

<< Attached in Word Format and Rich Text Format is the revised Draft Interim Progress Report. Please review and provide comments and editorial changes to me by 8:30 a.m., Tuesday July 17. We will address your concerns and comments at that time and send you a copy of the Report when it is submitted to the Secretary DHHS. Several Commission members contributed sections of the report that received considerable re-writing and editing. I hope we have been able to capture the spirit of your thoughts and directions from the discussion held at the July 2-3 meeting.

Please contact me if you have any questions on the report. Our toll-free number for your use is 1-866-373-1124. If you have any difficulty opening the document please send me a note and I will send the document as a full text document. I can also be reached at home at 301-424-1273.

Best wishes to all and we await your thoughtful comments and suggestions.

Steve >>

These issues deserve thoughtful discussion; it is good that they are being raised now. Given the divergence of opinions, I strongly recommend that we

issue an interim report that is based solely on factual information--e.g., here are the members, here is when we met, we heard oral testimony from x people, written testimony from y more, we listened to a wide divergence of opinions and recommendations, here are some of the issues that are under consideration (without making any recommendations on these issues at this time). The report may be only a few pages long, which is fine for now. Less is more.

It is now apparent that there are a number of basic issues that we have not worked out among ourselves. There are legitimate differences of opinion, and many are passionately felt on different sides. Clearly, these are not going to be resolved within the next 48 hours. For example, are we going to take an advocacy position or a more neutral one? Do we need to reach consensus or are we going to have separate dissenting opinions? What do we think about many specific issues that have not yet been resolved?

We can use the time in our remaining meetings to discuss these issues among ourselves rather than hearing more testimony. We can work on drafts of the report via e-mail in-between meetings, and we can schedule telephone conference calls as needed. We can try to find common ground and build consensus with each other. Nothing is more likely to undermine moving the field forward than having dissenting opinions on an interim report. Especially at this vulnerable stage, we all need to feel completely comfortable with what is issued.

The interim report can be used to build consensus with the general public and legislators and avoid giving ammunition to critics at a vulnerable time. I understand that there may be opportunities for legislation in this session, but nothing will make this legislation more vulnerable than mobilizing critics with an interim report that provides easy targets for them. This is a marathon, not a sprint; legislation is an ongoing process. By analogy, it took my colleagues and I more than seven years before HCFA finally agreed to move forward with a demonstration project. An interim report that takes an advocacy position may mobilize powerful forces that will make it much more difficult to advance the field.

I know that a lot of work has been put into drafting this interim report, so my suggestion may arouse a certain amount of frustration. However, none of this work will not be lost or wasted, as it will form the basis for the next round of discussions as we move forward together.

I would value your thoughts and comments.

Respectfully,

Dean

Dean Ornish, M.D.
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Groft, Stephen (NCCAM)

From: EhrlichFins@aol.com
Sent: Saturday, July 14, 2001 5:23 PM
To: sg18b@nih.gov; jjfins@mail.med.cornell.edu
Subject: re Interim Report

14 July 2001

Dear Steve,

As we discussed this afternoon, I wanted to formally inform you that I have decided to abstain on the interim report on procedural grounds. As I noted during the July 2-3 meeting, I feel that we have had an adequate opportunity to discuss the report as a whole deliberative body and that without additional discussion we will not be able to properly fulfill our mandate. I strongly urge that we reconvene for a one day meeting to address the interim report in the amount of detail that it deserves. Please inform my fellow Commissioners of my views and this recommendation.

NOT I SEE

Thanks to you and your staff for all of your continued efforts on behalf of the Commission.

Best,
Joe

Joseph J. Fins, M.D.

Groft, Stephen (NCCAM)

From: EastWestQi@aol.com
Sent: Wednesday, July 18, 2001 3:35 AM
To: Groft, Stephen (NCCAM)
Subject: Interim Report comments....

Dear Steve,

I would agree with Dean Ornish's note with the addition of these:

1. A statement that there are numerous definitions for CAM and give NCCAM's operational definition and a couple of others as an example.
3. There is a need to define "evidence-based".
4. The only real consensus from the people who testified and the commissioners is for the establishment of a center: To act as a clearinghouse and to continue work and also to further carry out the recommendations of WHCCAMP. Recommendations will be forthcoming with the final report. Definitely a statement that denotes the tremendous diversity of opinions, practices which are put under the whole umbrella of CAM in light of over a thousand testimonies that has been heard. And give a brief page on the range of organizations and institutions and individuals who testified to assure them that this process involved have been a very diversified groups.

There are so many unresolved issues.

I think the staff have been a wonderful ongoing supportive group. Thanks.

Loving Qi,
Effie

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DRAFT Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy

July 12, 2001

(NOT FOR RELEASE TO PUBLIC)

I. Introduction

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order 13147 on March 7, 2000, to develop legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public.

The Commission was created by the President and Congress in response to the public's interest in the use of complementary and alternative medicine (CAM) modalities and approaches and in a variety of self-care practices. The Commission was charged with submitting a final report to the President and Congress by March 7, 2002.

This Interim Progress Report provides a brief overview of CAM as well as the Commission and its activities. It also discusses the Commission's progress to date in reaching consensus and developing recommendations around the four major topic areas outlined in the President's Executive Order. Individuals and organizations are encouraged to provide written comments on this Interim Progress Report for further consideration by the Commission through its website or by letter to the Commission staff.

The Commission's Charge

The President's Executive Order (see Appendix 1) charged the Commission to consider four broad topics related to CAM:

- Coordinated research to increase knowledge about CAM practices and products;
- The provision to health care professionals of reliable and useful information about CAM that can be made readily accessible and understandable to the general public;
- Guidance for appropriate access to and delivery of CAM; and
- The education and training of health care practitioners in CAM.

The Commission sees its role as recommending policies to ensure the American public's access to safe and efficacious CAM practices and products and to the practitioners who offer them. It is

also the Commission's responsibility to recommend strategies to increase the availability of authoritative information about the safety and efficacy of all CAM practices, techniques, practitioners, and products.

A. Overview of CAM

Complementary and alternative medicine (CAM) refers to the modalities, practices, techniques, and systems of healing that are used together with ("complementary to") or instead of ("alternative to") conventional medicine. Among the modalities that are most often associated with the term CAM are chiropractic, acupuncture, massage therapy, mind-body techniques (e.g., biofeedback, guided imagery, yoga, and meditation), nutritional therapy, dietary supplements, and herbal products, as well as homeopathy, naturopathic medicine, and various forms of energy healing.

Although the percentage of the use of CAM modalities, practices, and products reported in the published literature varies depending on the population studied and the criteria used to define "CAM," it is clear that CAM use in the United States is significant. One study in 1997 indicated that more outpatient visits were made to CAM practitioners than to primary care physicians. Over the past decade, several nationwide surveys have documented a substantial and growing usage of CAM practices by the American public.[1-4] Furthermore, a number of studies of specialialized clinic populations have documented particularly high use of CAM therapies in individuals with chronic and life-threatening conditions.[5-7] For example, a study published in the July 2000 issue of the Journal of Clinical Oncology[6] indicated that almost 70 per cent of the patients at the MD Anderson Cancer Center in Houston, Texas, were using some form of CAM therapy along with their conventional medical treatment.

National surveys[1-4] have found that most CAM users seek out conventional medical treatment first, and then turn to CAM practitioners and practices. Most people appear to use CAM in conjunction with, not as a replacement for, conventional medical therapy. Users appear to be particularly appreciative of the added time that the CAM practitioners spend with their patient and their focus on the "whole person".

B. An Overview Of The Commission: Its Membership and Activities To Date

Commission Membership

The Commission includes twenty Commissioners representing a diverse range of expertise in medical, scientific research, and CAM fields. The Commissioners include the Chair, James S. Gordon, M.D.; George M. Bernier, Jr., M.D.; David E. Bresler, Ph.D.; Thomas M. Chappell; Effie Poy Yew Chow, Ph.D.; George T. DeVries, III; William R. Fair, M.D.; Joseph J. Fins, M.D.; Veronica Gutierrez, D.C.; Wayne B. Jonas, M.D.; Sister Charlotte R. Kerr, BSN., M.P.H., M.Ac.; Linnea S. Larson, LCSW; Tieraona Low Dog, M.D., A.H.G.; Dean Ornish, M.D.; Joseph

E. Pizzorno, Jr., N.D.; Conchita M. Paz, M.D.; Buford L. Rolin; Julia Scott; Xiaoming Tian, M.D.; and Donald W. Warren, D.D.S. (Appendix 2)

Activities To Date

To date, the Commission has held seven formal meetings in Washington D.C., all of which have included sessions for open public comment. In addition, the Commission held four Town Hall meetings, where hundreds of people gave testimony. In total, the Commission has heard from more than 1,000 speakers and received nearly 2, 000 individual comments and recommendations from the public. The Commission also continues to solicit additional written comments and suggestions from the general public by e-mail, fax, and mail (see below).

Each of the Commission meetings have focused on one or more of the four major topics in the Presidential Executive Order, as follows:

- July 13-14, 2000: Planning Meeting
- October 5-6, 2000: Coordination of CAM Research;
- December 4-5, 2000: Access and Delivery of CAM Services and Products;
- February 22-23, 2001: Education, Training and Credentialing for CAM Practices;
- March 26-27, 2001: Wellness, Self-Care, and Prevention and the Development and Dissemination of CAM Information to the Public; and
- May 14-16, 2001: Coverage and Reimbursement of CAM Services and Coordination of CAM Research.
- July 2-3, 2001: Discussion of the Interim Progress Report and draft recommendations. missing in bul

At the four Town Hall meetings--held in San Francisco, Seattle, New York City and Minneapolis-- testimony was presented on subjects related to all four topic areas. Appendix 3 contains a detailed description of the subjects discussed during the Commission and Town Hall meetings. In addition, the transcripts, agenda, and other information pertaining to all Commission Meetings and Town Halls are available on the Commission's website, http://whccamp.hhs.gov. Additional information, such as Commissioner biographies and a schedule of future meetings, also is readily available at the website. Periodic visits to the website are the best mechanisms to view ongoing activities of the Commission. Comments, recommendations, and suggestions can be sent to the Executive Director though the website, or to whccamp@mail.nih.gov.

II. The Commission's Progress To Date

In developing policy recommendations to ensure the public's health and safety, the Commission recognizes that recommendations about the appropriate use of safe and effective CAM practices and products must be grounded in sound scientific and ethical principles. The Commission, therefore, has placed an emphasis on considering recommendations that promote rigorous science and the appropriate use of the scientific method as well as making the current evidence for CAM practices and products more widely and easily available. Human also emphasizing patient safety in research that complies c̄ Human Research protection

at this point the commission

Other principles the Commission has adopted in its deliberations include: an emphasis on health promotion and wellness in addition to disease prevention and the treatment of illness; a recognition that the body has a remarkable capacity for healing that can be facilitated by addressing the underlying causes of illness and suffering; and attention to all aspects of life that can impact health—physical, mental, emotional, and spiritual; an understanding that each person has unique needs that must be attended to in every therapeutic setting and encounter; and a belief that education in self-care is integral to all and should be taught to all health professionals, as well as to the public at all ages.

The Commission also is focused on maximizing the potential benefits of CAM by considering recommendations that promote collaborations between conventional and CAM health care professionals and researchers and encourage the integrated delivery of CAM along with conventional medicine, where appropriate. Furthermore, the Commission recognizes that consumers have a basic right to choose freely among CAM practitioners and products they believe are beneficial to their health and must be included as partners in any policy or regulatory decisions about CAM access, delivery, and research.

The Commission's final recommendations, which will be based on these principles and informed by the evidence presented and gathered during its deliberations, will be included in the Final Report. The diverse perspectives reflected in the testimony heard, from both advocates and critics, will be considered in the context of these principles and the potential benefits and risks of CAM use in this country. Sections A through D below present an overview of the issues and recommendations under consideration by the Commission along the four major topics outlined in the President's Executive Order.

Section E addresses the need for a centralized office to coordinate CAM efforts at the Federal level to ensure maximal access of the public to safe and efficacious CAM services and products, including reliable and timely information. The need for such an office or coordinating process is something that has emerged out of the Commission's deliberations as well as from public testimony.

In addition, a number of speakers noted that many CAM systems of practice place a significant emphasis on promoting wellness rather than just treating illness and dysfunction. There was considerable public support for the Federal government to take a significant role in helping to shape health promotion initiatives and disseminate information to the public on CAM as well as conventional approaches to wellness and disease prevention. The public testimony and Commission deliberations regarding this issue are presented in Section F.

A. Coordination Of Complementary And Alternative Medicine Research

Americans are increasingly seeking out and using complementary and alternative medicine (CAM) products and practices. In many cases decisions to use these products and practices are being made

without the scientifically-based information necessary to make informed choices about safety and efficacy. Many who testified, from both the CAM and conventional medical communities, agreed on the [redacted] need to make information readily available on the results of CAM research that already exist as well as for more high-quality scientific research as the basis for increasing information for practitioners and the public.

