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Neuroscience Building
National Institutes of Health
Conference Rooms C & D
6001 Executive Boulevard
Bethesda, Maryland

PERFORMANCE REPORTING
Phone: 301.871.0010 Toll Free: 877.871.0010

PARTICIPANTS:

Chairperson

James S. Gordon, M.D., Director
The Center for Mind-Body Medicine

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University of Texas Medical Branch

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The Bresler Center, Inc.

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Tom's of Maine, Inc.

Effie Poy Yew Chow, Ph.D., R.N., DiplAc (NCCA)
Qigong Grandmaster
President, East-West Academy of Healing Arts

George T. DeVries, III [Not Present]
Chairman, CEO, American Specialty Health Plans

William R. Fair, M.D.
Attending Surgeon, Urology (Emeritus)
Memorial Sloan-Kettering Cancer Center
Chairman, Clinical Advisory Board of Health, LLC

Joseph J. Fins, M.D., F.A.C.P.
Associate Professor of Medicine,
Weill Medical College of Cornell University
Director of Medical Ethics,
New York Presbyterian Hospital-Cornell Campus

Veronica Gutierrez, D.C.
Gutierrez Family Chiropractic

Wayne B. Jonas, M.D.
Department of Family Medicine
Uniformed Services University of the Health Sciences
F. Edward Hebert School of Medicine

Charlotte Kerr, R.S.M.
Traditional Acupuncture Institute, Inc.

PARTICIPANTS (continued)

Linnea S. Larson, LCSW, LMFT
Associate Director
West Suburban Health Care
Center for Integrative Medicine

Tieraona Low Dog, M.D., A.H.G.
(Private Practice)

Dean Ornish, M.D. [Not Present]
President/Director
Preventive Medicine Research Institute
Clinical Professor of Medicine
University of California, San Francisco

Conchita M. Paz, M.D.
(Private Practice)

Joseph E. Pizzorno, Jr., N.D.
Co-Founder/Founding President, Bastyr University

Buford L. Rolin [Not Present]
Poarch Band of Creek Indians

Julia R. Scott
President
National Black Women's Health Project

Xiaoming Tian, M.D., LAc
Director, Wildwood Acupuncture Center
Academy of Acupuncture & Chinese Medicine

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James Swyers
Writer/Editor

C O N T E N T S

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P R O C E E D I N G S

[8:10 a.m.]

DR. GORDON: Let's just take a minute to sit quietly, and we will begin.

[Moment of silence observed.]

DR. GORDON: Thank you. I hope everybody had some rest last night. I just wanted to say again how much I appreciated the way we worked together yesterday, and everyone's willingness not only to contribute, but also to work toward consensus on some sometimes difficult issues. So it was really terrific, and I appreciate it greatly, and I am looking forward to today.

Steve, any announcements before we begin?

DR. GROFT: We don't have that large of an audience, but for that are here, we are changing the agenda a little bit. So you will see as we go on, it will be the second and third session that will change from yesterday.

DR. GORDON: The other thing is that because of changes in plane schedules, I have to leave at 4:00. Don Warren is going to be chairing the Public Comment Session.

So, Don, thank you very much. I appreciate that. And I appreciate it, those of you who can stay. I have to go to the West Coast tonight, and unfortunately, the later planes aren't running anymore. So I will be leaving at 4:00 today.

DR. GROFT: We will mention the fact that several of the commission members, because of the added security and having to leave early and catch planes, will not be here for the open public session. So it is just something we have to deal with, but we will make sure that those who do have to leave early will get copies of all the testimony that is presented at that time.

DR. GORDON: Great. We are going to begin, and we will be having sort of an informal lunch session in here, once again. We will ask the public to leave the room, and we will have the room to ourselves.

We will begin with Information Development and Dissemination. David is, as you know, ill and not here, so Tieraona will be -- Julia is doing this one? Okay.

So come on up, Julia.

Session V: Information Development and Dissemination

MS. SCOTT: Okay, I am under heavy pressure.

Sitting in for David is quite a challenge, but at any rate, I will attempt to walk us through and get consensus under CAM Information, Development, and Dissemination; Issues 1 through 6, and Tieraona will do 7 through 10.

As has been our routine, I would like to go to the recommendation first, and then if there are any comments about supporting information for that recommendation, to deal with that secondly.

So we will start with the first recommendation.

DR. GORDON: Do you want us to be looking in the text rather than in the summary of recommendations?

MS. SCOTT: I prefer the text.

DR. GORDON: Okay.

MS. SCOTT: Thank you.

The first recommendation, under Information, Development, and Dissemination: The Commission recommends that the Secretary of DHHS establish an interdepartmental task force to identify and eliminate existing gaps in the development and dissemination of CAM information in the federal government, and that increased resources be provided to centralize CAM information for the public and the media.

This should include a toll free number that directs callers to the appropriate department, agency, and/or person for specific CAM information.

Comments?

DR. WARREN: Wasn't this one of the possible functions of our CAM Central?

MS. SCOTT: This is listed in the federal CAM office. As throughout the report, for each category, there are a number of tasks that we felt, if there was going to be a federal CAM office, belonged there. And so, this particular one has been also listed under that office.

DR. WARREN: Good.

MS. SCOTT: No comments? Are we ready to move fast?

DR. FINS: In the background section, there was a very successful cancer CAM phone number that was used in the beginning of the 70s, I think, for information for cancer patients. So maybe there is some parallel legislative history or background that could justify this 800 number concept.

MS. AXELROD: There are actually a lot of 800

numbers, so we can list some of them if you think that would strengthen the text.

MS. SCOTT: Yes, so it is not a new concept.

Okay. Is there consensus on Recommendation No. 1?

DR. GORDON: Yes? Okay, good.

MS. SCOTT: Great. Oh, I'm sorry. Joe Pizzorno?

DR. PIZZORNO: I think an important that has to be dealt with here, or it would be nice if we could deal with it, is standards of evidence because it would be providing information to the consumer how we go about determining the quality of that information and how it should be recommended.

So I think there needs to be some strong discussion about different levels of quality of evidence and how that should be used to determine all information dissemination.

MS. SCOTT: Further on in the recommendations, I believe we do have a recommendation that speaks to the quality of the information.

MS. AXELROD: Eight-hundred numbers, typically,

are referrals, they are clearinghouses. So NCCAM, NCI, others, would be providing them with information. The 800 number people are not going to be developing it.

The other part of your comment, I think Julia did say, will be elsewhere.

MS. SCOTT: There is a recommendation that follows, having to do with the quality of the information standards.

Recommendation No. 2.

DR. GORDON: Did you want to say anything more about that now, or are you okay with waiting until later?

DR. PIZZORNO: I don't believe the later recommendation addresses that, but when we get to it, I will bring it up again.

DR. GORDON: Okay.

MS. SCOTT: Well, why don't we get to it, and if we come up with a sentence, then we can decide whether it goes with the first recommendation or the recommendation that we are coming to.

Recommendation No. 2 has to do with the issue of availability and adequacy of CAM information for diverse groups of consumers.

The Commission recommends that resources be made available to (A) develop CAM informational materials at a level that most of the adult general public can understand and utilize; and (B) support national and local community leaders and organizations in identifying strategies and developing materials to enhance the availability of CAM information to the communities they represent and help prevent special populations from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental.

A little wordy.

DR. LOW DOG: Want a period somewhere?

MS. SCOTT: Yes. Probably a period and maybe some of this could actually in the text, is my thinking.

