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on
COMPLEMENTARY and ALTERNATIVE MEDICINE POLICY

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C O N T E N T S

P R O C E E D I N G S

[7:17 a.m.]

Opening Remarks

DR. GORDON: Thank you all for being here, so bright-eyed at this early hour. And Ming, thank you for the wonderful party last night.

[Applause.]

DR. GORDON: So let's just sit for a moment, gather ourselves together, and then we will begin.

[Moment of silence observed.]

DR. GORDON: I wanted to give Dean a chance, and ask Dean if he would take a few minutes to express some of his hopes and concerns for the meeting, just as we all did at the beginning of yesterday's meeting.

I also wanted to thank you, Dean, for the detailed Email that you sent, and for the thoughts you expressed to us there.

After Dean is finished, we will move back into the final part of the CAM Central discussion.

DR. ORNISH: Well, thank you, Jim. I want to again say I was sorry that I couldn't be here because of a prior conflict.

I won't repeat most of what is in my Email, since I think most of you have a copy of it, and there is so much to cover, I don't want to spend too much time doing that, except to say, I guess the summary of my concerns is that I want our report to be effective and I want it to make a difference, and I think we have a real opportunity to make a difference here in advancing the field.

My concern is that if we get too far ahead of the evidence, we may lose our opportunity, that we may become ineffectual if we become easy targets for people, if we go beyond what the evidence suggests, and, in that sense, compromise our credibility.

To the extent that we are viewed as zealots or advocates or crusaders, as opposed to a more reasoned, dispassionate, White House commission that systematically reviewed the evidence, and heard testimony from a variety of different people, and synthesized that, and made recommendations that don't get ahead of what the evidence is, I think we can be very effective.

I was pleased to hear that yesterday a lot of progress was made in that direction. I think having to

write dissenting opinions, or having to people take their names off the paper is really going to make it even more ineffective and just gives people that much more ammunition for trying to dismiss for what we have done.

And so, to whatever degree we can find a middle ground, as I mentioned in my memo, it's a very unusual position for me to be in, to be on the more conservative end of the spectrum of any group of people. Yet, I think that because I feel so strongly about this commission and have such respect for you all and really want this to be something that is more than just a document that gets read and tossed aside, I think that it is important that we address these issues.

So, thank you.

DR. GORDON: Thank you very much, Dean. We were mindful, both of your concerns yesterday and also of the concerns of others. I agree, I think we have moved in a wonderful direction of coming together and really finding that middle ground among us.

Steve, do you want to say anything before we move into the rest of the day?

DR. GROFT: It will be an extremely busy day.

I think we set a nice tone yesterday when we got into a pattern of review and revising. I do just want to caution the group, when we get into Access and Delivery, Michele is not going to be here.

In fact, what you received during the mail was a revision of what she had written by several of the staff members. We took time to go through it and tried to make revisions. So there could be some weaknesses, as we go along today, trying to make an explanation of why certain things are included or why they were omitted.

I think what we are asking you to do is to identify the areas that need work, need to be added, and among the staff members, we will try to correct it and get it going the way you would like it to be.

DR. GORDON: Great. Thank you, Steve.

We are going to begin, as I said, with finishing up the discussion of CAM Central, and then we will move into Information, then we will go to Access and Delivery, Reimbursement, then this afternoon we will focus on Wellness, and then either before or after the public testimony -- hopefully, we will be able to start before -- we will go over once again the steps that we

will be taking in the next two weeks to bring everything to fruition.

So let's conclude with CAM Central. Then, Tom, you have a couple of points you want to make, too, about insertion of fillings, right? Thank you.

Coordination of Federal CAM Activities (Continued)

DR. GORDON: Don, do you want to pick up where we left off?

DR. WARREN: Yesterday, we went over the recommendation. I believe the Commission accepted that. Then we had three action points.

Linnea, did you have a fourth that you came up with last night? Can you read it for us?

MS. LARSON: This has to do with the insertion of a sentence in the second paragraph. I will read the sentence that we inserted, and then I will read the action item that relates to it.

So the sentence is on the first page. This is after the sentence "The Commission agrees" at line 21. Following that: "This office should include the full range of complementary and alternative medicine perspectives as part of the decisionmaking dialogue that

guides this office's policy and implementation process."