Prevalence of CAM use makes it significant important health issue

Testimony to the Commission described a growing interest in and increasing support for CAM research, not only on the part of the CAM community and the public, but also at the Federal level, in academic health centers, in community hospitals, and in mainstream private practices. This interest has further stimulated CAM professional schools and businesses that manufacture CAM products to enhance their own research capacity. Since public interest in and use of CAM is the primary driving factor for CAM research, the importance of public input in the development of CAM research priorities was often raised during testimony and discussion.

Speakers before the Commission identified various types of CAM research programs they believed were needed including the study of basic mechanisms of action, clinical safety and efficacy, treatment outcomes and health services, including cost effectiveness or health care delivery. Underlying all research, however, is the paramount goal of producing dependable and relevant information for practitioners and the public. They and the Commissioners agreed that to be methodologically sound, all CAM-related studies must have a clear question; a sound study design; a qualified research team; verifiable data; and balanced conclusions that meet acceptable standards of evidence. There was general agreement that the research should meet high standards of design and execution consistent with the type of information needed, and that strategies be applied that appropriately incorporate step-wise approaches to research sequence and design, as is done in many areas of conventional medical research.

Many of those who testified agreed that research on CAM products and practices might be best served by collaborations between conventional and CAM researchers and clinicians, including collaborations with institutional review boards (IRBs). Testimony emphasized the need for continued support for training CAM and conventional researchers to study CAM modalities; increased support for developing research infrastructures; and developing funding initiatives for studying promising unpatentable products. One of the goals of these collaborations would be the production of high-quality research results that meet the rigorous publication requirements of the published and on-line peer-reviewed journals that already set standards for the conventional medical community.

Full range of research should be conducted with concern for the protection of human subjects, and appropriate IRB reviews

The Commission heard testimony identifying as key to progress in CAM research: (1) continuing support for the National Institutes of Health's (NIH) National Center for Complementary and Alternative Medicine, the Office of Dietary Supplements, and the Office of Cancer and Complementary and Alternative Medicine; and (2) continuing interest in and attention to CAM research by other collaborating NIH Institutes and Centers as well as the Agency for Health Research and Quality, and the Food and Drug Administration. Also discussed was support for CAM-related activities by the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Center for Medicaid and Medicare Services (formerly the Health Care Financing Administration), the Centers for Disease Control and Prevention, the Federal Trade Commission, the Consumer Products and Safety Commission, the Veterans Administration, the National Science Foundation, and the Department of Defense. Broad support and coordination for CAM research by the Federal government was seen as essential to assure the types and quality of studies needed.

In addition, there was considerable public support for encouraging the private sector--foundations, product manufacturers, and pharmaceutical companies--to support CAM research and collaborate with the Federal sector in strengthening research efforts and support research infrastructures.

Regulatory Activities

The goal of effective regulations is serving and protecting the public, and effective regulation is shaped by good research. Regulatory activities serve and protect the public by ensuring compliance with standards and removing harmful products from the marketplace.

Testimony provided to the Commission revealed growing concern that the content and purity of CAM products, particularly herbs and dietary supplements, is inconsistent. There is evidence that some products do not contain the ingredients or the amount of ingredients listed on the label, resulting in consumers receiving more, less, or something other than what they understand the label to indicate. All of these could potentially have negative health consequences.

Public testimony supported the importance of the Federal government's role in ensuring that CAM products are safe. This finding is consistent with a recent nationwide survey showing that a majority of Americans support increased government regulatory efforts to ensure that dietary supplements are consistent, pure, and safe.[8] Testimony before the Commission consistently indicated that FDA has this authority through the Dietary Supplement Health and Education Act (DSHEA) but that its resources have not been commensurate with these responsibilities.

A number of speakers, including many from the herb and dietary supplement industries, said it was necessary for the FDA to quickly establish regulations on Good Manufacturing Practices (GMPs) for quality control and standardization. Such GMPs would be a minimum standard for the safety and integrity of all products.

Several speakers also asked for a strengthening and expansion of the FDA's adverse event reporting (AER) system and for this information to be made widely available. The AER is a system through which serious or clinically significant adverse events related to the use of CAM products could be rapidly identified and disseminated. Although the occurrence of adverse events from the use of dietary supplements is considered to be quite small, any adverse event can become a public health issue. A recent report from the Office of the Inspector General (OIG) of the Department of Heath and Human Services, describes the current limitations of the AER for all products and provides recommendations to improve it.

Several CAM investigators also asked that the FDA establish product standards for research investigations. If reliable research results are to be obtained for a particular CAM product, such as an herbal remedy or a dietary supplement, the research community needs a readily available supply of such products with consistent composition from industry sources. There was also support for the establishment of a dedicated CAM-related office and/or CAM-related core review teams to facilitate the regulatory review of CAM products.

Health professionals identified the need for joint Federal and private sector research efforts to develop accurate and useful information for health professionals, including: the use and safety of all CAM products, including any limitations; known interactions with drugs, foods, and other health products; and possible risks to vulnerable populations, including children, the elderly, pregnant and nursing women, and those with certain health conditions or compromised immune systems.

After hearing public testimony and examining additional evidence, the Commissioners agreed that:

- The FDA should fully implement the Dietary Supplement Health and Education Act (DSHEA) and be provided with adequate resources to do so.
- The FDA should continue its work with the herbal and dietary supplements industries to issue and implement the Good Manufacturing Practices for quality control and standardization of ingredients.
- The FDA needs adequate professional staff with expertise in dietary supplements, particularly botanical products. This can be accomplished by hiring new staff with this expertise, by providing training to current staff, and by consulting with skilled CAM clinicians and researchers.

- The recommendations of the OIG report should be implemented to strengthen the adverse event reporting system.

- Manufacturers should make information readily available to consumers and health care professionals on the benefits and risks of dietary supplements through methods such as package inserts,. ~~if available~~.

- Federal agencies and the private sector should develop coordinated efforts to establish and implement guidelines standardizing the identity and purity of products and to address possible contaminants and adulterants.

- The Federal government should support programs and partnerships both in the public and private sector that are seeking to develop standards for product composition, quality, and safety of herbal and dietary supplements.

B. Providing Reliable, Useful Information on CAM to Healthcare Professionals and the Public

The Commission heard testimony that the quality, accuracy, accessibility, and timeliness of information on CAM practices and products vary greatly. There is a significant need for accurate, authoritative, and up-to-date information about CAM. In particular, people with life-threatening and chronic illnesses, as well as those who want to be healthy and prevent future illness, want to know which CAM approaches might work for them, where they can find professionals qualified to provide these services, and how CAM therapies might interact with their conventional treatments. Clinicians, likewise, are interested in assessing the state-of-the-art of the various approaches and learning enough about them so that they can converse with their patients about CAM and make appropriate and authoritative recommendations and referrals.

Internet, Radio, Television, and Print Media

The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and health care providers. The Federal Trade Commission projects predicts that 30 million Americans will seek health information online ~~by 2001 and that this~~ this year number is increasing dramatically.[15] There are numerous CAM-specific web sites as well as a variety of general health information sites that include some CAM information. According to public testimony, some of these sites provide accurate and current information, while many others contain inaccurate, misleading, self-serving, or outdated information.

Despite the expanded use of the Internet as an information source, many people are still without personal access to the Internet or the necessary skills for gaining access to Internet to find accurate information on CAM. The National Library of Medicine(NLM) and the public libraries, through the American Library Association, are helping these groups of people gain access to health information on the Internet. It was suggested that these efforts also could be used to focus on CAM practices and products for all population groups.

As with Internet-based information, television, radio, and print media coverage of CAM benefits and safety issues are often uneven, incomplete, or biased. Media representatives said that the NCCAM, the NLM, the National Cancer Institute (NCI), the Agency for Healthcare Quality and Research (AHRQ), the FDA were all important and useful resources for information on CAM research. However, they said they are hampered in their efforts to obtain objective, comprehensive information about CAM by the lack of an authoritative resource within the Federal government from which questions on diverse policy, programmatic, and other non-research CAM issues can be answered quickly and reliably.

Many members of the general public also testified that they have had difficulty in obtaining adequate information about safety, efficacy, and applicability of CAM practices and products. Many said there is a pressing need for a central repository of CAM information to facilitate public access to such information. Public testimony also focused on the great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups and the need for the development and promotion of CAM information that is targeted to diverse population groups in the United States.

Based on this testimony and information submitted, Commissioners recommended that:

- The Federal government assume a greater leadership role in providing and coordinating authoritative information about CAM practices and products. This information should be provided to the public by a visible and easily accessed format that ensures consistency and quality of the information.

- Federal agencies that provide information to the public through fact sheets, the Internet, etc. should provide information on CAM topics (e.g., reimbursement policies, regulatory issues, use with specific disease, etc.) where it is relevant to their mission and activities.

- The Federal government establish a public education campaign that includes information for consumers to critically analyze all information they receive on treatments that have not been evaluated by the FDA, and teaches them how to evaluate or assess such information.

- The Federal government should help to create a public-private partnership to establish a voluntary code of standards for information available on the Internet and through other media, including standards for ethics and disclosure of conflicts of interest.

- The Federal government should extend privacy protections for health information on the Internet to users of CAM-related sites.

Regulatory Activities

Advertising, marketing, and labeling are important mechanisms for disseminating reliable, useful information to the public about the safety and efficacy of CAM products. The Commission heard

testimony that there is a significant amount of false and misleading advertising, marketing, and labeling of CAM products, particularly in the herbal and dietary supplements arenas. Of particular concern are the vulnerable elderly, non-English speaking people, and low-income populations to whom products or services are marketed that may be unnecessary, harmful, exorbitantly priced, or otherwise detrimental. False and misleading advertising may lead people to seek treatments that not only deprive them of their money but may also delay or interfere with more appropriate or approved treatments. Testimony underscored the urgent need for increased consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising. The involvement of trusted community leaders is essential to successfully educate all consumers and develop strategies to prevent consumer exploitation.

There was public support for sufficient resources for Federal agencies with oversight of advertising of products and services, particularly the Federal Trade Commission (FTC) and the Consumer Products Safety Commission. For example, it is the FTC's responsibility to identify false and deceptive CAM-related health claims, and to take appropriate action to minimize the occurrence of these claims in all media.

C. Access, Delivery, Utilization of CAM Practices And Products

As the number of Americans using CAM practices and products increases, so do the ways that CAM services are offered. Health care systems are responding to consumer "demand" and developing innovative models that expand the traditional meaning of health care services. Patterns of CAM use now include self-care; use of the "solo" CAM practitioner; use of free-standing CAM facilities offering multiple modalities; collaborative models that support referrals, consultation, and co-management; and a variety of integrative models in which CAM and conventional practitioners work together with conventional practitioners recommending, referring, and sometimes providing CAM services. Access to and delivery of health care is a very broad and complex topic, both for conventional health care and CAM. While issues of access to CAM services overlap in many areas with those of conventional medicine, there are also some that are distinct to CAM.

Consumer Choice and Safe Access to CAM Practices and Products

Americans want to be free to choose from among conventional and CAM practitioners, products, and modalities, and they want assurances that practitioners are qualified and that products are safe. A number of people who testified described factors that affect an individual's choice in obtaining CAM services. Key barriers include health insurance and managed care rules (primarily in the areas of coverage and constraints in the use of designated provider networks); availability of providers; and State licensure, certification, and scope of practice laws.

State licensure and certification enables practitioners to lawfully provide the health care services (within a defined "scope of practice") for which they were trained and/or passed examinations for entry to practice. These State regulatory programs sanction a profession and help ensure the

quality and accountability of the profession while protecting the public. Testimony illustrated state-by-state variability in licensure, certification and scope of practice laws for CAM modalities. States may license certain CAM modalities while not licensing others. According to data provided to the Commission, chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 41, 30, and 11 states respectively.

In addition to mandatory licensure or certification, other regulatory approaches include voluntary registration, exemption from licensure, and combinations of these, depending on the specific CAM modality. These variations can impact on the ability to obtain malpractice insurance, the mobility of CAM providers, and reciprocity of CAM services between States.

Several Commission witnesses testified that licensure or certification is not feasible for some categories of CAM practitioners such as Native American and other traditional healers who do not have accredited educational facilities and who function under local community standards. Likewise, the Commission heard from several conventional practitioners who incorporate a number of CAM modalities in their practices and are concerned that their integrative approach does not lend itself to the licensure process. There was also testimony that licensure or certification may not be appropriate or necessary for certain CAM practices, such as Reiki (energy therapy) or the Feldenkrais method (motion therapy), and others that are spiritually-based or educational.

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Incorporating CAM into the U.S. Health Care System

There are challenges and opportunities to face as CAM moves from a more limited role to a fully contributing part of the whole health care system. Witnesses appearing before the Commission testified that greater knowledge and understanding of CAM practices and products on the part of conventional practitioners is needed to facilitate this process. For example, conventional practitioners should have some understanding of botanicals that patients may be using to appreciate possible benefits and potential interactions. They should also have enough knowledge to make appropriate referrals to CAM practitioners when appropriate. Knowledge and respect of other modalities will enhance cooperation and collaboration, and requires ongoing communication and education. CAM practitioners should also know the limits of their modality, and be able to appropriately direct consumers to conventional and other CAM therapies.