Joe?

DR. PIZZORNO: Why are we only concerned about protecting special populations? It seems this applies to everyone.

DR. GORDON: What we might do is talk about everyone, and then say there will also be special attention for special populations, that there be particular efforts made to address this issue as it

relates to special populations.

DR. PIZZORNO: Maybe another way is that some portions of the population are especially vulnerable to this and will require additional. Maybe something of that nature.

DR. GORDON: Do you want to provide some wording for that?

MS. SCOTT: It is in the text. It is here simply because we entitled this "For Diverse Groups." Are you suggesting that perhaps we need a general for the general population?

DR. PIZZORNO: I think all of this relates to everybody, but some populations are particular vulnerable.

MS. SCOTT: Right.

DR. PIZZORNO: So I was thinking maybe instead of "the communities they represent, and help prevent special populations from being targeted," we can reword it to something like "represent, with special attention to vulnerable populations." Just remove "help prevent special populations," and say "with special attention to vulnerable populations."

MS. SCOTT: I remember I was one of the dissenting people. I think I wanted something specifically that spoke to diverse groups, and especially the populations that typically are at the tail end of everything that is suggested. I think, very often in recommendations, when you do one for the general population, and then have a few words that say "with special attention to the special populations," very often, you don't get there.

So I think my argument for having a special recommendation for diverse populations was to bring it up a notch in priority. I mean, I agree with what you are saying, that everything that is here should be available for the total population, but somehow I wanted to see something with a little focus directly on those populations.

DR. FINS: Jim, one point on Part A, when you talk about understandability of this information, I think we should say something about it being available in a bilingual format for the Hispanic population, which is our major second language. I think we heard testimony from Dr. Huerta and others that this population was

especially vulnerable.

The second point on the vulnerable special population question, there are ethnic communities that are vulnerable, but there are also lifecycle communities that are vulnerable.

We talked last time about hearings that Senator Breaux convened in the Senate Committee on Aging, where we heard about the elderly being horribly exploited through advertising campaigns, and taken advantage of, using the resources that they don't have to make purchases that they can't afford, and that will not help them, and perhaps even hurt them.

So I think we also may need to make special attention, and we can cite the hearings that Senator Breaux convened over the summer.

MS. SCOTT: So you think that that should be added to the text, or under Recommendations?

DR. FINS: I don't want someone to look at special population, or vulnerable population, and only think of it as an ethnic community, but also lifecycle, the elderly. I don't know what the right language is, but I just want that concept in.

MS. SCOTT: Okay. The text does include the different racial ethnic and culture groups, and does speak about language. But do you think there needs to be more?

DR. FINS: I think we should mention specifically the elderly, because that was the focus of the Senate hearings.

MS. SCOTT: Okay.

DR. GORDON: I would add the elderly and people with life-threatening illnesses, who are also vulnerable in that same way.

DR. FAIR: Maybe we should do a pilot project in Florida where they can't follow an arrow to a name down there, and if it passes there, it can pass anywhere.

DR. GORDON: The question Julia had, thought, was, are there any changes for the wording of the recommendation? I would like to get those now, if there are.

DR. WARREN: Could we look at Suggestion A, there, Development of CAM informational materials. The rest of that sentence, could we put that in the text somehow?

DR. GORDON: We could just say "easily comprehensible," or something like that.

MS. SCOTT: We have a lot of information out there that people cannot access because it is too technical, too medical-ese kind of talk. And so, our point here was that information is only useful if people can understand it. So I think we felt strongly, but I agree with Jim's little two words, easy to understand. We can work with that.

DR. WARREN: What about the statement: "CAM information to the communities they represent"? Can we eliminate "to the communities they represent"? You have already talked about the national and social community leaders and organizations. Maybe it is a little wordy there.

MS. SCOTT: Oh yes, it is definitely wordy. So you are suggesting let it stop at "information," and take out "to the communities they represent."

DR. WARREN: Yes.

MS. SCOTT: Or, just take this all out after it?

DR. WARREN: No, just "to the communities they

represent." Then you would have a (C). After "and" there, you would have a (C), "help prevent special populations." So there are three parts to that recommendation.

DR. FINS: You could use a phrase like "underserved populations, the elderly and the chronically and terminally ill" as three categories in Part C.

MS. SCOTT: Actually, what you are suggesting for Part C is more descriptive of the rest of Part B. I mean, we could still name those special populations. It's not a problem.

DR. GORDON: Do you want to read it the way it is now?

MS. SCOTT: Do you have it, Corinne?

MS. AXELROD: "The Commission recommends that resources be made available to (A) develop CAM informational materials that are easy to understand and utilize; (B) support national and local community leaders and organizations in identifying strategies and developing materials to enhance the availability of CAM information; and (C) help prevent populations" --

MS. SCOTT: You said no (C).

MS. AXELROD: So forget the (C). "And help prevent populations such as the underserved, elderly, chronically or terminally ill from being targeted for products or services that are unnecessary, harmful, exorbitantly priced, or otherwise detrimental."

It is still a little wordy.

DR. GORDON: Great. Before we go on to 3, I want to go back to 1, because I have been reading it over and I agree with Joe. I just want to add one little piece in there. I'm sorry, it will be good for me.

"Interdepartmental task force, which includes representatives of the public and the CAM professions." It may be obvious, but I think it needs to be in there. The beginning of Recommendation No. 1, "The Commission recommends that the Secretary establish an interdepartmental task force which includes."

MS. SCOTT: Oh, I see.

DR. GORDON: We didn't use our phrasing "empowered and informed."

DR. GORDON: I'm sorry, what, Joe? Go ahead.

DR. FINS: Which includes "empowered and informed representatives of the community," which is our

general phrase now for that.

DR. GORDON: Right, and "people with expertise in CAM therapies." The reason I am recommending this is because in the past, regulations have gotten promulgated where people don't know anything about CAM therapies, and it hasn't worked.

MS. AXELROD: I am not sure that it is then an interdepartmental task force, so we may have to change that because an interdepartmental task force is bringing people from the different departments within the federal government to look at their own materials and see where the gaps are. It doesn't preclude them from bringing in experts to assist them. But that is what an interdepartmental task force is.

DR. GORDON: We need to have people within the government who are expert as well.

MS. SCOTT: So we will just add "which includes people with expertise in CAM."

DR. GORDON: And then the representatives of the public as well.

MS. SCOTT: Informed and empowered representatives of the public. Okay. Effie?

DR. CHOW: Sorry, I want to go to No. 2, if we are finished with No. 1. I thought that ethnic minorities were going to be included in there, the aging, the chronically ill, somewhere, because that was one of the major concerns.

MS. SCOTT: Absolutely.

DR. CHOW: And the languages. So with the ethnic community in either (A) or (C).

MS. SCOTT: Yes, you are right. That was my point, too. I prefer to "ethnic" as opposed to "underserved" because I think a lot of people think of "underserved" as only being poor, and it doesn't deal with racial and ethnic discrimination.

DR. FINS: Can we put both in? Because there are underserved populations that are mainstream demographic that are vulnerable, and there are ethnic populations that are vulnerable, too.

MS. SCOTT: Fine. Okay, we are agreed? Do we need to read it again?

DR. FINS: More calls. We have a winner.

MS. SCOTT: Okay. Let's move on to No. 3. This also is dealing with Issue No. 2, which is

Availability and Adequacy of CAM Information for Diverse Groups of Consumers.