DR. GORDON: Which page is this on, Linnea?

MS. LARSON: The first page. On page 1 after the first line.

DR. WARREN: Could you read that one more time?

MS. LARSON: Okay.

DR. GORDON: Page 1, line 24.

MS. LARSON: This is inserted on page 1, beginning line 24. After the sentence, it goes: "This office should include the full range of complementary and alternative medicine perspectives as part of the decisionmaking dialogue that guides this office policy and implementation process."

Then the action item that follows is: "The selection process for advisory committee members should guarantee that the full range of complementary and alternative medicine perspectives are part of the decisionmaking dialogue that guides this office's policy and implementation activities."

DR. GORDON: Great. Thank you. So that that is part of 1.2. Is that right? Or, is it a separate one?

MS. LARSON: Well, I thought of it as a separate one that then leads to 1.2.

DR. GORDON: Okay. Discussion about this?

Sorry, Tieraona. Go ahead.

DR. LOW DOG: I just want to reiterate that I think that to make this not seem as strictly an advocacy position that is just going to bring a bunch of people who believe in CAM to make decisions about it, if you are going to start specifying who all you are going to have on there, you are going to need to take the balanced approach in there, as well, to include language that there needs to be people with rigorous scientific backgrounds and those that are not strictly advocates.

I do think Steven Strauss has been able to make some good headway, because many people believe that he is not an advocate.

DR. GORDON: Would you like to amend Linnea's language in some way to include that?

DR. LOW DOG: Well, I just heard about it, and it's 7:00. So I'm going to have to warm up to it, but I'm not saying I am opposed to having that because I think the language is important. I'm just saying it

seems lopsided now.

DR. GORDON: Other comments? Julia?

MS. SCOTT: First, I would like clarification. You're talking about the advisory committee, or the staffing of the office?

MS. LARSON: The advisory council.

MS. SCOTT: Oh, okay. Then I will think about that some more, the advisory council.

DR. ORNISH: Are we talking about Recommendations 1.1 through 1.3? Because this is an example of what I was trying to say before. I think that rather than saying we should create an office to coordinate and facilitate integration, again, there is a presumption that these things work, and I think that, really, we should be creating an office to assess and evaluate.

For those that are then found to be effective and safe, I am not sure that there are enough -- I mean, again, there is a presumption that there is a body of CAM modalities that have proven to be safe and effective sufficient that it is worthy of establishing an office to figure out how to implement these, and I don't think we

are there yet.

I think that we need to be a little more modest in what we are recommending and say there isn't enough -- I don't personally think there is enough out there to talk about the President, the Secretary of Health and Human Services, and Congress to start to finger how we can implement these in the Nation's health system. I think we should be more in the evaluation and assessment end of the spectrum for now.

DR. GORDON: David, and then Tom.

DR. BRESLER: I understand your concerns about this, Dean, but on the other hand, I am dealing with patients who are asking very reasonable questions about why acupuncture is not covered by Medicare when there is plenty of sufficient evidence in the arena of pain control and arthritides and things of this sort that it is an effective modality.

I think this is part of the potential of the Commission, is to open the doors for things for where there is sufficient evidence of efficacy and safety to begin the integration process. I think it needs to be done critically, but I think there is sufficient evidence

for some of the CAM modalities to begin this process in integration.

DR. GORDON: Tom.

MR. CHAPPELL: I would use language to accomplish what I heard both Linnea and Tieraona talking about that sounds like this: Following "advisory council," "The office should charter an advisory council inclusive of members" -- or, "inclusive of practitioners from both conventional and CAM health systems."

DR. GORDON: We are working on two pieces. There is Linnea's recommendation and then Dean has gone back, so I would like to focus first on Linnea's, and then we can take up Dean. Linnea has either amended 1.2, or made a separate 1.4.

So I would like to get some sense of where we stand, and both Tom and Tieraona have suggested that we include conventional. I would say conventional researchers as well as practitioners on the advisory council.

Linnea, do you want to speak to it?

MS. LARSON: I am simply agreeing. I really do agree with what Tieraona was saying about it should not

be an us and them, and it should be a little bit wider range, and it should include people with rigorous scientific training, researchers.