Another challenge will be maintaining the philosophy and integrity of CAM as various collaborative and integrative approaches are tried. Testimony indicated the concern on the part of some CAM practitioners that in the process of integration, some CAM therapies may be compromised as they are pulled away from their philosophical and historical roots, and that the effectiveness of the therapy will be diminished and possibly lost.

An area of opportunity for CAM is the special needs of certain populations. The conventional health care system has a history of working on access issues associated with the uninsured, underinsured, chronically ill, terminally ill, disabled, and other vulnerable populations. CAM

We recognize access as a problem.

practitioners also have experience with a number of these populations, and testimony was presented to the Commission on the promising use of several CAM approaches for cancer patients, HIV+ and AIDS patients, persons with addictions, persons with chronic pain, and others.

Coverage And Reimbursement Of CAM Practices And Products

Surveys of employer-sponsored health plans indicate increasing interest in and coverage of CAM services. Surveys have found that these plans have been created as a response to widespread employee demands . Employers are increasingly active in the area of providing CAM benefits mostly as a response to employee requests, to help attract and retain employees, to help improve health, and on some occasions to comply with state mandates. Some employers offer coverage (usually with limitations) as part of a basic benefit package, at least for certain CAM services such as chiropractic care. Other employers offer information programs, on-site services, or a CAM benefit account (such as a $500 annual maximum benefit, with employee co-payments). Others offer discount programs whereby employees may receive CAM services and pay a discounted fee by using a prescreened panel of CAM providers. Also available are benefit riders where employees may opt to participate in a CAM managed care plan that offers certain services through a credentialed network of CAM providers and with utilization controls. Federally sponsored health plans, including military and veterans treatment facilities, are beginning to be make some CAM benefits available.

Still an overwhelming majority of Americans do not have coverage or reimbursement for CAM services or products. They must pay for CAM services for the treatment of diseases as well as prevention and wellness out of pocket. Thus, access to CAM products and practices is limited largely by the ability to pay.

Expanding current insurance coverage to CAM practices and products rests primarily with the purchasers of health plans. Employers and other health plan sponsors are the major purchasers and, in conjunction with insurance and managed care companies, determine what health benefits are covered for most Americans, and how the services are reimbursed.

Federal and State governments are also major purchasers of health care. The Federal government, often through Congressional process, makes decisions regarding the health benefits for Medicare, Medicaid (although this authority is shared with States), the military, veterans, Federal employees, and others. States establish health plans for their employees and other State-sponsored endeavors, and may enhance the benefits available under Medicaid and for the medically indigent. Federal and State programs also help provide a safety net for uninsured and under-insured people.

A range of payers and purchasers testified about the processes, parameters, and hurdles they face in adding covered benefits. The insurance and managed care industries expressed openness to considering expansion of existing benefit plans to coverage of CAM provided that:

- The services and products are no longer investigational;
- The services and products are safe and of consistently high quality;
- Criteria, particularly those of medical necessity, are available to determine when such services should be covered;
- Standards of practice are available for the service or product (for guiding utilization assuring quality care, and managing financial risk in view of the potential for malpractice/ medical liability suits); and
- Practitioners are adequately and reliably educated and trained, as well as qualified by licensure and/or certification.

Health care purchasers interested in offering CAM services often must base their decisions on incomplete information on safety, efficacy, and cost effectiveness. Purchasers testifying before the Commission identified a need for efforts to: (1) develop appropriate coding for CAM services, (2) improve the collection of claims data to examine cost-benefits of CAM, and (3) develop data bases for managing information and conducting research on the cost-effectiveness and utilization of CAM. They also expressed an interest in supporting research to determine whether CAM services and products would be replacements for or "add-ons" to conventional services and products.

Based on the testimony provided to date, the Commission has reached consensus on several areas where specific recommendations need to be made. These areas include:

- Data collection: Public agencies and private organizations should co-sponsor a conference or conferences that could aid in the development of data on the delivery of CAM services and products, such as utilization and cost effectiveness, and encompassing claims data and coding.

- Health services research: Health services research and demonstration projects should be funded by public, private and joint public-private sources regarding the efficacy, cost-effectiveness, and cost-benefits of CAM practices and products.

- Dissemination of research findings. The Federal government should establish and adequately fund efforts to make CAM research results available and accessible to the public and to industry, particularly employers, insurers, and policymakers.

Additional recommendations will be developed for the Final Report.

D. The Education and Training of Health Care Practitioners in CAM.

Increasing the knowledge and understanding of conventional health care practitioners in CAM is essential to the public's health. During testimony, a consistent theme that emerged was the need for a basic or core CAM curriculum for all conventional health care professionals to be developed

at the professional school, postgraduate, and continuing education levels. Such curricula in CAM fundamentals should be developed in conjunction with CAM experts and would establish a sound basis for conventional health professionals to discuss CAM use with their patients, to make referrals to appropriately trained CAM professionals, and to develop an understanding of the interactions between conventional and CAM treatments.

Currently, many patients are reluctant to disclose their CAM usage to their conventional medical physicians out of concern that their doctors may not be accepting of CAM. This situation was identified as a potential health hazard because conventional practitioners often do not know that their patients may be taking herbal or nutritional supplements, for example, which may interact with medical treatments or surgical procedures.

Another significant issue that emerged during testimony was the need to educate CAM practitioners in the basics of conventional medicine so that they can recognize the limits of their clinical expertise and make appropriate referrals to conventional physicians and other health care providers. A number of CAM representatives said that in order to accomplish this objective, there is a need for equal access to funding and other resources for faculty, curricula, and program development. It was suggested that a basic curriculum for CAM students and practitioners should include information on both conventional health care and other CAM modalities and systems of heath care. The training of CAM professionals should include postgraduate and continuing education programs that resemble those currently available to conventional physicians.

The Commission learned about several models of cooperative and collaborative CAM education and training. These innovative programs include ones which expose conventional and CAM students to each other's philosophies and practices and establishing continuing education programs for audiences composed of both conventional and CAM practitioners.

Based on the testimony provided, the Commission is recommending:

- A core curriculum on the fundamentals and principles of CAM, including traditional systems of healing, should be a component of the training of conventional healthcare providers at the graduate, postgraduate, and continuing education levels to facilitate discussions with patients about CAM use and referral to CAM practitioners when appropriate.
- CAM practitioners should be educated on the basics of conventional medicine and the fundamentals and principles of other CAM modalities to maximize opportunities for collaboration and referral procedures to conventional health care providers when appropriate.
- All students in accredited schools, who are learning health professions, whether conventional or CAM, should have equal access to loan and scholarship opportunities.

E. Coordinating And Centralizing Federal CAM Efforts

Despite the interdisciplinary scope of CAM, no centralized Federal administrative entity exists to coordinate CAM activities broadly within government and the private/nonprofit sector. While the Commission will fulfill its mandate to provide recommendations to maximize the benefits of CAM use, addressing the public's health, ensuring the safety of consumers, and integrating safe and effective CAM practices into the current health care system are some tasks that can only be addressed over time. With this understanding in mind, many witnesses, from all sectors of the public and the conventional and CAM communities, recommended the creation of a centralized Federal function be established at the level of the Secretary of Health and Human Services or the Assistant Secretary for Health.

The Commission will continue to review the public's health and safety needs related to CAM use, as provided in testimony. However, based on the initial recommendations proposed in this Interim Progress Report, and in anticipation of those to be proposed in the Final Report, the Commission strongly recommends that the Secretary establish a central coordination office at this time, with well-defined tasks and an adequate budget and staff to accomplish them. The mandates of this Office will include, but not be limited to implementation of the recommendations made by the White House Commission on Complementary and Alternative Medicine Policy.

This office should become the central location for coordinating all Federal non-research CAM activities, for interacting with the public, (including citizens groups, CAM and conventional providers, employers and insurance companies) for providing authoritative and reliable information to the public; for relating to similar offices in other countries; and for ensuring, on an ongoing basis, that the benefits of safe and effective CAM will continue to be made available to all Americans.

The activities of a coordinating office should not preempt or supplant those Federal efforts already in place, particularly the research activities or agenda of the NIH's NCCAM, or the responsibilities of regulatory agencies, such as the FDA, but should serve solely to coordinate, support and enhance Federal efforts at all levels of the Federal sector.

An Advisory Council, with specific representation from the licensed health professions, emerging health professions, and consumers, should be established to ensure adequate and appropriate guidance from all sectors of the public to help guide Federal efforts in CAM. Working closely with the Advisory Council, the office should establish and support joint conferences and working groups and provide consensus recommendations to the Secretary of Health and Human Services, and Congress on key areas of need, particularly those identified by this Commission's Report.

F. CAM In Wellness, Self-Care, And Prevention

The role of CAM in wellness, self-care, and prevention was a topic emphasized throughout the testimony provided to the Commission and was a focus of much discussion by the Commissioners.

For the past 30 years, the U.S. Public Health Service, through the office of the Surgeon General, has provided leadership to the Nation in developing and monitoring goals for health promotion and disease prevention. Beginning in 1979 with the publication of *Healthy People: The Surgeon General's Report on Health Promotion and Disease*, a process was begun that set out goals and objectives for the Nation's health. The most recent report, *Healthy People 2010*, includes the involvement of all of the agencies within the Public Health Service, as well as State and local health departments and a wide range of private sector health organizations.

Testimony presented to the Commission repeatedly illuminated the congruence between the goals of *Healthy People 2010* and the principles and practices of CAM. This testimony also supported and recommended the exploration of CAM practices and products in health promotion, disease prevention, and enhancement of the quality of life. Witnesses testified that the integration of CAM in health promotion and disease prevention can have profound consequences on the wellness and quality of life of individuals, and may impact on the health care delivery system of the United States.

Many CAM practices and products are derived from cultural traditions and practices that are rooted in connections between the body, mind, and spirit and between individual health and social welfare These traditions and their practices seek to promote health and achieve a state of optimal physical, emotional, social, and spiritual functioning for individuals and communities.

Many witnesses supported the view that the current health care system is primarily disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating disease. Prevention activities that are incorporated into the current conventional health care system are often secondary prevention efforts, such as disease screening for early treatment and prevention of worsening of symptoms (e.g., colorectal screening, mammograms, etc.), or offered in response to an already identified illness or condition (e.g., physical therapy for stroke patients, nutrition counseling for diabetics, etc.). Experts believe that the emphasis on wellness, self-care, and prevention in the current health care system needs to be improved, and the incorporation of CAM principles and practices would significantly advance this effect. Indeed, many feel that one of the most important and enduring contributions of CAM will be its emphasis on maintaining wellness and the important role of self-care.

Based on the testimony provided, the Commission is recommending:

- Teaching and encouraging CAM principles (e.g. maintaining a healthy body, mind, and spirit, etc.) at all levels of the educational system, as they apply to wellness, self-care, and prevention.

- Ensuring that conventional health professionals have some training in the role of CAM in wellness, self-care, and prevention.

- Integrating CAM approaches to wellness, self-care, and prevention into workplace health activities.

- Exploring ways to integrate CAM principles (e.g. connection of body, mind and spirit) and practices (e.g., stress reduction techniques) into a national health and wellness initiative.

III. Conclusion

The Commission continues to deliberate at some level on all of the issues discussed in this Interim Report and others in order to fully comply with the Executive Order. Final recommendations may expand upon those offered in this report, and will provide additional proposals for legislative and administrative actions. The Commission continues to study working models from many sources, including those from other countries, to develop recommendations that reflect the diversity of possibilities, as well as what works. The Final Report will provide a contextual overview of complementary and alternative medicine so that recommendations provided enforce principles that guide good health care, including empowering consumers through choice and reliable, accurate information; maximizing access and delivery of safe and efficacious health care; and promoting health and preventing illness by encouraging the well-being of the whole person. In the development of final recommendations, the Commission will continue to solicit and consider the input of the public.

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Appendix 1 Executive Order 13147

Appendix 2 Commission Membership Roster

Appendix 3 Schedule of Commission Meetings and Material Subjects Reviewed

Commission Meetings

July 13-14, 2000 - Planning Meeting

- Discussion of Vision, Issues and Concerns of the Commission Members on Issues Presented in Executive Order
- Development of Meeting Schedule
- Discussion of Website Development and Content

October 5-6, 2000 - Coordination of CAM Research & Achievements, Opportunities, Obstacles and Solutions

- Public Input and Research Priorities
- Federal Support for CAM Research
- Academic Centers and Support for CAM Research
- Research Support and Collaborations at the NIH

- Facilitating CAM Research and Regulatory Challenges
- Research in the Regulatory Framework
- Outcomes Research - Interface between CAM Research and Regulatory Agencies
- Outcomes Research - CAM Research and Experimental Study Design
- Guiding Principles of CAM Perspectives and Practices
- Support for CAM Research - The Not-for-Profit Sector
- Support for CAM Research - The Private Sector
- Support for CAM Research - Federal Agency Support

December 4-5, 2000 - Access and Delivery of CAM Services

- Utilization of CAM Services and Products
- Cost Effectiveness of Selected CAM Services
- Clinical Effectiveness of Selected CAM Services
- Use of CAM for Selected Health Conditions
- Issues in Integrating CAM in Service Delivery
- Meeting Public Needs: Systems of CAM Delivery at Community Health Clinics, in Private Practice and Hospital-based Centers, in Hospice Care, at Academic Research Centers and in Managed Care Organizations.