"The Commission recommends that current efforts of the National Library of Medicine and the American Library Association, which are detailed in the text, to develop training materials and provide training to librarians in guiding people to find health information be expanded to include CAM information."

Joe.

DR. FINS: Can I put some specific language in here? I think that patients, when they are consumers, they go to their public library, and for many people who do not have Internet access or are not necessarily all that health literate, the librarian should know how to use PubMed and MEDLINE.

I would maybe like to just put in a recommendation that the National Library of Medicine, if they don't already have some sort of program --

DR. LOW DOG: They do.

DR. FINS: They do.

DR. LOW DOG: Maybe just to continue funding it.

DR. FINS: Does it address the skill set for resourcing CAM questions?

MS. SCOTT: Health.

DR. LOW DOG: They have started to include CAM, though.

DR. FINS: It does? Okay.

MS. SCOTT: And this is what this recommendation is.

DR. FINS: Do we have data to know whether that is adequately funded?

DR. LOW DOG: Maybe just to ensure adequate funding for CAM.

DR. FINS: Because I think the current level probably should be expanded.

MS. SCOTT: You mean the funding.

DR. FINS: As Jefferson said, "To march an education is impossible," right? The library is the centerpiece of that. So I think we should direct resources to the local libraries, however we can.

DR. GORDON: I think, actually, this is a good instance where a specific funding recommendation could make a difference.

MS. AXELROD: We are going to be talking with the National Library of Medicine, so we will ask them if additional resources are needed. So we can put that in, but just as a caveat. We want to run it by them and see.

DR. FINS: The other to mention is that hands-on teaching is maybe very important for librarians to learn how to do these skills, and there are regional branches of the National Library of Medicine. So maybe we can get the National Library of Medicine in conjunction with its regional partners or something, so that there is an opportunity for an on-site training program.

DR. GROFT: I think, if you remember Dr. Lindberg's testimony, they do have training sessions throughout the country, and so it is something that I think we could provide a greater emphasis.

MS. SCOTT: Let's see what we have.

MS. AXELROD: "The Commission recommends that increased funding be provided to expand the current efforts of the National Library of Medicine and the American Library Association and its regional partners to develop training materials and provide training to

librarians in guiding people to find health information, including CAM information."

DR. FINS: The regional partners would refer to the National Library of Medicine, not American Library Association.

MS. SCOTT: Okay? Are you all right with that? Consensus? Passed.

DR. GORDON: Yes.

Okay. We are on to Issue 3, which is accuracy and quality of CAM information on the Internet. Recommendation No. 4, "The Commission recommends that the Secretary of DHHS form a public-private partnership to review new and existing websites and develop voluntary standards that will promote accuracy, fairness, comprehensiveness, and timeliness of information on CAM Internet sites as well as disclosure of sources of support and any conflicts of interest. Sites reviewed and found in compliance with the standards could publicize this achievement and display a logo identified with this level of merit."

This recommendation is also one that is included in the federal CAM Office should it be funded.

Comments?

DR. FINS: I would just change two words in the last line on 262, "Publicize this accreditation and display a logo associated with this level of merit," or "level of compliance." "Merit" is okay because it is meritocracy.

MS. SCOTT: Anyone else?

DR. GORDON: Julia, do you just want to comment on the precedent for disclosure of sources of support and any conflicts of interest? Is this really a new idea that we are coming up with or has it been instituted elsewhere?

MS. SCOTT: It has been instituted elsewhere, a lot with drugs. If there is a study done to have to say whether or not it was done by the --

DR. GORDON: Oh, I know. But has it been done on the Internet before?

MS. SCOTT: Well, you can answer that. I don't know that.

MS. AXELROD: Yes.

DR. GORDON: Who has done it? I am just curious.

MS. AXELROD: I don't recall the names of the organizations offhand. There have been attempts, as was addressed in the text, to do this with CAM sites but they have really not been effective.

DR. GORDON: What I am suggesting is that in the text it would be important to talk about this and that this is really a significant step forward to have not only the voluntary standards but also that kind of disclosure, that it is regarded as good ethical practice at medical meetings and that we feel the same needs to be taken onto the Internet.

MS. SCOTT: I think that's a good point.

So that information will be added to the text that would back this.

Are we okay with the recommendation as it is stated?

[No response.]

MS. SCOTT: Passed, great, with those changes.

We are on to Issue 4, availability of CAM information from other --

DR. GORDON: We have Nos. 5 and 6 to go.

MS. SCOTT: Oh, I'm sorry.

DR. GORDON: That's okay.

MS. SCOTT: I'm really moving ahead.

Okay. Recommendation 5. We are still on Issue 3: Accuracy and quality of CAM information on the Internet. "The Commission recommends that funding be provided to the Secretaries of DHHS and Department of Education to jointly conduct a public education campaign that teaches people, including students, how to evaluate health care information, including CAM information, particularly on the Internet."

Consensus? George?

DR. BERNIER: You have split an infinitive there. I don't know if you want to do that.

[Laughter.]

MS. SCOTT: Thank you, George. Corinne will take care of that.

[Laughter.]

MS. AXELROD: I am so embarrassed.

DR. FINS: Just to add to the text section, because I think a lot of these recommendations are generically good, above and beyond CAM, I just think we could say something about scientific literacy as an

important skill of the citizen having to make choices from things like cloning to echinacea, as it were, and all of these educational interventions will bring everybody's knowledge base up. I just think it is generically good. It is not just about CAM literacy, it is a generic kind of skill set.

DR. GORDON: I just have a quick question. Do you think cloning is alternative medicine?

[Laughter.]

MS. SCOTT: No, echinacea.

DR. FINS: Only when done by aliens.

[Laughter.]

MS. AXELROD: Joe, did you want that in the recommendation, or in the text? The scientific literacy part, not the cloning.

MS. SCOTT: Joe? In the text?

DR. FINS: I am being abducted by an alien, I'm sorry.

[Laughter.]

MS. SCOTT: In the text?

DR. FINS: Yes.

MS. SCOTT: Thank you.

So we have consensus on Recommendation 5. Hearing no dissent, except for the split infinitive, which we will correct when we figure out what it is.

[Laughter.]

MS. SCOTT: No, it's okay.

MS. AXELROD: Tell us what it is.

MS. SCOTT: "Jointly conduct."

DR. BERNIER: When you say "to jointly conduct." It should be "to conduct jointly."

MS. SCOTT: "Jointly," okay. Back in school.

Recommendation 6: "The Commission recommends that Congress protect the privacy of individuals using CAM Internet sites by, (A) requiring all health information sites, including CAM sites, to disclose if users are tracked and how that information is utilized, including whether that information is sold to third parties and stored; and, (B) expanding existing legislation or regulations to assure that the privacy of CAM health information seekers on the Internet is protected."

Comments?

DR. FAIR: Since we are on literacy, I think it

is "ensure."

DR. LOW DOG: We would like to make a recommendation that all the staff take a course in literacy.

[Laughter.]

MS. SCOTT: With that change, do we have consensus?

[No response.]

MS. SCOTT: Great, okay.

Issue 4: Availability of CAM information from other countries and in other languages. We have one recommendation: "The Commission recommends that barriers to identifying and translating relevant articles, reports, and other materials be identified; strategies be developed to overcome these barriers; and that relevant and high-quality scientific materials are made available to researchers, clinicians, policymakers, and others."

Joe?

DR. FINS: I like the spirit of this recommendation, but I think it is exceedingly ambitious and difficult to achieve, and I might tone it down a little bit by saying that PubMed and the National Library

of Medicine should at least provide abstracts of relevant articles that are coming from other countries in different languages.