DR. GORDON: So, Tieraona or Linnea, either one, can we have a rewording of what you would like to see here and then we can get an up or down on it, and then we can go back and address the issue that Dean and David were discussing?

DR. LOW DOG: Well, yesterday, we had also said that we did not want to really tell them what their advisory council should be comprised of. I mean, I thought that was where we were, and then we sort of slipped in CAM and conventional practitioners.

So yesterday, there was discussion that we shouldn't be telling them what they should comprise their advisory council on, and I guess if we are going to add that we are going to have this full range, I would just say that if you are going to have a full range, it should include those with expertise in CAM and conventional medical practice, scientists with rigorous backgrounds.

But, see, my problem is I don't know that we can sit here right now and say what the best constitution

of that advisory council should be, and I am not sure we should be listing in the recommendation who they should choose.

DR. GORDON: Since Joe Pizzorno is not here, let me raise the concern that he raised that Wayne also spoke to yesterday, which was that in the past, what has happened is that when -- and this happened at NIH -- is that when committees were set up to deal with CAM, that sometimes people who knew anything about CAM were excluded from those committees, and that was Joe's concern.

That was certainly what happened with the first review committees of CAM projects even after OAM was set up, when it was left to the NIH as a whole, and I think that is the concern that he was speaking to, and I don't know, Wayne, if you want to speak to it again.

I thought we came down on the side of understanding that even though we might not want to dictate all details, we wanted to give a certain broad picture.

Wayne.

DR. JONAS: Julia asked to speak.

MS. SCOTT: I think, Tieraona, my experience has been with the setting up of advisory committees that while we might not want to have a very prescriptive charge, I think you do have to state when you want to make sure that certain representation happens. It happened when we decided we needed to have women on some of these NIH research committees, that we needed to have minorities, and it has to be said.

Now, I agree. I don't think we need to make a long list. I thought yesterday, after this discussion, we had agreed to simply including. So that, it didn't mean that we were going to list everybody that needed to be there, but it said including those with CAM expertise and CAM and conventional, that that was enough to say that we wanted to make sure we had an advisory committee that knew what they were doing.

So I still feel like we need to at least make that statement.

DR. GORDON: Wayne.

DR. JONAS: Yes, I agree. I think if we just specify that it should be a balanced committee that includes CAM and conventional, those with CAM and

conventional expertise, that should be the end of it.

DR. GORDON: Joe.

DR. FINS: Maybe in the action item, the original action item as written in the book, 1.2, and it might have been revised yesterday, but let's just go with that. Suppose we simply said, "The office should charter an advisory council with members with expertise and diverse backgrounds and training necessary to guide and advise the office about its activities."

It is simply to say that they have to have the expertise and diverse backgrounds necessary to perform this function, and then in the text be more specific about it.

DR. GORDON: Tieraona.

DR. LOW DOG: Yes. I am fine with that. I could go with that, I could go with including those with CAM and conventional expertise, not just practitioners. I don't have an issue. I just think that when you start getting into full cadre or full ranges of that, you know, that could be 20 people, I mean just in that one area. So I just have some concerns.

DR. GORDON: Effie, and then I would like to

come to a close on this. We really need to move ahead.

DR. CHOW: Yes. My experience is also that many people are put into positions of decision that have not had CAM experience nor have any knowledge of it. So I want to just reiterate support for that.

DR. GORDON: There are basically two proposals on the floor. One is that it be more general, which is Joe's, and the other is that it be more specific and name people and say "expertise in CAM and conventional health care."

DR. CHOW: I support the CAM and conventional expertise. Be specific.

DR. GORDON: CAM and conventional expertise.

DR. CHOW: Yes.

DR. GORDON: Okay. Can we get a sense of which of the -- I mean, we are all in the same ball park here. Linnea, would you agree that --

MS. LARSON: Yes. I think that Joe Fins actually had a resolution to that in his expression.

MS. SCOTT: Jim, I think if we put this in the text, this more descriptive sentence in the text, then in the action 1.2, we then include the language that Joe --

DR. GORDON: Okay. So, Joe, do you want to repeat the language and let's see if we can agree on Julia's proposal, which seems to be what Linnea is supporting and Tieraona is shaking her head as well.