February 22–23, 2001 - Training, Education, Credentialing and Licensing of CAM Practices

- CAM Education and Training: Establishing Educational Programs
- Continuing CAM Education and Training - Building Knowledge and Skills
- CAM Credentialing and Licensure - Assuring Quality and Accountability in CAM Practices

March 26-27, 2001 - Development and Dissemination of CAM Information

- CAM in the Media - Newspapers, Magazines, Television and Radio
- CAM in the Media - The Internet
- Evaluation of available CAM Information
- Marketing and Advertising of CAM Services and Products

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities
- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

- Not-for-Profit Support for CAM Research
- Investigating the Scientific Bases of CAM Practices
- Approaches to Evaluating CAM Research Literature
- Challenges of CAM Research and Research Training

- Peer Reviews of CAM Research Results in the Published Literature

May 15-16, 2001 - Coverage and Reimbursement of CAM Services

- Health Care Financing in the United States
- Federal Purchasers
- State Perspectives
- Employer Coverage
- The Underinsured, Uninsured and Minorities
- Health Plans and CAM Benefits
- Healthcare Insurance - Providers Perspectives
- Evolving Health Care Systems

also July 2-3 meeting

Town Hall Meetings

September 8, 2000	- San Francisco, CA
October 30-31, 2000	- Seattle, WA
January 23, 2001	- New York City, NY
March 16, 2001	- Minneapolis, MN

testimony from state

Topics Discussed

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems
- Dietary Supplements and Herbal Products
- Education of CAM Providers
- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

Future Meeting Dates of the Commission

- October 4-5, 2001 Washington, D.C.
- December 6-7, 2001 Washington, D.C.

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Issues

Told - Commissioner has not been briefed discussed

Office - not

Well well argued -

Uncomfortable signing on

Abstain - Meet again to discuss - Procedurally

Med to discuss issues

Claim; med data
* Wellness
* Access + Delivery
* Office

Treasons Four dog

Sufficient data needs to be developed to make accessible

CAM - Should or Should Not be

Natall CAM is at some stage of development

Terms - Section A B

All

60.5% of CAM practitioners

10% Loma Linda

Health Trends

Adventist Weight Watchers

Renew Recommendation taking under advisement

39% believe in Astrology

Groft, Stephen (NCCAM)

From: Dr. Joe Pizzorno [drpizzorno@qwest.ent]
Sent: Tuesday, July 17, 2001 11:24 AM
To: Groft, Stephen (NCCAM)
Subject: RE: re Interim Report - Pizzorno Edits

Interim Report - Pizzorno Edit...

Steve,

Attached is the Interim Report with my edits. They are highlighted in yellow to make them easier for you to find.

I must admit to some pretty strong mixed feelings about this version of the Interim Report. I think the original staff draft presented at the July 2&3 meeting far superior. While much of the discussion is quite good and the description of the testimony we received well done, I feel the report has subtly become quite MD-centric. In particular, much of the language recognizing the importance of CAM institutions, professions and established standards has been systematically edited out or redefined as simply modalities. Even the much more moderate, CAM institution and CAM profession supportive recommendations agreed to by the Commission seems to have been removed. For example, the Commissioners clearly agreed to the following quite reasonable education recommendation: "Provide access for accredited or licensed CAM institutions, professions and practitioners to educational and training funding and other resources." Yet, inexplicably, this is not in the Report's recommendations. As I stated in my last e-mail in response to your requests for my evaluation of the education recommendations, this must be included to be consistent with the Commissioners' agreements.

Throughout the text, I have made several recommendations of wording changes to improve (at least from my perspective!) the balance of the Report.

Thanks for your attention and good luck!

Joe

DRAFT Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy

July 12, 2001

(NOT FOR RELEASE TO PUBLIC)

I. Introduction

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order 13147 on March 7, 2000, to develop legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public.

The Commission was created by the President and Congress in response to the public's interest in the use of complementary and alternative medicine (CAM) modalities and approaches and in a variety of self-care practices. The Commission was charged with submitting a final report to the President and Congress by March 7, 2002.

This Interim Progress Report provides a brief overview of CAM as well as the Commission and its activities. It also discusses the Commission's progress to date in reaching consensus and developing recommendations around the four major topic areas outlined in the President's Executive Order. Individuals and organizations are encouraged to provide written comments on this Interim Progress Report for further consideration by the Commission through its website or by letter to the Commission staff.

The Commission's Charge

The President's Executive Order (see Appendix 1) charged the Commission to consider four broad topics related to CAM:

- Coordinated research to increase knowledge about CAM practices and products;
- The provision to health care professionals of reliable and useful information about CAM that can be made readily accessible and understandable to the general public;
- Guidance for appropriate access to and delivery of CAM; and
- The education and training of health care practitioners in CAM.

The Commission sees its role as recommending policies to ensure the American public's access to safe and efficacious CAM practices and products and to the practitioners who offer them. It is

also the Commission's responsibility to recommend strategies to increase the availability of authoritative information about the safety and efficacy of all CAM practices, techniques, practitioners, and products.

A. Overview of CAM

Complementary and alternative medicine (CAM) refers to the modalities, practices, techniques, and systems of healing that are used together with ("complementary to") or instead of ("alternative to") conventional medicine. Among the modalities that are most often associated with the term CAM are chiropractic, acupuncture, massage therapy, mind-body techniques (e.g., biofeedback, guided imagery, yoga, and meditation), nutritional therapy, dietary supplements, and herbal products, as well as homeopathy, naturopathic medicine, and various forms of energy healing.

Although the percentage of the use of CAM modalities, practices, and products reported in the published literature varies depending on the population studied and the criteria used to define "CAM," it is clear that CAM use in the United States is significant. One study in 1997 indicated that more outpatient visits were made to CAM practitioners than to primary care physicians. Over the past decade, several nationwide surveys have documented a substantial and growing usage of CAM practices by the American public.[1-4] Furthermore, a number of studies of specialialized clinic populations have documented particularly high use of CAM therapies in individuals with chronic and life-threatening conditions.[5-7] For example, a study published in the July 2000 issue of the Journal of Clinical Oncology[6] indicated that almost 70 per cent of the patients at the MD Anderson Cancer Center in Houston, Texas, were using some form of CAM therapy along with their conventional medical treatment.

National surveys[1-4] have found that most CAM users seek out conventional medical treatment first, and then turn to CAM practitioners and practices. Most people appear to use CAM in conjunction with, not as a replacement for, conventional medical therapy.[1] Users appear to be particularly appreciative of the added time that the CAM practitioners spend with their patient and their focus on the "whole person".[1]

B. An Overview Of The Commission: Its Membership and Activities To Date

Commission Membership

The Commission includes twenty Commissioners representing a diverse range of expertise in medical, scientific research, and CAM fields. The Commissioners include the Chair, James S. Gordon, M.D.; George M. Bernier, Jr., M.D.; David E. Bresler, Ph.D.; Thomas M. Chappell; Effie Poy Yew Chow, Ph.D.; George T. DeVries, III; William R. Fair, M.D.; Joseph J. Fins, M.D.; Veronica Gutierrez, D.C.; Wayne B. Jonas, M.D.; Sister Charlotte R. Kerr, R.N., M.P.H., M.Ac.; Linnea S. Larson, LCSW; Tieraona Low Dog, M.D., A.H.G.; Dean Ornish, M.D.; Joseph

E. Pizzorno, Jr., N.D.; Conchita M. Paz, M.D.; Buford L. Rolin; Julia Scott; Xiaoming Tian, M.D.; and Donald W. Warren, D.D.S. (Appendix 2)

Activities To Date

To date, the Commission has held seven formal meetings in Washington D.C., all of which have included sessions for open public comment. In addition, the Commission held four Town Hall meetings, where hundreds of people gave testimony. In total, the Commission has heard from more than 1,000 speakers and received nearly 2, 000 individual comments and recommendations from the public. The Commission also continues to solicit additional written comments and suggestions from the general public by e-mail, fax, and mail (see below).

Each of the Commission meetings have focused on one or more of the four major topics in the Presidential Executive Order, as follows:

- July 13-14, 2000: Planning Meeting
- October 5-6, 2000: Coordination of CAM Research;
- December 4-5, 2000: Access and Delivery of CAM Services and Products;
- February 22-23, 2001: Education, Training and Credentialing for CAM Practices;
- March 26-27, 2001: Wellness, Self-Care, and Prevention and the Development and Dissemination of CAM Information to the Public; and
- May 14-16, 2001: Coverage and Reimbursement of CAM Services and Coordination of CAM Research.
- July 2-3, 2001: Discussion of the Interim Progress Report and draft recommendations.

At the four Town Hall meetings--held in San Francisco, Seattle, New York City and Minneapolis--testimony was presented on subjects related to all four topic areas. Appendix 3 contains a detailed description of the subjects discussed during the Commission and Town Hall meetings. In addition, the transcripts, agenda, and other information pertaining to all Commission Meetings and Town Halls are available on the Commission's website, http://whccamp.hhs.gov. Additional information, such as Commissioner biographies and a schedule of future meetings, also is readily available at the website. Periodic visits to the website are the best mechanisms to view ongoing activities of the Commission. Comments, recommendations, and suggestions can be sent to the Executive Director though the website, or to whccamp@mail.nih.gov.

II. The Commission's Progress To Date

In developing policy recommendations to ensure the public's health and safety, the Commission recognizes that recommendations about the appropriate use of safe and effective CAM practices and products must be grounded in sound scientific and ethical principles. The Commission, therefore, has placed an emphasis on considering recommendations that promote rigorous science and the appropriate use of the scientific method as well as making the current evidence for CAM practices and products more widely and easily available.

Other principles the Commission has adopted in its deliberations include: an emphasis on health promotion and wellness in addition to disease prevention and the treatment of illness; a recognition that the body has a remarkable capacity for healing that can be facilitated by addressing the underlying causes of illness and suffering; and attention to all aspects of life that can impact health—physical, mental, emotional, and spiritual; an understanding that each person has unique needs that must be attended to in every therapeutic setting and encounter; and a belief that education in self-care is integral to all and should be taught to all health professionals, as well as to the public at all ages.

The Commission also is focused on maximizing the potential benefits of CAM by considering recommendations that promote collaborations between conventional and CAM health care professionals and researchers and encourage the integrated delivery of CAM along with conventional medicine, where appropriate. Furthermore, the Commission recognizes that consumers have a basic right to choose freely among CAM practitioners and products they believe are beneficial to their health and must be included as partners in any policy or regulatory decisions about CAM access, delivery, and research.

The Commission's final recommendations, which will be based on these principles and informed by the evidence presented and gathered during its deliberations, will be included in the Final Report. The diverse perspectives reflected in the testimony heard, from both advocates and critics, will be considered in the context of these principles and the potential benefits and risks of CAM use in this country. Sections A through D below present an overview of the issues and recommendations under consideration by the Commission along the four major topics outlined in the President's Executive Order.

Section E addresses the need for a centralized office to coordinate CAM efforts at the Federal level to ensure maximal access of the public to safe and efficacious CAM services and products, including reliable and timely information. The need for such an office or coordinating process is something that has emerged out of the Commission's deliberations as well as from public testimony.

In addition, a number of speakers noted that many CAM systems of practice place a significant emphasis on promoting wellness rather than just treating illness and dysfunction. There was considerable public support for the Federal government to take a significant role in helping to shape health promotion initiatives and disseminate information to the public on CAM as well as conventional approaches to wellness and disease prevention. The public testimony and Commission deliberations regarding this issue are presented in Section F.

A. Coordination Of Complementary And Alternative Medicine Research

Americans are increasingly seeking out and using complementary and alternative medicine (CAM) products and practices. In many cases decisions to use these products and practices are being made

without the scientifically-based information necessary to make informed choices about safety and efficacy. Many who testified, from both the CAM and conventional medical communities, agreed on the urgent need to make information readily available on the results of CAM research that already exist as well as for more high-quality scientific research as the basis for increasing information for practitioners and the public.

Testimony to the Commission described a growing interest in and increasing support for CAM research, not only on the part of the CAM community and the public, but also at the Federal level, in accredited CAM and conventional academic health centers, in community hospitals, and in mainstream private practices. This interest has further stimulated CAM professional schools and businesses that manufacture CAM products to enhance their own research capacity. Since public interest in and use of CAM is the primary driving factor for CAM research, the importance of public input in the development of CAM research priorities was often raised during testimony and discussion.