I mean, I think there is a mechanism to do this. It is very hard to translate things into full text, but we do get abstracts, in English, of foreign language publications, and then the investigator and the public can get that information.

Then, it is a problem, but I think it is a huge generic problem, and there is a mechanism to expand it under the rubric of the abstract service that is on PubMed.

DR. GORDON: The problem I have is that the abstracts are relatively easy to get in translation. It is the full text that is the difficult issue here. I agree it is a huge task.

Wayne, I am wondering if you have any thoughts in this realm of how we can make some differentiations between how we can get some full-text translations, or make a category of full-text translations without trying to go for all of them, so it will make it more feasible.

DR. JONAS: Well, you can't, obviously, do all

of them, but what you do is, you have individuals who are knowledgeable about the literature, and in the native language do summaries of the area, and then select out the most pertinent studies and do full-text translations of those. I think that is the only feasible approach.

It's like the qi gong literature in Chinese medicine, it's a huge literature.

MS. SCOTT: Joe?

MR. PIZZORNO: I actually very much like the idea of going for full text. I don't know if you saw the article in JAMA in December '99, but they looked at 11 of the leading conventional medical journals and found that two-thirds of the abstracts were wrong -- I'm sorry, had inaccuracies in them, and that people, going by the abstracts, would often actually arrive at the wrong conclusions. So we need to have full-text translations for these evaluations.

DR. FINS: Maybe we just need to say something about the NCCAM. Maybe NCCAM, because this is an academic exercise, should review the pertinent literature and designate leading articles that they are aware of for translation, because I think to translate everything out

there, we will get nothing, but if there is some kind of winnowing or editorial selection process, we are more likely to have the articles that you would want to read available in translation.

MR. GROFT: I think it could be a joint project between NCCAM and the Library of Medicine, and also, then, other governments or nations that are involved. There seems to be more and more international relationships being built, that we should take advantage of those opportunities.

DR. FINS: We should say the National Library of Medicine, in conjunction with NCCAM and other international bodies, should augment their editorial services to identify and translate leading articles.

DR. GORDON: That could be in the text, though. Are we okay with that? Because I think the recommendation would still be okay the way it is.

MS. SCOTT: Right, because it doesn't say that everything should be translated in the recommendations. It says relevant and high-quality scientific --

MR. GROFT: I think we would like to talk with the National Library of Medicine, also, before we come to

total closure on this, and they may have some thoughts.

DR. FINS: I am just trying to point out --

MR. GROFT: We all want this to happen, and we need to think a little more about the feasibility side of it.

DR. GORDON: So, for now, can we then have some discussion, Steve, about the text, and stay with the recommendation as it is?

DR. FAIR: The only problem is that there have been several groups, American Society of Clinical Oncology -- [inaudible]. You have got to get individual acquiescence from the publisher to translate. Just simply having the Library of Medicine or PubMed do it -- [inaudible].

MS. SCOTT: Charlotte, if you leave yours on, then Bill is unable to speak. There is something going on between microphones.

SISTER KERR: But you need to know, which I have reported, this thing keeps going on. So it is calling us to speak.

MS. SCOTT: So we are going to leave the recommendation as is stated and beef up the text. Okay,

thank you.

Issue No. 5: Information on training, certification, and other qualifications to enhance consumer knowledge and choice. We have two recommendations: "The Commission recommends that the states and local governments require all persons providing any kind of health services or products, including CAM, to make information easily accessible to consumers that explains their level and scope of training, so that consumers can make informed choices."

I guess, we did consider moving this to the Access section, but we will see. Comments?

DR. FINS: I think it is consistent with what we are going to recommend later, and under the rubric of informed consent and informed choices. People need to know who is doing what and who is accredited and whatever. So I think we might want to go back and tweak the recommendation and have parallel structure. What is going to happen next is delivery, but I think conceptually it is on target.

DR. WARREN: We started including CAM health services or products including CAM. Should we also put

"and conventional"?

MS. SCOTT: Any kind of health service or product.

DR. WARREN: Then why do we put "including CAM"?

MS. SCOTT: You just want to put any kind of --

DR. WARREN: Put in there "provide any kind of health products," and then leave out "including CAM".

DR. GORDON: We may need, Don, to refer the recommendations back to CAM, so that there is a specificity about them.

DR. WARREN: I understand that, but are we also going to include "conventional" in that?

DR. GORDON: It's already happening in most jurisdictions, "conventional or CAM."

MS. SCOTT: "Conventional or CAM" instead of "including CAM." Okay, with that change --

DR. GORDON: I think there is confusion here. I think we are really talking about the providers and their scope of training. A product does not have a scope of training. So I think it is really, here, focused on the practitioner side, and not the product side. That is

covered in DSHEA, and in supplements and things.

DR. LOW DOG: Where would you put health store clerks and people that are dispensing lots of medical information?

DR. FINS: I think that comes when we talk about --

DR. LOW DOG: You don't cover all that?

DR. FINS: We don't cover that. That was your committee.

[Laughter.]

DR. GORDON: I think that is an important area. Are all persons providing any kind of health services or advice about products --

DR. FINS: We are getting to products and practices in the next issue. I think we have to distinguish people who are professionally accredited practitioners. The role of health food store clerk, I think, needs to be addressed in the context of the information that is available.

DR. GORDON: Joe, that's true, but what about the whole area of people who are providing information about products who may not be offering services? You may

come into an herbal store. There are a lot of places that just provide these products and they may or may not be offering the service, or they may offer a service and the products.

DR. FINS: They are offering a service, then they are practicing without appropriate certification, licensure, or registration. So, in others words, the question is, should they have some level of registration.

DR. GORDON: No, that is not the question we are addressing here. The question is, should they provide information about who they are and what they know.

MS. SCOTT: Right.

DR. GORDON: Regardless of what the regulations are. Do you understand what I am saying?

DR. FINS: Yes.

DR. GORDON: Because they may be licensed, they may be registered, they may just be hanging out on a street corner, but we are saying, let people know what your training is.

DR. FINS: I think we should start, in this recommendation, talking about people who are actually

practicing in some degree to identify themselves. The issue of the people who are around the supplement question should probably be addressed when we address supplements.

So that, if we talk about any kind of modification to DSHEA or to labeling we should say that people who provide information, who sell these products should be adequately informed.

DR. GORDON: So you are basically saying this only applies to service providers?

DR. FINS: Right. I think you have to distinguish people who are vendors versus practitioners, and to try to put everything in the same recommendation is confusing.

MS. SCOTT: Well, actually, the text really only refers to the providers of health services. There is nothing in here that talks about folks who work in herbal stores or nutritional supplement stores. So if you are going to keep it in here we would have to go back into the text and get a paragraph or two about that group of people, so I think, to me, it sounds simpler to take out the "all products" and to deal with it when we get to

the dietary supplements.

DR. FINS: Well, I think we can say --

MS. SCOTT: Yes.

DR. FINS: Can I suggest just for the practitioner side, "CAM practitioners or conventional practitioners dispensing CAM products," and then you address that product issue in the context of a practitioner. But you can't really -- I mean, the question is, these people are not pharmacists. And it raises a question: should an herbalist be registered like a pharmacist? We haven't addressed that at all.

DR. GORDON: I don't think this has anything to do, as I said, with registration or licensure or anything else. It just has to do with what people are doing. So the rules differ in different places for what you can do, but what we are saying is that anybody who is providing these services or providing products should let people know what they know.