Go ahead, Joe.

DR. FINS: Again, this would be with the additional information in the text. "The office should charter an advisory council with members with expertise and diverse background and training necessary to advise and guide the office about its activities."

DR. GORDON: Are we okay with that one, Tieraona? Yes?

DR. LOW DOG: Yes.

DR. GORDON: Everybody, can I see nodding of heads? Okay. Great.

Let's go back just for a moment, Dean.

Yes, David, I'm sorry.

DR. BRESLER: I think there is a way to reconcile the concern. The recommendation itself does take an advocacy position in the sense that it is asking for integration before the fact. I think what we want the recommendation itself to say is that CAM Central is

to coordinate federal efforts and federal activities rather than to say it is going to implement CAM into conventional health care. I think the recommendation itself needs to be less of an advocacy position. The real focus is to coordinate the activities of the federal government.

DR. GORDON: Is that satisfactory to you, Dean?

DR. ORNISH: Yes. I was going to say something similar to that, that it would be more along "efforts to coordinate and facilitate evaluation," as opposed to "integration." One has a very different connotation. Or, the efforts for something, but "integration" implies that you already know these things work and you are ready to rocket.

I also think there should be something in the discussion that says that we recognize that most CAM modalities are yet unproven, but some are. Certainly, acupuncture is one of the few that really is proven, and even then, for certain modalities. If we could say something in that, that we recognize that most of them are not yet proven but that because more research efforts are going on within CAM and others, it would be useful to

have an office to integrate things as they become more proven.

DR. GORDON: See, I think that you are narrowing the scope of the office too much. The office is not just about research, the office is about many things that are already going on, public information activities. The office is about services that are already underway.

DR. ORNISH: I wasn't limiting it to research. When talking about evaluation, it is not just research.

DR. GORDON: No, but what I am saying is, as opposed to the research section, that the office has many functions, and when you read the section on the office, part of it is providing information, part of it is working with different agencies so they can talk to each other about what they think about CAM activities.

So I am not against striking the "integration" and working that in a different way. All I'm saying is that the office does not stand or fall on the research evidence. The office is not created because the state of the research evidence is great or poor. The office is created to help provide information about the research, whatever it is.

It is there to help people in different agencies who are considering CAM activities to talk with each other. It is a different kind of function, is all I am saying, and I just want to make sure we don't lose sight of what the function is.

DR. ORNISH: I understand, but if you are talking about facilitating integration, I think that is ahead of where we are, that's all.

DR. GORDON: No, I heard that.

Yes, Joe.

DR. FINS: When you use a word like "integration," well, it's too soon. We are not ready for integration. Then the other implication vis-a-vis Tom's comments yesterday, is, it means that we are going to subsume.

So I think when you start getting specific, you lose potential roles for this office. You say, simply, "to coordinate federal policy with respect to complementary and alternative medicine," and the specific actions are in No. 1.3 and elsewhere.

DR. GORDON: Tom.

MR. CHAPPELL: Thank you, Joe.

So I think the language could be "to coordinate and facilitate the accountability of safe and effective complementary and alternative health care practices and products into public health."

DR. GORDON: I think that is certainly possible. All I am saying is, when you say "accountability," there again, it is hard to know exactly what that means. I like Joe's wording better because we get lost in "accountability." That word kind of takes it a little bit off track because the office doesn't have that authority.

MR. CHAPPELL: Okay. What I'm trying to do is avoid this presumption that we have to squeeze it all through the existing system. So, Joe, if you have language that accomplishes the intent.

DR. FINS: The question that Tom is raising about accountability is one that I think we have to address. I mean, who will be accountable for the actions of this office and CAM policy in the country?

Let's say there is an assistant secretary. He or she would answer up the chain of command, and would ultimately would be accountable to the Secretary. So

there are lines of authority in that regard, simply by its position in the government.

So I think it is implicit, and I think if we said, just, "coordinate federal policy with respect to complementary and alternative medicine," we don't have the overstating and we don't have the subsuming concerns on both sides of the table.

DR. GORDON: How does that sound? Don, how does that sound to you? You've been working on this.

Dean, how does it sound to you?