Speakers before the Commission identified various types of CAM research programs they believed were needed including the study of basic mechanisms of action, clinical safety and efficacy, treatment outcomes and health services, including cost effectiveness or health care delivery. Underlying all research, however, is the paramount goal of producing dependable and relevant information for practitioners and the public. They and the Commissioners agreed that to be methodologically sound, all CAM-related studies must have a clear question; a sound study design; a qualified research team; verifiable data; and balanced conclusions that meet acceptable standards of evidence. There was general agreement that the research should meet high standards of design and execution consistent with the type of information needed, and that strategies be applied that appropriately incorporate step-wise approaches to research sequence and design, as is done in many areas of conventional medical research.

Many of those who testified agreed that research on CAM products and practices might be best served by collaborations between conventional and CAM researchers and clinicians, including collaborations with institutional review boards (IRBs). Testimony emphasized the need for continued support for training CAM and conventional researchers to study CAM disciplines, therapies and modalities; increased support for developing research infrastructures, particularly at accredited CAM institutions; and developing funding initiatives for studying promising unpatentable products. One of the goals of these collaborations would be the production of high-quality research results that meet the rigorous publication requirements of the published and on-line peer-reviewed journals that already set standards for the conventional medical community.

The Commission heard testimony identifying as key to progress in CAM research: (1) continuing support for the National Institutes of Health's (NIH) National Center for Complementary and Alternative Medicine, the Office of Dietary Supplements, and the Office of Cancer and Complementary and Alternative Medicine; and (2) continuing interest in and attention to CAM research by other collaborating NIH Institutes and Centers as well as the Agency for Health Research and Quality, and the Food and Drug Administration. Also discussed was support for CAM-related activities by the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Center for Medicaid and Medicare Services (formerly the Health Care Financing Administration), the Centers for Disease Control and Prevention, the Federal Trade Commission, the Consumer Products and Safety Commission, the Veterans Administration, the National Science Foundation, and the Department of Defense. Broad support and coordination for CAM research by the Federal government was seen as essential to assure the types and quality of studies needed. Inclusion of licensed CAM providers in advisory boards and legislation authorizing these activities was frequently recommended as critical to full integration of CAM into the healthcare system.

In addition, there was considerable public support for encouraging the private sector--foundations, product manufacturers, and pharmaceutical companies--to support CAM research and collaborate with the Federal sector in strengthening research efforts and support research infrastructures.

Regulatory Activities

The goal of effective regulations is serving and protecting the public, and effective regulation is shaped by good research. Regulatory activities serve and protect the public by ensuring compliance with standards and removing harmful products from the marketplace.

Testimony provided to the Commission revealed growing concern that the content and purity of CAM products, particularly herbs and dietary supplements, is inconsistent. There is evidence that some products do not contain the ingredients or the amount of ingredients listed on the label, resulting in consumers receiving more, less, or something other than what they understand the label to indicate. All of these could potentially have negative health consequences.

Public testimony supported the importance of the Federal government's role in ensuring that CAM products are safe. This finding is consistent with a recent nationwide survey showing that a majority of Americans support increased government regulatory efforts to ensure that dietary supplements are consistent, pure, and safe.[8] Testimony before the Commission consistently indicated that FDA has this authority through the Dietary Supplement Health and Education Act (DSHEA) but that its resources have not been commensurate with these responsibilities.

A number of speakers, including many from the herb and dietary supplement industries, said it was necessary for the FDA to quickly establish regulations on Good Manufacturing Practices

(GMPs) for quality control and standardization. Such GMPs would be a minimum standard for the safety and integrity of all products.

Several speakers also asked for a strengthening and expansion of the FDA's adverse event reporting (AER) system and for this information to be made widely available. The AER is a system through which serious or clinically significant adverse events related to the use of CAM products could be rapidly identified and disseminated. Although the occurrence of adverse events from the use of dietary supplements is considered to be quite small, any adverse event can become a public health issue. A recent report from the Office of the Inspector General (OIG) of the Department of Heath and Human Services, describes the current limitations of the AER for all products and provides recommendations to improve it.

Several CAM investigators also asked that the FDA establish product standards for research investigations. If reliable research results are to be obtained for a particular CAM product, such as an herbal remedy or a dietary supplement, the research community needs a readily available supply of such products with consistent composition from industry sources. There was also support for the establishment of a dedicated CAM-related office and/or CAM-related core review teams to facilitate the regulatory review of CAM products.

Health professionals identified the need for joint Federal and private sector research efforts to develop accurate and useful information for health professionals, including: the use and safety of all CAM products, including any limitations; known interactions with drugs, foods, and other health products; and possible risks to vulnerable populations, including children, the elderly, pregnant and nursing women, and those with certain health conditions or compromised immune systems.

After hearing public testimony and examining additional evidence, the Commissioners agreed that:

- The FDA should fully implement the Dietary Supplement Health and Education Act (DSHEA) and be provided with adequate resources to do so.

- The FDA should continue its work with the herbal and dietary supplements industries to issue and implement the Good Manufacturing Practices for quality control and standardization of ingredients.

- The FDA needs adequate professional staff with expertise in dietary supplements, particularly botanical products. This can be accomplished both by hiring new staff with this expertise, by providing training to current staff, and by consulting with skilled CAM clinicians and researchers.

- The recommendations of the OIG report should be implemented to strengthen the adverse event reporting system.

- Manufacturers should make information readily available to consumers and health care professionals on the benefits and risks of dietary supplements through methods such as package inserts, if available.

- Federal agencies and the private sector should develop coordinated efforts to establish and implement guidelines standardizing the identity and purity of products and to address possible contaminants and adulterants.

- The Federal government should support programs and partnerships both in the public and private sector that are seeking to develop standards for product composition, quality, and safety of herbal and dietary supplements.

B. Providing Reliable, Useful Information on CAM to Healthcare Professionals and the Public

The Commission heard testimony that the quality, accuracy, accessibility, and timeliness of information on CAM practices and products vary greatly. There is a significant need for accurate, authoritative, and up-to-date information about CAM. In particular, people with life-threatening and chronic illnesses, as well as those who want to be healthy and prevent future illness, want to know which CAM approaches might work for them, where they can find professionals qualified to provide these services, and how CAM therapies might interact with their conventional treatments. Clinicians, likewise, are interested in assessing the state-of-the-art of the various approaches and learning enough about them so that they can converse with their patients about CAM and make appropriate and authoritative recommendations and referrals.

Internet, Radio, Television, and Print Media

The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and health care providers. The Federal Trade Commission predicts that 30 million Americans will seek health information online by 2001 and that this number is increasing dramatically.[15] There are numerous CAM-specific web sites as well as a variety of general health information sites that include some CAM information. According to public testimony, some of these sites provide accurate and current information, while many others contain inaccurate, misleading, self-serving, or outdated information.

Despite the expanded use of the Internet as an information source, many people are still without personal access to the Internet or the necessary skills for gaining access to Internet to find accurate information on CAM. The National Library of Medicine(NLM) and the public libraries, through the American Library Association, are helping these groups of people gain access to health information on the Internet. It was suggested that these efforts also could be used to focus on CAM practices and products for all population groups.

As with Internet-based information, television, radio, and print media coverage of CAM benefits and safety issues are often uneven, incomplete, or biased. Media representatives said that the NCCAM, the NLM, the National Cancer Institute (NCI), the Agency for Healthcare Quality and Research (AHRQ), the FDA were all important and useful resources for information on CAM research. However, they said they are hampered in their efforts to obtain objective, comprehensive information about CAM by the lack of an authoritative resource within the Federal government from which questions on diverse policy, programmatic, and other non-research CAM issues can be answered quickly and reliably.

Many members of the general public also testified that they have had difficulty in obtaining adequate information about safety, efficacy, and applicability of CAM practices and products. Many said there is a pressing need for a central repository of CAM information to facilitate public access to such information. Public testimony also focused on the great variability in CAM therapies and usage among people of different racial, ethnic, or cultural groups and the need for the development and promotion of CAM information that is targeted to diverse population groups in the United States.

Based on this testimony and information submitted, Commissioners recommended that:

- The Federal government assume a greater leadership role in providing and coordinating authoritative information about CAM practices and products. This information should be provided to the public by a visible and easily accessed format that ensures consistency and quality of the information.

- Federal agencies that provide information to the public through fact sheets, the Internet, etc. should provide information on CAM topics (e.g., reimbursement policies, regulatory issues, use with specific disease, etc.) where it is relevant to their mission and activities.

- The Federal government establish a public education campaign that includes information for consumers to critically analyze all information they receive on treatments that have not been evaluated by the FDA, and teaches them how to evaluate or assess such information.

- The Federal government should help to create a public-private partnership to establish a voluntary code of standards for information available on the Internet and through other media, including standards for ethics and disclosure of conflicts of interest.

- The Federal government should extend privacy protections for health information on the Internet to users of CAM-related sites.

Regulatory Activities

Advertising, marketing, and labeling are important mechanisms for disseminating reliable, useful information to the public about the safety and efficacy of CAM products. The Commission heard

testimony that there is a significant amount of false and misleading advertising, marketing, and labeling of CAM products, particularly in the herbal and dietary supplements arenas. Of particular concern are the vulnerable elderly, non-English speaking people, and low-income populations to whom products or services are marketed that may be unnecessary, harmful, exorbitantly priced, or otherwise detrimental. False and misleading advertising may lead people to seek treatments that not only deprive them of their money but may also delay or interfere with more appropriate or approved treatments. Testimony underscored the urgent need for increased consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising. The involvement of trusted community leaders is essential to successfully educate all consumers and develop strategies to prevent consumer exploitation.

There was public support for sufficient resources for Federal agencies with oversight of advertising of products and services, particularly the Federal Trade Commission (FTC) and the Consumer Products Safety Commission. For example, it is the FTC's responsibility to identify false and deceptive CAM-related health claims, and to take appropriate action to minimize the occurrence of these claims in all media.

C. Access, Delivery, Utilization of CAM Practices And Products

As the number of Americans using CAM practices and products increases, so do the ways that CAM services are offered. Health care systems are responding to consumer "demand" and developing innovative models that expand the traditional meaning of health care services. Patterns of CAM use now include self-care; use of the "solo" CAM practitioner; use of free-standing CAM facilities offering multiple modalities; collaborative models that support referrals, consultation, and co-management; and a variety of integrative models in which CAM and conventional practitioners work together with conventional practitioners recommending, referring, and sometimes providing CAM services. Access to and delivery of health care is a very broad and complex topic, both for conventional health care and CAM. While issues of access to CAM services overlap in many areas with those of conventional medicine, there are also some that are distinct to CAM.

Consumer Choice and Safe Access to CAM Practices and Products

Americans want to be free to choose from among conventional and CAM practitioners, products, and modalities, and they want assurances that practitioners are qualified and that products are safe. A number of people who testified described factors that affect an individual's choice in obtaining CAM services. Key barriers include health insurance and managed care rules (primarily in the areas of coverage and constraints in the use of designated provider networks); availability of providers; and State licensure, certification, and scope of practice laws.

State licensure and certification enables practitioners to lawfully provide the health care services (within a defined "scope of practice") for which they were trained and/or passed examinations for entry to practice. These State regulatory programs sanction a profession and help ensure the

quality and accountability of the profession while protecting the public. Testimony illustrated state-by-state variability in licensure, certification and scope of practice laws for CAM modalities. States may license certain CAM modalities while not licensing others. According to data provided to the Commission, chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 41, 30, and 11 states respectively.

In addition to mandatory licensure or certification, other regulatory approaches include voluntary registration, exemption from licensure, and combinations of these, depending on the specific CAM modality or discipline. CAM modalities are typically regulated within CAM disciplines through national accreditation standards and specialty boards. These variations can impact on the ability to obtain malpractice insurance, the mobility of CAM providers, and reciprocity of CAM services between States.

Several Commission witnesses testified that licensure or certification is not feasible for some categories of CAM practitioners such as Native American and other traditional healers who do not have accredited educational facilities and who function under local community standards. Likewise, the Commission heard from several conventional practitioners who incorporate a number of CAM modalities in their practices and are concerned that their integrative approach does not lend itself to the licensure process. There was also testimony that licensure or certification may not be appropriate or necessary for certain CAM practices, such as Reiki (energy therapy) or the Feldenkrais method (motion therapy), and others that are spiritually-based or educational. Testimony and discussion in breakout groups suggested that CAM professions have the choice to enter the mainstream healthcare delivery through the accepted mechanisms of credentialing.

Incorporating CAM into the U.S. Health Care System

There are challenges and opportunities to face as CAM moves from a more limited role to a fully contributing part of the whole health care system. Witnesses appearing before the Commission testified that greater knowledge and understanding of CAM practices and products on the part of conventional practitioners is needed to facilitate this process. For example, conventional practitioners should have some understanding of botanicals that patients may be using to appreciate possible benefits and potential interactions. They should also have enough knowledge to make appropriate referrals to CAM practitioners when appropriate. Knowledge and respect of other modalities will enhance cooperation and collaboration, and requires ongoing communication and education. CAM practitioners should also know the limits of their modality, and be able to appropriately direct consumers to conventional and other CAM therapies.