MS. AXELROD: Add something to the text.

MS. SCOTT: The American Herbalist Guild took us on years ago and developed for its member that you had to give an informed disclosure when people came to see

you because herbalists are not registered, licensed, or otherwise. So you put basically what your philosophy was and what your level of education was, what your training is or what it is not, and it was an attempt to try to let people know this. This is who I am and this is what I know and this is how I got that information. And then the consumer makes the decision if they want to see that person or not. I mean, they make that decision.

I am not attached to having "or products" here. I think that a significant amount of what goes on in the world right now is that, especially in the area of multi-level marketing, there is a tremendous amount of information that goes on. "Use this product to treat this, use that product to treat this." A tremendous amount of information is actually going on in that arena, and I am not sure if you consider that a service or not. They are not charging for their service, they are charging for the product which they sell, but that is a big, big area.

DR. FINS: That is an FTC issue, as we have talked about in other contexts, and --

MS. SCOTT: See, I am trying to separate out

the --

DR. FINS: -- the media content.

MS. SCOTT: -- regulatory aspect here. All we are talking about here is information.

DR. FINS: The thing is, people who don't know what they don't know can't tell you that they don't know it.

MS. SCOTT: Yes, they can.

DR. FINS: I mean, we are going to talk about this next. Maybe we should defer this aspect, but the point is that the reason we have external bodies regulating people is so that there is external review of their scope of practice. I mean, do you think the person who is untrained is in a position to express their level of lack of training? I mean, there is an old saying, the more you know, the less you do, right?

MS. SCOTT: What they have been trained.

DR. GORDON: I think this is aside from regulation. This is stating a principal. If you are selling magnets and multi-level marketing, you should say, "All I know is what I read in the company promotional materials. This is who I am. I am not a

magnetologist with an advanced degree in magnets. I am not a doctor." And I think we are stating a principal that is apart from the idea of regulation, and that is why I think it belongs under public information.

DR. FINS: What confuses me here is that you have --

MS. SCOTT: When you say training --

DR. FINS: No. You have two things here that the state is requiring people to report their level of knowledge and scope of training, which is something that the state also could keep a registry on for the practitioner folks, everything from registration to life insurance certification. So that is one category.

The other thing is disclosure, but disclosure may not constitute adequate protection as you go up into more risk benefit kinds of interventions.

DR. TIAN: I think the product and the services should be separated, and first of all, the regulated license people, you mentioned all the people. That is confusing. When you are talking about CAM providers, of course, they should report -- they should introduce themselves to the consumers to say what level, what kind

of training. And the people selling products, they don't have to be CAM providers. They are not, they are salesmen. So we are talking about product, so I think there are two things we should separate.

DR. GORDON: Tieraona, where are you with this?

DR. LOW DOG: Well, I don't have a problem taking out the "or products" and leaving this if you are talking about just license. I mean, you get into this big thing then. I mean, it just becomes never-ending of who then is the state going to have to require to have what, so I certainly understand the problem there.

I also just don't want to minimize or I want to go on record as stating that I think that a lot of the misinformation out there and bad information that is being given out there is actually through the salespeople and salesforce of people who think perhaps they know more than they do. I am not sure how you are going to regulate or do that, and I am not sure this is the place. This is information.

MS. SCOTT: Okay.

DR. LOW DOG: So maybe we can take out the "or products" here but we have to address it some place.

MS. SCOTT: Well, another option would be to take out the "states and local governments." "The Commission recommends that all persons providing any kind of services or products."

DR. LOW DOG: There you go.

MS. SCOTT: So that we remove the concern.

DR. FINS: No. 9 actually captures the intention better.

MS. SCOTT: Right, right. So that might be a better choice, to just take out "state and local governments require." This was our thinker here. Corinne.

Yes, Joe?

MR. PIZZORNO: I think we should leave in "products" and take out "services" because this is "services" are addressed later and also more thoroughly in access. This is about people providing products and information about products. I think that is what is the core of this recommendation.

DR. LOW DOG: It is also services information. I think it is what you are also providing. I like the idea, let me just say, of taking out "state and local."

This is information so it is --

MS. SCOTT: Right. It is purely information.

DR. LOW DOG: We are recommending that people who provide health services or products, conventional or CAM, let the people that they are taking care of know what their level and scope is.

MS. SCOTT: Yes.

DR. GORDON: I would like to see if we have a consensus on this. Can we have a reading of it the way it is?

MS. SCOTT: Sure. "The Commission recommends that all persons providing any kind of health services or products, conventional or CAM, to make information easily available to consumers that explains their level and scope of training so that consumers can make informed choices."

Effie?

DR. CHOW: Then who is going to be sure that that is carried out?

MS. SCOTT: You can't.

DR. FINS: I mean, I think No. 9 captures it. In other words, the way I disclose what I do is I have a

license that the state gave me and it goes on my wall. Someone sees it, they see what my title is, and they know what the scope of that practice is. So I think No. 9 captures it for the practitioners. I think where people who fall below the radar screen for even registration and are more like vendors or salespeople, that comes under commerce and it is business practices. It is not medical practice, it is not CAM practice. It is vending.

DR. GORDON: I am not saying this statement is not that also, it is that.

MS. SCOTT: Right.

DR. GORDON: I think this is a very important statement for us to make publicly, to make to the people because what we are saying is we want full disclosure regardless of whether you are commercial. Whatever you are doing, if you are in this field we believe as a commission that you need to tell people who you are, what you are doing, what you know, and what you don't know. We are setting a standard. We can't enforce it but we are making, I think, a very important public statement. So people need to know that this is where we are coming from.

DR. LOW DOG: Isn't this what Minnesota did?

DR. GORDON: And it is about information.

DR. LOW DOG: Isn't this what Minnesota ended up doing? It was basically you have to tell people who you are and what you know.

I am not attached to the "products."

DR. GORDON: I think "products" should be in there. I think that you made a good case for it. I mean, this is my opinion. I think it is really important, that we need to be saying to people in the health food stores and everywhere else you tell people what you know and what you don't know.

DR. FINS: This is more of a conceptual idea. It is really not a recommendation because it doesn't have any way to be effectuated. Why don't we simply just put it in the text?

DR. GORDON: I will tell you why it is important to have it as a recommendation.

MS. SCOTT: Yes.

DR. GORDON: I think it is one of those things that will be picked up publicly and that we can use publicly to state our position. I think that people will

respond. I can see the press already interested in this one, that we are taking a stand. We are not just going along with anything anybody does. I mean, I want people to do that for me and for my patients because I see this as a major public health issue.

MS. SCOTT: And I think, frankly, as some people think that we are all a pro-CAM commission that this really says that we hold these standards for everybody including those of us who support CAM.

DR. FINS: I think what I am troubled with is that this is necessary but it is not sufficient.

DR. GORDON: We are not saying it is necessarily sufficient. I think we are saying that it is an aspect of what needs to be done.

MS. SCOTT: Right.

DR. FINS: But I think it is important to say that because simple disclosure in and of itself is not enough to regulate or to have --

DR. GORDON: We are talking about information.

DR. FINS: But that is what it is. We are talking about disclosing one's level of competence or scope of practice, but that in and of itself is not

enough.

DR. GORDON: No. 9 speaks to it.

MS. SCOTT: Right. We do need to go back to the text and make sure that we have something that relates to that.