Another challenge will be maintaining the philosophy, and integrity and established standards of CAM disciplines as various collaborative and integrative approaches are tried. Testimony indicated the concern on the part of some CAM practitioners and professional organizations and institutions that in the process of integration, some CAM therapies may be compromised as they are pulled away from their philosophical and historical roots, and that the effectiveness of the

therapy will be diminished and possibly lost. These issues have been discussed in the British Medical Journal (January 2001) series on integrated health care and significant concern was shown China, India and other countries. Established CAM standards of training in licensed CAM disciplines and credentialed modalities are a valuable resource for accountable integration.

An area of opportunity for CAM is the special needs of certain populations. The conventional health care system has a history of working on access issues associated with the uninsured, underinsured, chronically ill, terminally ill, disabled, and other vulnerable populations. CAM practitioners also have experience with a number of these populations, and testimony was presented to the Commission on the promising use of several CAM approaches for cancer patients, HIV+ and AIDS patients, persons with addictions, persons with chronic pain, and others.

Coverage And Reimbursement Of CAM Practices And Products

Surveys of employer-sponsored health plans indicate increasing interest in and coverage of CAM services. Surveys have found that these plans have been created as a response to widespread employee demands . Employers are increasingly active in the area of providing CAM benefits mostly as a response to employee requests, to help attract and retain employees, to help improve health, and on some occasions to comply with state mandates. Some employers offer coverage (usually with limitations) as part of a basic benefit package, at least for certain CAM services such as chiropractic care. Other employers offer information programs, on-site services, or a CAM benefit account (such as a $500 annual maximum benefit, with employee co-payments). Others offer discount programs whereby employees may receive CAM services and pay a discounted fee by using a prescreened panel of CAM providers. Also available are benefit riders where employees may opt to participate in a CAM managed care plan that offers certain services through a credentialed network of CAM providers and with utilization controls. Federally sponsored health plans, including military and veterans treatment facilities, are beginning to be make some CAM benefits available.

Still an overwhelming majority of Americans do not have coverage or reimbursement for CAM services or products. They must pay for CAM services for the treatment of diseases as well as prevention and wellness out of pocket. Thus, access to CAM products and practices is limited largely by the ability to pay.

Expanding current insurance coverage to CAM practices and products rests primarily with the purchasers of health plans. Employers and other health plan sponsors are the major purchasers and, in conjunction with insurance and managed care companies, determine what health benefits are covered for most Americans, and how the services are reimbursed.

Federal and State governments are also major purchasers of health care. The Federal government, often through Congressional process, makes decisions regarding the health benefits for Medicare, Medicaid (although this authority is shared with States), the military, veterans, Federal employees, and others. States establish health plans for their employees and other State-

sponsored endeavors, and may enhance the benefits available under Medicaid and for the medically indigent. Federal and State programs also help provide a safety net for uninsured and under-insured people.

A range of payers and purchasers testified about the processes, parameters, and hurdles they face in adding covered benefits. The insurance and managed care industries expressed openness to considering expansion of existing benefit plans to coverage of CAM provided that:

- The services and products are no longer investigational;
- The services and products are safe and of consistently high quality;
- Criteria, particularly those of medical necessity, are available to determine when such services should be covered; medical necessity should be determined by credentialed providers trained in the system under review;
- Standards of practice are available for the service or product (for guiding utilization assuring quality care, and managing financial risk in view of the potential for malpractice/ medical liability suits); and
- Practitioners are adequately and reliably educated and trained, as well as qualified by licensure and/or certification.

Health care purchasers interested in offering CAM services often must base their decisions on incomplete information on safety, efficacy, and cost effectiveness. Purchasers testifying before the Commission identified a need for efforts to: (1) develop appropriate coding for CAM services, (2) improve the collection of claims data to examine cost-benefits of CAM, and (3) develop data bases for managing information and conducting research on the cost-effectiveness and utilization of CAM. They also expressed an interest in supporting research to determine whether CAM services and products would be replacements for or "add-ons" to conventional services and products.

Based on the testimony provided to date, the Commission has reached consensus on several areas where specific recommendations need to be made. These areas include:

- Data collection: Public agencies and private organizations should co-sponsor a conference or conferences that could aid in the development of data on the delivery of CAM services and products, such as utilization and cost effectiveness, and encompassing claims data and coding.

- Health services research: Health services research and demonstration projects should be funded by public, private and joint public-private sources regarding the efficacy, cost-effectiveness, and cost-benefits of CAM practices and products.

- Dissemination of research findings. The Federal government should establish and adequately fund efforts to make CAM research results available and accessible to the public and to industry, particularly employers, insurers, and policymakers.

Additional recommendations will be developed for the Final Report.

D. The Education and Training of Health Care Practitioners in CAM.

Increasing the knowledge and understanding of conventional health care practitioners in CAM is essential to the public's health ~~as is supporting education at accredited CAM institutions~~.

During testimony, a consistent theme that emerged was the need for a basic or core CAM curriculum for all conventional health care professionals to be developed at the professional school, postgraduate, and continuing education levels. Such curricula in CAM fundamentals should be developed in conjunction with CAM experts ~~from accredited CAM institutions~~ and would establish a sound basis for conventional health professionals to discuss CAM use with their patients, to make referrals to appropriately trained CAM professionals, and to develop an understanding of the interactions between conventional and CAM treatments.

Currently, many patients are reluctant to disclose their CAM usage to their conventional medical physicians out of concern that their doctors may not be accepting of CAM. This situation was identified as a potential health hazard because conventional practitioners often do not know that their patients may be taking herbal or nutritional supplements, for example, which may interact with medical treatments [9,10] or surgical procedures. [11]

Another significant issue that emerged during testimony was the need to educate CAM practitioners in the basics of conventional medicine, if this was not already a component of their education, so that they can recognize the limits of their clinical expertise and make appropriate referrals to conventional physicians and other health care providers. A number of CAM representatives said that in order to accomplish this objective, there is a need for equal access to funding and other resources for faculty, curricula, and program development. It was suggested that a basic curriculum for CAM students and practitioners should include information on both conventional health care and other CAM modalities and systems of heath care. The training of CAM professionals should include postgraduate and continuing education programs that resemble those currently available to conventional physicians.

The Commission learned about several models of cooperative and collaborative CAM education and training. These innovative programs, include ones which expose conventional and CAM students to each other's philosophies and practices as well as establishing continuing education programs for audiences composed of both conventional and CAM practitioners.

Based on the testimony provided, the Commission is recommending:

- A core curriculum on the fundamentals and principles of CAM, including traditional systems of healing, should be a component of the training of conventional healthcare providers at the graduate, postgraduate, and continuing education levels to facilitate discussions with patients about CAM use and referral to CAM practitioners when appropriate.
- CAM practitioners should be educated on the basics of conventional medicine and the fundamentals and principles of other CAM modalities to maximize opportunities for collaboration and referral procedures to conventional health care providers when appropriate.
- All students in accredited schools, who are learning health professions, whether conventional or CAM, should have equal access to loan and scholarship opportunities.
- Provide access for accredited or licensed CAM institutions, professions and practitioners to educational and training funding and other resources.

E. Coordinating And Centralizing Federal CAM Efforts

Despite the interdisciplinary scope of CAM, no centralized Federal administrative entity exists to coordinate CAM activities broadly within government and the private/nonprofit sector. While the Commission will fulfill its mandate to provide recommendations to maximize the benefits of CAM use, addressing the public's health, ensuring the safety of consumers, and integrating safe and effective CAM practices into the current health care system are some tasks that can only be addressed over time. With this understanding in mind, many witnesses, from all sectors of the public and the conventional and CAM communities, recommended the creation of a centralized Federal function be established at the level of the Secretary of Health and Human Services or the Assistant Secretary for Health.

The Commission will continue to review the public's health and safety needs related to CAM use, as provided in testimony. However, based on the initial recommendations proposed in this Interim Progress Report, and in anticipation of those to be proposed in the Final Report, the Commission strongly recommends that the Secretary establish a central coordination office at this time, with well-defined tasks and an adequate budget and staff to accomplish them. The mandates of this Office will include, but not be limited to implementation of the recommendations made by the White House Commission on Complementary and Alternative Medicine Policy.

This office should become the central location for coordinating all Federal non-research CAM activities, for interacting with the public, (including citizens groups, CAM and conventional providers, employers and insurance companies) for providing authoritative and reliable information to the public; for relating to similar offices in other countries; and for ensuring, on an ongoing basis, that the benefits of safe and effective CAM will continue to be made available to all Americans.

The activities of a coordinating office should not preempt or supplant those Federal efforts already in place, particularly the research activities or agenda of the NIH's NCCAM, or the responsibilities of regulatory agencies, such as the FDA, but should serve solely to coordinate, support and enhance Federal efforts at all levels of the Federal sector.

An Advisory Council, with specific representation from the licensed CAM and conventional health professions, emerging health professions, and consumers, should be established to ensure adequate and appropriate guidance from all sectors of the public to help guide Federal efforts in CAM. Working closely with the Advisory Council, the office should establish and support joint conferences and working groups and provide consensus recommendations to the Secretary of Health and Human Services, and Congress on key areas of need, particularly those identified by this Commission's Report.

F. CAM In Wellness, Self-Care, And Prevention

The role of CAM in wellness, self-care, and prevention was a topic emphasized throughout the testimony provided to the Commission and was a focus of much discussion by the Commissioners.

For the past 30 years, the U.S. Public Health Service, through the office of the Surgeon General, has provided leadership to the Nation in developing and monitoring goals for health promotion and disease prevention. Beginning in 1979 with the publication of *Healthy People: The Surgeon General's Report on Health Promotion and Disease*, a process was begun that set out goals and objectives for the Nation's health. The most recent report, *Healthy People 2010*, includes the involvement of all of the agencies within the Public Health Service, as well as State and local health departments and a wide range of private sector health organizations.

Testimony presented to the Commission repeatedly illuminated the congruence between the goals of *Healthy People 2010* and the principles and practices of CAM. This testimony also supported and recommended the exploration of CAM disciplines, modalities and practices and products in health promotion, disease prevention, and enhancement of the quality of life. Witnesses testified that the integration of CAM in health promotion and disease prevention can have profound consequences on the wellness and quality of life of individuals, and may impact on the health care delivery system of the United States.

Many CAM disciplines, modalities and practices and products are derived from cultural traditions and practices that are rooted in connections between the body, mind, and spirit and between individual health and social welfare These traditions and their practices seek to promote health and achieve a state of optimal physical, emotional, social, and spiritual functioning for individuals and communities.

Many witnesses supported the view that the current health care system is primarily disease-focused, with most of research, education, training, reimbursement, and information development and dissemination directed toward identifying and treating disease. Prevention activities that are incorporated into the current conventional health care system are often secondary prevention efforts, such as disease screening for early treatment and prevention of worsening of symptoms (e.g., colorectal screening, mammograms, etc.), or offered in response to an already identified illness or condition (e.g., physical therapy for stroke patients, nutrition counseling for diabetics, etc.). Experts believe that the emphasis on wellness, self-care, and prevention in the current health care system needs to be improved, and the incorporation of CAM disciplines, principles and practices would significantly advance this effect. Indeed, many feel that one of the most important and enduring contributions of CAM will be its emphasis on maintaining wellness and the important role of self-care.

Based on the testimony provided, the Commission is recommending:

- Teaching and encouraging CAM principles (e.g. maintaining a healthy body, mind, and spirit, etc.) at all levels of the educational system, as they apply to wellness, self-care, and prevention.

- Ensuring that conventional health professionals have some training in the role of CAM in wellness, self-care, and prevention.

- Integrating CAM approaches to wellness, self-care, and prevention into workplace health activities.

- Exploring ways to integrate CAM principles (e.g. connection of body, mind and spirit) and practices (e.g., stress reduction techniques) into a national health and wellness initiative.

- Committing to healthcare pluralism by supporting integration of diverse systems of healing which are rich resources of important strategies, knowledge and practices, which implement the principles enumerated above and foster health promotion.

III. Conclusion

The Commission continues to deliberate at some level on all of the issues discussed in this Interim Report and others in order to fully comply with the Executive Order. Final recommendations may expand upon those offered in this report, and will provide additional proposals for legislative and administrative actions. The Commission continues to study working models from many sources, including those from other countries, to develop recommendations that reflect the diversity of possibilities, as well as what works. The Final Report will provide a contextual overview of complementary and alternative medicine so that recommendations

provided enforce principles that guide good health care, including empowering consumers through choice and reliable, accurate information; maximizing access and delivery of safe and efficacious health care; and promoting health and preventing illness by encouraging the well-being of the whole person. In the development of final recommendations, the Commission will continue to solicit and consider the input of the public.

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Appendix 1 Executive Order 13147

Appendix 2 Commission Membership Roster

Appendix 3 Schedule of Commission Meetings and Material Subjects Reviewed

Commission Meetings

July 13-14, 2000 - Planning Meeting

- Discussion of Vision, Issues and Concerns of the Commission Members on Issues Presented in Executive Order
- Development of Meeting Schedule
- Discussion of Website Development and Content

October 5-6, 2000 - Coordination of CAM Research & Achievements, Opportunities, Obstacles and Solutions

- Public Input and Research Priorities
- Federal Support for CAM Research
- Academic Centers and Support for CAM Research
- Research Support and Collaborations at the NIH
- Facilitating CAM Research and Regulatory Challenges
- Research in the Regulatory Framework
- Outcomes Research - Interface between CAM Research and Regulatory Agencies
- Outcomes Research - CAM Research and Experimental Study Design
- Guiding Principles of CAM Perspectives and Practices
- Support for CAM Research - The Not-for-Profit Sector
- Support for CAM Research - The Private Sector
- Support for CAM Research - Federal Agency Support

December 4-5, 2000 - Access and Delivery of CAM Services

- Utilization of CAM Services and Products
- Cost Effectiveness of Selected CAM Services
- Clinical Effectiveness of Selected CAM Services
- Use of CAM for Selected Health Conditions
- Issues in Integrating CAM in Service Delivery
- Meeting Public Needs: Systems of CAM Delivery at Community Health Clinics, in Private Practice and Hospital-based Centers, in Hospice Care, at Academic Research Centers and in Managed Care Organizations.

February 22–23, 2001 - Training, Education, Credentialing and Licensing of CAM Practices

- CAM Education and Training: Establishing Educational Programs
- Continuing CAM Education and Training - Building Knowledge and Skills
- CAM Credentialing and Licensure - Assuring Quality and Accountability in CAM

Practices

March 26-27, 2001 - Development and Dissemination of CAM Information

- CAM in the Media - Newspapers, Magazines, Television and Radio
- CAM in the Media - The Internet
- Evaluation of available CAM Information
- Marketing and Advertising of CAM Services and Products

March 27, 2001 - CAM in Wellness and Self Care

- Integrative Approaches to Wellness - Children, Families and Communities
- Integrative Approaches to Wellness - Nutrition
- Integrative Approaches to Wellness with Self-Care

May 14-15, 2001 - Coordination of CAM Research

- Not-for-Profit Support for CAM Research
- Investigating the Scientific Bases of CAM Practices
- Approaches to Evaluating CAM Research Literature
- Challenges of CAM Research and Research Training
- Peer Reviews of CAM Research Results in the Published Literature

May 15-16, 2001 - Coverage and Reimbursement of CAM Services

- Health Care Financing in the United States
- Federal Purchasers
- State Perspectives
- Employer Coverage
- The Underinsured, Uninsured and Minorities
- Health Plans and CAM Benefits
- Healthcare Insurance - Providers Perspectives
- Evolving Health Care Systems

Town Hall Meetings

September 8, 2000	- San Francisco, CA
October 30-31, 2000	- Seattle, WA
January 23, 2001	- New York City, NY
March 16, 2001	- Minneapolis, MN

Topics Discussed

- Access, Financing and Reimbursement of CAM Practices and Products
- Integration of CAM into Health Care Delivery Systems
- Dietary Supplements and Herbal Products

- Education of CAM Providers
- Education of Health Professionals
- Culturally - Based Healing Traditions
- Regulation of CAM Practices and Products
- Washington State and Minnesota State Legislation of CAM Practices and Products
- Development and Dissemination of CAM-Related Information
- Accountability of CAM Providers

Future Meeting Dates of the Commission

- October 4-5, 2001 Washington, D.C.
- December 6-7, 2001 Washington, D.C.

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Axelrod, Corinne (NCCAM)

From: Groft, Stephen (NCCAM)
Sent: Thursday, July 19, 2001 2:23 PM
To: 'jsgordon@mindspring.com'; Axelrod, Corinne (NCCAM); Chang, Michele (NCCAM); Fisher, Ken (NCCAM); Jim Swyers; Kaczmarczyk, Joseph (NCCAM); Kingsbury, Doris (NCCAM); Miller, Maureen (NCCAM); Pollen, Geraldine (NCCAM)
Subject: Revised Version of the E-Mail to Commissioners

Attached is the revised version, based on the comments of all. I took Jim Gordon's version and added editorial changes.

Steve

DRAFTB Email to All Commissioners, staff

Subject: Urgent Request for Consideration of Draft Interim Progress Report

Thank you for taking the time to review the Commission's Draft Interim Progress Report and sending us your comments. Some shared their comments with other Commissioners. (Please note you can always do this by pressing the "Respond to All" button) We have reviewed all of the comments we've received up to this time. As could be expected, we have a diversity of opinions on how to proceed with no clear consensus. Now, we need your guidance.

The majority of you responded quite favorably to the general structure and content of the Report and offered specific suggestions on how to improve it. Several Commissioners expressed concern, however, that the Commission recommendations in the most recent draft went too far too fast. There were two major concerns here. 1) Though we did arrive at a consensus on many of the recommendations in the July 2-3rd meeting, ~~the Commission~~, more discussion and specificity are needed before we put Recommendations forward as Commission Recommendations and/or that we would be better served by waiting until the Final Report to make our recommendations.

2) There were two areas - Access and Delivery and the Creation of a Coordinating Office at DHHS - which we did not, ~~because of our discussion on "guiding principles"~~, have a chance to review as a whole Commission in the meeting. Therefore recommendations should not be presented in these areas. Also, there were a number of conflicting comments on the discussion of the major issues

Because we believe it is essential for the Commission to move ahead with consensus, we're now asking each of you to consider three possible options that we can all agree on for the Interim Report. They're listed below, along with the advantages and disadvantages for each. We want you to consider them and let us know what you think. Steve will be calling each of you between now and close of business Friday, July 20th, to discuss them with you. We are hoping to submit the final Interim report to Secretary Thompson by the middle of next week.

1) **The "Basic Facts" Version with no recommendations or discussion of issues identified by the public. A less is better approach.**

Advantages: No controversy, ease in preparation, ease of clearance.
Disadvantages: No information will be provided to the public, Congress and the Administration for action. This approach will raise questions about what the Commission has been doing with the public's money for the

last 12 months. There will be a very limited basis on which to have discussions with Congress or the Administration about the Commission's work, possible legislation, or Administrative change. This will inhibit the engagement of the public in debate about any of the issues before the Commission. Stakeholders may be disappointed by the lack of information.

This represents the position of some Commissioners but does not represent the position of the vast majority of Commissioners.

2) **"Middle-of-the-Road" approach. Identification and discussion of the issues as raised by the public in each of the areas we've covered as we've presented in the Draft, taking your comments into account.** This would focus on what we've heard from the public, but the Commission itself would make no recommendations at this time, deferring them to the Final Report.

Advantages: little controversy and criticism of report; ease of clearance; suggests direction of Commission's thoughts; will generate public discussion on the issues; will provide a sense of the Commission's work and its scope to the public; will offer a platform to begin discussions of possible legislation and administrative recommendations; would offer the public an opportunity to provide input; will shield the Commission from potential criticism at this time; will leave to the Final Report the force of our recommendations. This represents a position which may be the easiest for Commissioners who are unsure about many recommendations to concur with.

Disadvantages: May slow the Commission's momentum: without firm Commission positions or recommendations, efforts at formulating legislation or advancing administrative changes will move more slowly; does not provide our supporters in Congress with specific proposals on which to build legislation in this session of Congress; will likely cause confusion and consternation in stakeholders who have been actively engaged in the Commission process. This position may be particularly distressing to those present at July 2-3 meeting or the many to whom reports of that meeting are circulating. ~~Why they will wonder if~~ we reached consensus about recommendations, are we now withdrawing them? They may wonder why, if consensus was reached, are the recom. being held back?

This represents the position of several Commissioners.

3) **"Modified Version of the July 12th Draft" recently circulated on which Commissioners have made comments.** The modifications would include recommendations in the report but would delete any recommendations about Access and Delivery and the Central Office, because of lack of full Commission discussion.

Advantages: Makes the Commission's work and its considered thought on matters presented clear to Congress, the Administration and the stakeholders; provides a clear basis for legislative and administrative recommendations now and for moving the process ahead in this session of Congress; adheres to public actions in July 2-3rd meeting; fulfills our commitment to Congress; will gain significant public attention. Represents the position we publicly agreed on at the July 2-3 meeting.

Disadvantages: May ~~indeed~~ be a premature representation of the Commission's collective positions; general recommendations will be made before specific implementation has been worked out; may put the Commission in high profile and exposed position; may provoke criticism from those who are opposed to recommendations; may focus too much attention on the Interim as opposed to the Final Report at a time when we're not prepared to discuss in detail the recommendations; Clearance process may be more difficult; may move too quickly for several Commissioners.

This position represents the view of a few Commissioners

We encourage you to tell us within the next day and a half how you feel about these options and talk with Steve

Groft, Stephen (WHCCAMP)

From: Fishback, Lorraine (HHS/OS)
Sent: Friday, September 28, 2001 3:05 PM
To: Groft, Stephen (WHCCAMP)
Cc: Farmer, Lisa (HHS/OS)
Subject: RE: Statof Interim prohgress

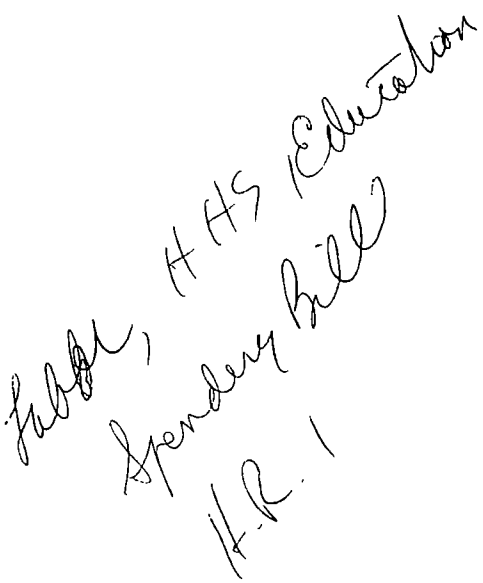
It will be signed and sent today.

-----Original Message-----
From: Groft, Stephen (WHCCAMP)
Sent: Friday, September 28, 2001 1:56 PM
To: Fishback, Lorraine (HHS/OS)
Subject: Statof Interim prohgress

Any news on signatures on the transmittal memo to the Congress for the Commission's Interim progress report?

Thanks.

Steve



Interim Progress Report
White House Commission on Complementary and Alternative Medicine Policy
September 18, 2001

I. Introduction

The White House Commission on Complementary and Alternative Medicine Policy (WHCCAMP) was established by Executive Order 13147 on March 7, 2000, to develop legislative and administrative policy recommendations that will maximize the benefits of complementary and alternative medicine (CAM) practices and products for the general public.

This Interim Progress Report provides a brief overview of CAM as well as the Commission and its activities. It also discusses the Commission's progress to date on developing recommendations around the four major topic areas outlined in the President's Executive Order. Individuals and organizations are encouraged to provide written comments on this Interim Progress Report for consideration by the Commission through its website or by letter to the Commission staff.

The Commission's Charge

The President's Executive Order (see Appendix 1) charged the Commission to consider four broad topics related to CAM:

- Coordinated research to increase knowledge about CAM practices and products;
- 0 The provision to health care professionals of reliable and useful information about CAM that can be made readily accessible and understandable to the general public;
- Guidance for appropriate access to and delivery of CAM; and
- The education and training of health care practitioners in CAM.

A. Overview of CAM

Definitions of complementary and alternative medicine (CAM) continue to evolve

These surveys have found that most CAM users seek out conventional medical treatment first, and then turn to CAM practitioners. Most people appear to use CAM in conjunction with, not as a replacement for, conventional medical therapy, and many seek out care that integrates the best of a variety of approaches.

B. An Overview Of The Commission: Its Membership and Activities To Date

Commission Membership The Commission includes twenty members representing a diverse range of expertise in biomedical research, medical and CAM fields.

Activities To Date

The Commission has held eight formal meetings in Washington D.C., all of which have included sessions for open public comment, and four Town Hall meetings, where hundreds of people gave testimony.

Each of the Commission meetings have focused on one or more of the four major topics in the Presidential Executive Order, as follows:

- July 13-14, 2000: Planning Meeting
- October 5-6, 2000: Coordination of CAM Research
- December 4-5, 2000: Access and Delivery of CAM Services and Products
- February 22-23, 2001: Education, Training and Credentialing for CAM Practices
- March 26-27, 2001: Wellness, Self-Care, and Prevention and the Development and Dissemination of CAM Information to the Public
- May 14-16, 2001: Coverage and Reimbursement of CAM Services and Coordination of CAM Research
- July 2-3, 2001: Discussion of the Interim Progress Report and Draft Recommendations
- October 4-6, 2001 Discussion of Draft Recommendations

At the four Town Hall meetings held in San Francisco, Seattle, New York City and Minneapolis, testimony was presented on subjects related to all four topics.

WEBSITE: http://whccamp.hhs.gov. .

II. The Commission's Progress To Date -Guiding Principles

The Commission supports the promotion of rigorous science and the appropriate use of the scientific method in research studies.