DR. WARREN: And your wording. We are addressing CAM and conventional practitioners but we are also talking about retail sales, multi-level. I know they are different, but we are talking about just giving forth your qualifications. Can we add in there "retailers, CAM and conventional practitioners" as a clarification of actually what we are addressing?

MS. SCOTT: To be in the text?

DR. FINS: I mean, Julia, my concern is I think there is a difference between "professional practice" --

MS. SCOTT: I hear your concern.

DR. FINS: -- and "business practice."

MS. SCOTT: Yes.

DR. FINS: So if we said people who are selling versus providing products should engage in good business practice, which is different than the provision of care. Vendors are not licensed.

DR. GORDON: As Tieraona pointed out, neither are many CAM practitioners.

DR. FINS: But they --

DR. GORDON: May not be.

DR. FINS: -- they may be.

DR. GORDON: But they may not be, also.

I think we need to come to consensus on this because there are a number of other issues that I know that we are going to have long discussion about, so if we can understand that this is a recommendation that has to do with information and that there are other discussions that will come up regarding regulation and other issues later on.

Can we get a consensus on this one? Okay? And come to No. 9, Julia? If we have consensus, then we can move on to No. 9.

MS. SCOTT: Okay. And again, we can still revisit this when we get to the "Access" section to see if we can do some wordsmithing that will make it something that we can all live with, okay?

Okay. Let's go to Recommendation 9. "The Commission recommends that states and local governments

make information on state guidelines, requirements, licensures, certification, and disciplinary actions of health providers, including CAM providers, readily available to the public."

DR. LOW DOG: Let me just go back to the last one just for a moment. Only that I don't want to set some standard for retail health food stores that is not required for other types of businesses. I know that there is a special issue here, but part of my problem is I could be a retailer and just sell glucosamine but I may not tell you anything about it. So do I have to list a whole disclosure thing just because I am selling glucosamine?

I mean, I think the part comes when you are providing health information to people or you are making recommendations about health. So I would need to say that we don't quite have consensus yet on 8, but we have those four choices. I would ask that this one just be allowed to come back to the working group. I am not saying we are going to get rid of it. I am just saying that maybe we could improve this. I think there needs to be a little bit more thinking and that I would ask that

we have just the permission of the group to work on this over the next 10 days and get something back to the group. We would do it quickly.

DR. FAIR: I think a little more data, too. You mentioned a very, very important thing, that is the multi-level marketing. That goes on among physicians also. Can we get information as to what percentage of sales come through things like pharmacies and multi-level marketers and things like that?

Tom, is that kind of information available? I think that would help us in making a decision because right now just my impression is that I see multi-level marketing springing up, again, in Florida where there are a lot of elderly people and don't understand what they are talking about. So if you could tell me that multi-level marketing was a 10 percent market I would feel different than it was a 50 percent market.

MS. SCOTT: Corinne?

DR. LOW DOG: Corinne just made a comment for trying to get some closure here. "The Commission recommends that persons providing information on health services or products, conventional or CAM, make

information easily available to consumers that explains their level." It is not so much that you are selling it, it is if you are providing information about it.

DR. GORDON: I think it has to be "providing services or information."

DR. LOW DOG: "Providing health services or information"?

DR. GORDON: "Information."

DR. FINS: "Providing services." Then, wouldn't it become the practice of an art? It gets into No. 9.

DR. GORDON: What I would like to do is either we move ahead with this or we send it back to the committee because we need to move ahead with the recommendations.

DR. FINS: But I think this little discussion here has put a spotlight on an area of regulation that we did not really consider before. You have got the supplement industry and the packaging and DSHEA, you have got the provider kinds of groups, and then you have the vendors, the retailers, and this is like what is happening at the store. Maybe it is something that our

group and your group can work on because I think it is a gap.

DR. GORDON: That sounds great. What is the decision about this? Do we have consensus or do we send it back?

MS. SCOTT: Yes.

DR. GORDON: Send it back?

MS. SCOTT: Yes, I think the committee wants it back.

DR. GORDON: Okay. Fine.

MS. SCOTT: And again, we will take note during the "Access" discussion. We might be able to do it at the end of this, but if not we will take that.

DR. GORDON: One of the reasons I am pushing here, Joe, is because a number of the issues that are coming up are extremely complex and we have some very strong feelings in the group about them. So there is going to need to be a lot of discussion, so I want to move ahead as quickly as we can.

MS. SCOTT: We have got consensus on No. 9, correct?

DR. FAIR: Now, Julia, can you let us know the

percentage? We have said a number of times that the primary source of information for the consumer is the 19-year-old clerk in the health food store, and I think we ought to see what the distribution is.

DR. GORDON: Joe, you and Bill are both asking this committee to begin to think about issues related to retailing and multi-level marketing and considering a recommendation, is that correct?

DR. FAIR: I think if we are going to make a reasonable recommendation we ought to know what the situation is right now.

DR. GORDON: Understood. Okay.

DR. FAIR: May I ask you one question from my ignorance? Or maybe Joe can answer. What is the difference between a naturopathic physician and a naturopathic doctor? That was a new one for me.

MR. PIZZORNO: Theoretically they are the same person. M.D. means naturopathic doctor. Naturopathic physician is how you are licensed in the state.

DR. FAIR: Okay.

MS. AXELROD: Actually, Joe, one of the documents provided to us went into great detail about the

differences, which was quite a surprise to us and it was very confusing, so that is how this ended up in here. I don't recall the specifics but it seemed to be like night and day.

MS. SCOTT: Well, we can deal with that in the break and come back because we really do need to move along because we are coming to some heavy-duty recommendations.

Okay. We are on yours. Issue 6, accuracy of advertising of CAM products and practices. We have one recommendation. "The Commission recommends that additional support be provided to the Federal Trade Commission to, (A) expand efforts to identify false and deceptive CAM-related health claims and take appropriate enforcement action; and, (B) increase consumer education in identifying deceptive and unsubstantiated claims in all forms of marketing and advertising."

This recommendation is also -- oh, I'm sorry. I forgot to say from the beginning. Everyone got the memo yesterday from George. He had some comments on several of these recommendations. This is one of them if you want to refer to that page.

DR. GORDON: There is a two-page stapled memo from George DeVries.

MS. SCOTT: George DeVries.

DR. GORDON: Does everybody have a copy of that? If not, I am sure we can get other copies.

MS. SCOTT: "The Commission suggests that the public be solicited in achieving this objective." That is the final sentence of this recommendation, a suggestion from George.

Veronica?

MS. GUTIERREZ: On this recommendation, I would like to amend it slightly. The chiropractic experience has been that the FTC came after a chiropractor that prints literature and charged them with false and deceptive advertising. It cost him literally hundreds of thousands of dollars in court with an attorney, and he did win and it was completely resolved in his favor.

But if we are going to have the Federal Trade Commission investigate, I would like to see that we amend this recommendation to say that they utilize appropriate health professionals or CAM professionals to assist in the investigation because the FTC does not have

experience in all the variety of professions.

MS. SCOTT: I am not sure if one can tell the FTC what to do, but your suggestion that we have it in a recommendation that they have people that they consult with with the appropriate expertise.

DR. FINS: In the text.

MS. SCOTT: In the text, okay. So that is acceptable.

Joe?

DR. FINS: Not to revisit Recommendation 8, but this Recommendation 10 really addresses it. It is as if you said, "and (B) increase consumer education and identify deceptive and unsubstantiated claims in all forms of marketing and advertising, including at point of purchase."