The Commission also supports making the current evidence for CAM practices and products more widely and easily available to the public and health care providers.

The appropriate use of safe and effective CAM practices and products must be grounded in sound scientific and ethical principles.

An emphasis on health promotion and wellness in addition to disease prevention and the treatment of illness

The body has a remarkable capacity for healing that can be facilitated by addressing the underlying causes of illness and suffering; an attention to all aspects of life that can impact health—physical, mental, emotional, environmental, and spiritual;

Each person has unique needs that must be attended to in every therapeutic setting and encounter; and a belief that

Self-care is integral to our nation's healthcare and should be taught to health professionals and the public.

Promote collaborations between conventional and CAM health care professionals and researchers,

Encourage the integrated delivery of CAM along with conventional medicine

Consumers have a basic right to choose freely among qualified CAM practitioners and safe products they believe are beneficial to their health,

Consumers must be included as partners in any policy or regulatory decisions about CAM access, delivery, and research.

Including the need for Federal efforts to ensure access by the public to safe and efficacious CAM services and products, and for reliable and timely information.

Promoting wellness in addition to treating illness and dysfunction. There was considerable public support for the Federal government to help shape health promotion initiatives and disseminate information to the public on CAM as well as conventional approaches to wellness and disease prevention.

A. Coordination Of Complementary And Alternative Medicine Research

More rigorous scientific research and more readily available, dependable and relevant information on the results of CAM research that already exist. .

Testimony to the Commission described a growing interest in and support for CAM research, not only on the part of the CAM community and the public, but also at the Federal level, in academic health centers, in community hospitals, and in mainstream private practices.

The importance of public input into the research agenda was discussed often during testimony.

Speakers identified several types of evidence-based medical research they believe are needed, such as studies on the basic mechanisms of action; clinical safety and efficacy; treatment outcomes; and health services, including cost-effectiveness and health care delivery.

Research Rigor - Methodologically sound, CAM-related studies must have a clear question (hypothesis); a sound study design; a qualified research team; objective, verifiable data; and balanced conclusions that meet acceptable standards of evidence.

There was general agreement that the research should meet high standards of design and execution consistent with the type of information being sought; that strategies be applied that appropriately incorporate step-wise approaches to research sequence and design, as is done in many areas of conventional medical research; and that clinical research comply with human subject protections and appropriate institutional review board guidelines.

CAM research will best be served by collaborations between conventional and CAM researchers and clinicians to produce research results that meet the rigorous publication requirements of published and on-line peer-reviewed journals that already set standards for the conventional medical community.

Testimony also emphasized the need for continued support for training conventional and CAM researchers to study CAM therapies; increased support for developing research infrastructures at accredited CAM and conventional institutions; and for developing funding initiatives to study promising non-patentable products.

Strong and continued support for agencies involved in CAM research and related activities and support for all other Federal agencies with research or related responsibilities.

In addition, there was considerable public support for encouraging the private sector--foundations, product manufacturers, and pharmaceutical companies--to support CAM research and collaborate with the Federal sector in strengthening research efforts.

Regulatory Activities

Ensure that CAM products are safe and the composition and purity of some CAM products,

Researchers asked for standards that will result in a readily available supply of products with consistent composition to assure reliable research results. There was also support for the establishment of a dedicated CAM-related office and/or CAM-related core review teams to facilitate the regulatory review of CAM products.

Strengthening and expanding of the FDA's adverse event reporting (AER) system and for this information to be made widely available

Testimony focused on the need for manufacturers to make information on the benefits and risks of herbs and dietary supplements readily available through methods such as improved labeling, package inserts, and information at points-of-sale. This information should include any limitations; known interactions with drugs, foods, and other health products; and possible risks to

vulnerable populations, including children, the elderly, pregnant and nursing women, and those with certain health conditions or compromised immune systems. [10]

B. Providing Reliable, Useful Information on CAM to Healthcare Professionals and the Public

The quality, accuracy, accessibility, and timeliness of information on CAM practices and products vary greatly, and there is a significant need for accurate, authoritative, and up-to-date information about CAM.

People want to know which CAM approaches might work for them, where they can find professionals qualified to provide these services, and how CAM therapies might interact with their conventional treatments.

Clinicians, likewise, need information on the safety and efficacy of various CAM approaches so that they can converse with their patients about CAM and make appropriate and authoritative recommendations and referrals.

Internet, Radio, Television, and Print Media

The Internet has emerged as a major source of health care information, including information related to CAM, for both consumers and health care providers.

Some of these sites provide accurate and current information, while many others contain inaccurate, misleading, self-serving, or outdated information.

The Commission heard that for people without access to the Internet

Television, radio, and print media coverage of CAM benefits and safety issues is often uneven, incomplete, or biased. Many people from the conventional and CAM professional communities, the public, and the media asked the Federal government to assume a greater leadership role in providing and coordinating authoritative information about CAM practices and products in an easily accessible form that ensures consistent, quality information.

Indigenous systems of healing and the use of culturally based CAM therapies among people of different racial and ethnic groups.

The development and promotion of information on the appropriate use of CAM therapies that would be targeted to diverse population groups in the United States.

Public testimony suggested that the Federal government establish a public education campaign that teaches consumers how to evaluate and assess information on treatments that have not been evaluated by the FDA.

A public-private partnership be created to establish a voluntary code of standards for information available on the Internet and through other media, including standards for ethics and disclosure of conflicts of interest.

Advertising, Marketing, and Labeling Regulatory Activities

There is a significant amount of false and misleading advertising, marketing, and labeling of CAM products and practices, especially herbal and dietary supplements. Of particular concern is the marketing of products or services that may be unnecessary, harmful, or otherwise detrimental to the general public, including low-income populations, the elderly, and non-English speaking people. False and misleading advertising may lead people to seek treatments that are not only costly, but also may delay or interfere with more appropriate or effective treatments.

The role of the FTC in identifying false and deceptive CAM-related health claims, and their efforts to minimize the occurrence of these claims. A need for sufficient resources for Federal agencies such as the FTC and the Consumer Product Safety Commission to improve oversight of CAM products and services..

C. Access to and Delivery of Complementary and Alternative Medicine

Many factors influence access to and delivery and utilization of health care services. These factors may include quality of care; distribution and availability of local providers; licensing, certification, and credentialing of providers; coverage and reimbursement; characteristics of the health care delivery system; and consumer outreach, education, and satisfaction.

As with conventional care, these factors often are more problematic for rural, uninsured, underinsured, and diverse populations of **different racial, ethnic, and cultural backgrounds, as well as geographic, economic, and condition-specific variations**

Americans want to be able to choose from conventional and CAM practices and products, and they want assurances that practitioners are qualified and products are safe. According to testimony, many Americans have neither this choice nor these assurances.

States regulate health care practitioners by helping to assure quality and accountability of professions and providing a process for professional conduct review and disciplinary action. These variations impact access to and delivery of CAM by limiting practitioners' ability to practice lawfully and obtain malpractice insurance.

While some CAM professions endorse licensure and certification to participate more fully in the health care delivery system, several witnesses testified that licensure or certification is not feasible for some categories of CAM practitioners.

Conventional practitioners who incorporate CAM modalities in their practices are concerned that their integrative approach does not lend itself to the licensure process. Some, but not all, of the

conventional practitioners who testified recommended that scope of practice laws be broadened to allow latitude for CAM modalities to be used.

Models of delivery of CAM services. These included solo CAM practitioners, freestanding CAM facilities offering multiple CAM approaches; collaborative models that support referrals, consultation, and co-management; and a variety of integrative models in which CAM practitioners work with conventional practitioners. There has been little evaluation of the effect on access, clinical outcomes, or cost-effectiveness of these models.

While many of those testifying supported integrative models of delivery, a perspective of some CAM practitioners was that the integrity, philosophy, and standards of CAM disciplines may be compromised, and the effectiveness of CAM practices may be diminished or lost, as various integrative approaches are explored. Other CAM practitioners suggested that if integration occurs, it should include entire systems of care and healing rather than only selective incorporation of CAM modalities that fit into the biomedical model.

The importance of educating conventional practitioners in the philosophical and historical roots of CAM disciplines was cited as an important step in preserving the integrity of these other systems of care and healing.

Coverage And Reimbursement Of CAM Practices And Products

Employers and other health plan sponsors are the major purchasers of health coverage and, in conjunction with insurance companies and managed care organizations, they determine which health benefits are covered and how the services are reimbursed for most Americans.

Testimony indicated increasing interest in and coverage of CAM services by employer-sponsored health plans in direct response to employee requests.

Various employer-sponsored health plans were described, including:

limited coverage for certain CAM services (e.g. chiropractic care) as part of a basic benefit package;

on-site services (e.g. yoga classes);

a CAM benefit account (e.g. a $500 annual maximum benefit, with employee co-payments),

discount programs (employees may receive CAM services and pay a discounted fee by using a pre-screened panel of CAM providers),

benefit riders (employees may opt to participate in a CAM managed care plan that offers certain services through a credentialed network of CAM providers and with utilization controls).

Despite such programs, an overwhelming majority of Americans do not have coverage or reimbursement for CAM services or products. They must pay out-of-pocket for CAM treatment of diseases and for prevention and wellness services. Thus, access to CAM products and practices appears to be limited largely by the ability to pay. Other witnesses noted that limited access to CAM practices and products is part of the larger problem of limited access to all health care.

Representatives of the insurance and managed care industries told the Commission that they are interested in adding covered benefits provided that **the services and products are safe**, of **consistently high quality, are no longer investigational**, and **that criteria exist for determining medical necessity**.

Insurance and Managed Care Orgs also want **standards of practice** to **guide utilization, assure quality care, and manage financial risk** (in view of the potential for malpractice/medical liability suits).

Another requirement they specified is that **practitioners are adequately educated, trained, and qualified by licensure and/or certification**.

Those health care purchasers who are interested in offering CAM services often must base their decisions on incomplete information on safety, efficacy, cost benefits, cost-effectiveness and utilization of CAM. They also expressed a strong interest in research on determining whether CAM services and products would be replacements for or additions to conventional services and products.

D. The Education and Training of Health Care Practitioners in CAM

A basic or core CAM curriculum for conventional health care professionals be developed at the professional schools, in postgraduate training programs, and at continuing education programs. It also was suggested that these curricula in CAM fundamentals and principles should be developed in conjunction with CAM experts.

Many people are reluctant to disclose their CAM use to their conventional health care providers whom they believe are not knowledgeable about CAM or interested in CAM approaches to healing.

The need to educate CAM practitioners in the basics of conventional health care so that they can recognize the limits of their clinical expertise and potential complications of their interventions, and make appropriate referrals to conventional health care providers.

Continuing education programs exist for audiences composed of both conventional and CAM practitioners.

A number of CAM representatives reported that there is a need for access to funding and other resources for faculty, curricula, and program development as well as for student access to loan

and scholarship opportunities. Testimony also suggested that training of CAM professionals should include high quality postgraduate and continuing education programs that resemble those currently available to conventional health care providers.

E. Coordinating And Centralizing Federal CAM Efforts

A centralized process at the Federal level to coordinate CAM activities Examples include the Office on Women's Health, or the Office on Minority Health, both established within the Office of the Secretary for Health and Human Services,

These Offices primarily serve to coordinate, support, and enhance ongoing and new Federal efforts relevant to their missions at all levels of the Federal sector. Thus, a centralized coordinating entity for CAM would neither preempt nor supplant those Federal efforts already in place, particularly the research activities or agenda of the NIH's National Center for Complementary and Alternative Medicine. Nor would it supplant the responsibilities of regulatory agencies, such as the Food and Drug Administration and the Federal Trade Commission.

F. CAM In Wellness, Self-Care, Health Promotion And Disease Prevention

The role of CAM in wellness, self-care, health promotion and disease prevention

Witnesses testified that the integration of CAM in health promotion and disease prevention could have profound positive consequences for the wellness and quality of life of individuals, and may impact on the health care delivery system of the United States.

Methods be explored to integrate CAM principles (e.g. connection of body, mind and spirit) and practices (e.g. stress reduction techniques and nutrition) into a national health and wellness initiative.

The incorporation of CAM principles and practices into the current health care system would improve the emphasis on wellness, self-care, health promotion and disease prevention. Many feel that one of the most important and enduring contributions of CAM will be its emphasis on maintaining wellness and the important role of self-care.

Witnesses described programs in schools, the workplace, geriatric centers, and other institutions that are integrating CAM approaches to wellness, self-care, and prevention into their activities, and recommended that these programs be studied and expanded.

III. Conclusion

The Commission continues to study working models from many sources, including those from other countries. The Final Report will provide detailed recommendations regarding the four topics identified in the Executive Order: coordinating research on CAM; providing access to and delivery of CAM practices and products; developing and providing reliable information on CAM;

and educating all health care practitioners in CAM. The recommendations will reflect principles that guide good health care; promote sound scientific inquiry related to CAM; maximize access and delivery of safe and efficacious health care; and promote health and prevent illness by encouraging the well-being of the whole person.