So if you think about it, when a sales clerk says, this supplement will make you younger, take 10 years off your life, happy, or whatever, that person is engaging in a kind of marketeering and advertising which is not unlike what we are trying to get the FTC to regulate on the airwaves.

DR. LOW DOG: That would just be huge. You are

going to have to take it on both ends, I think.

DR. FINS: I think the way it is written here, though, is it is not we are asking the FTC to do that. We are asking the consumer identifying deceptive and unsubstantiated claims, also, at the point of purchase.

So, in other words, we look back at our earlier recommendations on education, the libraries and all that. If a consumer could distinguish between a reasonable or an unreasonable or inflated claim at the point of purchase, that is kind of empowering the consumer. So they should not only listen with skepticism to what they hear on the radio, they should listen with skepticism to what they hear in the health food store.

MS. SCOTT: But that doesn't still address the people who work in those stores who should also --

DR. FINS: No, it is just a parallel recommendation.

MS. SCOTT: Okay, I see.

DR. FINS: So marketing including at point of purchase.

MR. CHAPPELL: Julia?

MS. SCOTT: I'm sorry, Tom?

MR. CHAPPELL: I just want to be sure everyone understands that a false claim on a product is still within the domain of the Food and Drug Administration so that in the case of a false claim or anything to do with a claim, that is still the business of the FDA. I am not sure people realize that.

I mean, it is one thing to say that DSHEA is handled by the FTC and that is true, but it is also true that the FDA is a regulatory body when it comes to the whole claim base.

I just also wanted the commissioners to know that it is very hard to get the FTC involved. You end up deciding whether you are going to write to the manufacturer and ask them to change. I mean, to use the leverage of the FTC is also very difficult.

MS. SCOTT: Tom, this recommendation deals specifically with advertising. We do get to the FDA's role in labeling and that kind of thing, but this recommendation is only aimed at advertising.

MR. CHAPPELL: Well, then I am only pointing out that advertising is a broad term. If you have an insert in a product, if you have a point-of-purchase

material, it gets to be a gray area as to who is involved.

MS. SCOTT: Do you have some words how you would change this?

DR. FINS: Tom, if you said, "FDA in conjunction with the FTC," that would serve as a joint thing.

MS. AXELROD: The FDA and the FTC have an agreement which delineates who covers what, so this is actually very clear amongst the two agencies as to what FDA is overseeing and what FTC is overseeing.

MR. CHAPPELL: And Corinne, you are saying that the word "advertising" is the delineating boundary?

MS. AXELROD: Yes. So if you are talking about inserts in a dietary supplement, that is FDA, but if you are talking about advertising on radio, television, Internet, billboards, that is FTC.

MR. CHAPPELL: Right. That is my understanding as well but you are right. Inserts or outserts or POPs, those are FDA.

MS. SCOTT: Right.

DR. FINS: We have a recommendation. If you

sit here, since really the FTC is the leading agency, getting back to what you meant by advertising, but to address Veronica's concern about having professional representation, we might want to say, "the FTC in conjunction with" or "in collaboration with the FDA" so that the overlap issue doesn't become a confounder, it just becomes additive. So, because we are making recommendations that the FDA have additional people on staff who have expertise in supplements down the road, so it would help mitigate the false prosecutions that were not indicated.

DR. GORDON: Can we have a recommendation for language here?

Joe, did you have a specific language there?

MS. SCOTT: I think Ken's got a clarifying quote.

DR. FISHER: Tom is absolutely right -- the term "health claim" is probably not the way to go -- and so is Joe, so it might well say, "expand efforts to identify false and deceptive advertising of CAM products and services and take appropriate action."

MS. AXELROD: Actually, Ken, this is directly

from FTC information.

DR. FISHER: That is correct, but what I am saying is in rereading this, Corinne, the phrase "health claims," somebody is going to misinterpret that. So even though that agreement exists, if we get rid of the term "health claims" and say "advertising of product and services," then it clearly gets into FTC. And it comes home if you also add the words that Joe suggested, "at point-of-purchase." Although it isn't just a problem with that point-of-purchase, it needs another phrase which I don't have on the tip of my tongue. Maybe it is because much of this is advertising in journals and things you pick up at the supermarket and what you read on the Internet, et cetera, et cetera.

DR. LOW DOG: I fully support removing "health claims" because of its dual meaning in this industry and to use the language that Ken suggested about the advertising.

DR. FISHER: Yes, take out "FDA." And the other request for information, Veronica, most of the FTC investigations that go beyond the first level do include external experts. Unfortunately, they don't identify

them all the time but we can put some language in the text to include that.

MS. SCOTT: Right. Okay. Can we have a rereading of the amended recommendation? Do you have it?

MS. AXELROD: "The Commission recommends that additional support be provided to the Federal Trade Commission to, (A) expand efforts to identify false and deceptive CAM-related health advertising and take appropriate enforcement action; and, (B) increase consumer education in identifying deceptive and unsubstantiated advertising in all forms of marketing and advertising, including" -- I guess that is a little redundant.

MS. SCOTT: At point-of-purchase.

MS. AXELROD: "Including at point-of-purchase."

DR. LOW DOG: Just a clarification. Does it read better "to identify false and deceptive advertising of CAM products and services"? To put the "advertising" in front of "CAM" and then keep it with "services and products" since we have taken out "health claims"?

DR. GORDON: Yes, it looks clearer to me.

We need to move along on this, Tom.

MR. CHAPPELL: I just want to make one more observation. The FTC does not intervene directly on these matters. You have to wait until a competitor complains about your claim. So I wonder if the commissioners are aware that that is how the process works, and if you aren't aware of that, do you want to be more intentional of your expectations of the FTC in this matter?

DR. GORDON: Maybe that is an issue that can be dealt with in the text, Tom, or what are you suggesting about the recommendation?

MR. CHAPPELL: Well, I think "expand efforts" isn't quite the right --

DR. GORDON: Does it have to be a competitor? It can't be a consumer?

MR. CHAPPELL: I don't know about that.

DR. GORDON: Steve is saying it can be anything.

MR. GROFT: I think if it is determined that there is a problem and I think it is the level of the problem as well as the seriousness of what is happening, so that is the criteria.

MR. CHAPPELL: The FTC is not playing a watchdog role here?

MR. GROFT: I cannot speak for the FTC, but what I have been able to see is that there just aren't sufficient resources to look at everything. But I think it is the same with FDA.

DR. FINS: The text says here -- I mean, the recommendation -- to identify, so it is not just to be responsive. And I think we can explain this problem in the text. I think people may want more of a surveillance role to identify.

MR. GROFT: And I think that is what George DeVries' add-on about the Commission suggests that public comment be solicited in achieving this objective to determine what are the problems and to look at it further and to come up with some possible solutions.

PARTICIPANT: Are people comfortable with George's addition?

MS. SCOTT: His suggestion was that it be in the text.

PARTICIPANT: I think he suggested public comment be solicited in achieving this objective.

MS. SCOTT: Oh, okay. George suggests that it be at the end of this recommendation and the Committee -- Corinne is telling us that the Committee suggests it be in the text.

DR. GORDON: Do we have consensus on this with the addition of George DeVries's sentence at the end?

PARTICIPANT: Yes.

DR. GORDON: Okay. Let's move ahead. I want to remind everybody that we have a number of recommendations that are complex coming up, so let's move as quickly as we can and really address the recommendation and recommendation language.

DR. LOW DOG: Okay. Issue No. 7, adequacy of information on manufacturing and safety of dietary supplements to assure consumer safety. We have Recommendation 11. "The Commission recommends that efforts of both the public and private sectors to assure the development, validation, and dissemination of analytical methods and reference materials for well-characterized dietary supplements to the public be enhanced and accelerated."

George DeVries added just as an addendum to the

end of that, "The Commission is aware that Congress has taken steps towards this end and recommends that this progress be continued."

Comments?

DR. WARREN: The whole statement, the whole recommendation.

DR. LOW DOG: Why?

DR. WARREN: Well, it doesn't have any way of implementation it doesn't seem like.

DR. LOW DOG: Oh, I would disagree. Office of Dietary Supplements, as well as a number of private groups, and you have also got USP. I mean, you have got a number of groups that are working on analytical methods right now well-characterized, especially botanical products. This is one of the biggest areas of problems that we face right now, is the ability to identify and use analytical methods to be able to identify and characterize these products.

DR. WARREN: The botanicals?

DR. LOW DOG: I mean, it is with other substances as well because you have got new products coming out all the time that need to have analytical

methods developed for them. The botanicals are a unique situation, not a problem necessary but a unique situation only because they are such complex compounds.

So I strongly feel that this recommendation needs to remain a recommendation, because within the dietary supplement field, this is very important, and it is already happening, but we sure need funds to be able to do it. It will go a long way to improving quality.

DR. WARREN: Can we add something in that, then, to add more direction as to what group needs to address this?

MR. GROFT: If you would indulge us. When the appropriations language is finally agreed upon in conference, what I have seen so far, that there is some language that is going to direct the Office of Dietary Supplements and others to look at this, and they are going to be provided additional resources.

So I would like to hold, maybe, a final edit on this, based on what comes out of that but maybe get acceptance for this right here. Then if we have to tweak it, we will let you know. Plus, I will provide you the appropriations language that finally is agreed upon when

it gets resolved, hopefully next week.

DR. WARREN: I am okay with that.

DR. LOW DOG: Any other issues? Veronica?

MS. GUTIERREZ: I would just like to suggest that George's last sentence -- it is more of an editorial comment -- that it go into the text and not remain part of the recommendation.

DR. LOW DOG: Okay. Do we have consensus, then, on the way Recommendation 11 stands, as it is in your text, with the addition of George's comments into the text?

[No response.]

DR. LOW DOG: Okay.

DR. FAIR: Minor point. Again, it is "ensure," not "assure."

MS. SCOTT: Corinne, Corinne, Corinne.

No. 12, "The Commission recommends that good manufacturing practices for dietary supplements be implemented to help assure the quality and composition of dietary supplements and that a study be commenced 12 to 18 months after the full implementation of the GMPs by an external organization to evaluate current efforts and

provide recommendations for improvement."

George's was to keep that but with the edit, "The Commission recommends the timely promulgation of final regulations for GMP for dietary supplements with oversight by the U.S. Congress within 18 months after final promulgation."

DR. GORDON: I actually think George's is a substitute for the one that we have, I think. Because I think what it is, is it is a stronger, pithier statement than the one we have made.

MS. SCOTT: Either/or, or some combination of them. Comments?

MR. PIZZORNO: Just a general question because I noticed in some of the other sections coming up we are doing this, we are giving timelines. And I am wondering if that is practical or realistic. I am a little concerned. I think we can say "immediate" if it is really important, but to put a timeline on it when we don't know how long it is going to take for all this to go through Congress, I wonder about.

DR. GORDON: I think that George's recommendation comes out of direct consultations with

Congress, and the 18-month timeline is one that they feel they can do and will do. I think it is one they would appreciate our guidance on in this recommendation.

DR. FINS: I want to echo what Joe is saying, but I think what we should do as a general framework is leave the timelines in the text. I think we should have some sort of preface saying that this body was constituted in a different time and that after the realities of September 11th the priorities, the funding, the budgetary constraints are different and we appreciate that not all these timelines will be started after we conclude our work and that we appreciate that there are different priorities.

I think it would be helpful to just contextualize the report in the context of the budgetary crisis, deficit spending, et cetera. Otherwise, I think we are going to be really perceived as being out of place. This way we have it both ways. We have we would like to do this in 18 months but we appreciate that the 18 months may not begin in this fiscal year, it may begin in the next fiscal year.

DR. GORDON: I just want to say with this one

we have had recent --

DR. FINS: I am not saying about this one. This one might go through. But I am saying we have other places where we have timelines in the report and I just think it is important for us to say that the timeline may not be initiated in the fiscal year that we might have anticipated because there are competing priorities. This way we have a schedule but we are not going to be perceived as having failed if the schedule doesn't begin when we thought it would start because everything has changed.

DR. LOW DOG: I want comments but I just want to put out there to move things along so that we can start to get comments. I feel absolutely comfortable with George's language with the "timely promulgation." I like that word. We probably just didn't know it; that is why we didn't use it. And with the "oversight." And I do believe that the 18 months is appropriate in this particular place.

DR. TIAN: A question about 12 months to 18 months. Who recommended the time frame? If 18 is the total, why is there a range?

DR. LOW DOG: We are going to put 18.

DR. TIAN: Okay. Thank you. Why 18?

DR. LOW DOG: That is what the Congress has agreed that they could handle.

DR. TIAN: Thank you.

MS. SCOTT: It seems to me there is a difference between George's edit and what was in the original recommendation. I am wondering what happens to our recommendation that this study "be commenced after full implementation of the GMPs by an external organization" versus the Congress?

DR. GORDON: It will have more effect having Congress do the oversight than some as yet unconstituted external organization. I think the thing here is that they have got the juice. They can make it happen and they can make sure it is enforced.

DR. LOW DOG: Are we comfortable with that?

Julia?

MS. SCOTT: That was fine.

DR. LOW DOG: Are there any other comments?

MR. GROFT: If I can just add, whenever there are proposed regulations you go out with a notice of

proposed rulemaking and you are given a period of time, 60 days, 90 days, to comment.

It has been known that some final regulations have languished for months, and I think is just an effort to make sure that it moves along in a timely fashion and 18 months seemed to be enough time to get things done, especially when you have agreed-upon GMPs.

DR. LOW DOG: Are there any additional comments?

[No response.]

DR. LOW DOG: Do we have consensus? It has been proposed that we take the following: "The Commission recommends the timely promulgation of final regulations through GMP for dietary supplements with oversight by the U.S. Congress within 18 months after final promulgation." Do we have consensus that we will accept that recommendation?

[No response.]

DR. LOW DOG: Okay. Then, No. 13, "The Commission recommends that appropriate federal entities work with manufacturers and importers to monitor the quality of imported" -- I thought we had taken out

"domestic" -- "imported dietary supplements to identify and prevent products that are contaminated or adulterated from entering the U.S. marketplace." And I thought we had intended to take out "and domestic" here.

Now, George had recommended that this recommendation be deleted as that there are already standards for this. My own recommendation would be that we consider that, "The Commission recommends that funding be increased to the appropriate federal entities to monitor the quality of imported dietary supplements to identify and prevent products that are contaminated or adulterated from entering the U.S. marketplace."

DR. GORDON: Are you proposing to do both 13 and 14 in that deal?

DR. LOW DOG: Yes.

DR. GORDON: Yes, okay.

DR. LOW DOG: I don't think we need both 13 and 14. I think that "and federal and other entities" perhaps because that could include some of the agencies that we have listed in 14. "To monitor imported," I don't think we need to have "domestic" because we are going to have GMPs in place some day, so I think that