DR. WARREN: It sounds an awful lot like what we first came up with.

[Laughter.]

DR. WARREN: The Commission wanted "safe and efficacious" in there, and "integration" out of it, so we put that in. Now the Commission says, well, we don't want "integration," we don't want "safe and effective."

So what are we going to do?

DR. ORNISH: Well, I certainly didn't say we don't want "safe and effective." I mean, that is something that I think should go in everything.

DR. WARREN: So we put "safe and effective" in

the initial recommendation, and it was "integration of safe and effective." That didn't imply research or shoving anything through the system.

DR. ORNISH: I like Joe's recommendation of, "coordinating federal policy."

DR. FINS: "With respect to complementary and alternative medicine."

DR. ORNISH: Yes. I can live with that.

DR. GORDON: Are we okay with that? My memory is being jogged. I recognize that is where we started, and maybe that is where we belong.

DR. WARREN: Could you repeat it again?

DR. ORNISH: "Coordinating federal policy." I would keep, certainly, the "safe and effective" in there, but instead of saying "facilitate integration," it would be "coordinating federal policy."

MS. SCOTT: "Regarding safe and effective"?

DR. GORDON: Let me just say that these are two different functions. The "safe and effective" was there when we were talking about integration. There is nothing wrong with "safe and effective" except that part of the office's function is to say what is not safe, what is not

effective, what is going on, what we know, and to present information about all the approaches.

So for me, "safe and effective" comes in if we are saying that something needs to go ahead, but part of the office's function is to say, what do we know. If we don't know anything, then we need to say that as well.

DR. ORNISH: That's what I was saying about "evaluate," and you said that was a bad idea.

DR. GORDON: I'm sorry?

DR. ORNISH: When I first started talking this morning, I said that the office should be about evaluating and coordinating, and you were saying that it shouldn't be about evaluating.

DR. GORDON: I think what I am saying is that I think Joe's description makes it very simple and doesn't get us bogged down in specific functions beyond the specific functions that we list in the action item.

DR. FINS: Can I just say --

DR. GORDON: Yes, go ahead.

DR. FINS: I agree that we need to evaluate these things, obviously, but it may be further downstream, and it may not be at this level.

Just as we can't, as a panel, evaluate modalities, this advisory body might have a composition that would not lend itself to the scientific evaluation of an herbal or something, but it should coordinate and delegate that responsibility to make sure that it is happening somewhere in the federal government. That is why "coordination" is the verb that I like, or the gerund.

DR. GORDON: Julia and Tieraona, please.

MS. SCOTT: I just want to make sure we are, again, not putting a lot of pressure on this body of people as different from other federal offices that coordinate activities around a specific area.

We are recommending that this office be under the auspices of DHHS. There is a whole chain of command, there is an evaluation process that has to happen. This happens with the Women's Department, this happens with the Office of Minority Health. I mean, it happens. So I don't think we have to add on all of this stuff.

My memory is, the original recommendation had, just, "coordinate," and then people got concerned about any kind of CAM coming through. So the language that we

agreed on was "integration of safe and effective," so that it was clear that this office wasn't just going to try to get all kinds of CAM, unproven CAM method therapies, shoved through the system.

So that is just a rationale for why we put those words in, and we are now agreeing that it muddies the water and we should take it out, but we did have a thoughtful process on why we included those words.

DR. LOW DOG: I just love Julia's memory. She always remembers everything.

I would just like to support the language of "coordinating the federal policy," and not include "safe and efficacious," though that is obviously a part. Federal policy may actually be about taking care of products, getting rid of products that are not safe. So this office may be in charge of a broad spectrum.

I move that we put Joe's language up for a vote.

DR. GORDON: Dean.

DR. ORNISH: I think it would be a real mistake to take out "safe and effective." I think there are ways of making it clear that if we are coordinating and

evaluating, or even just coordinating activities, that the goal is somehow to end up with ones that are safe and effective. I think taking that out would be really unwise, and a step backward.

DR. GORDON: So, Dean, how would you amend Joe's statement?

DR. ORNISH: Joe, read the wording that you have.

DR. FINS: "The President should create -- I'm sorry, where am I?

DR. ORNISH: "Should create an office to."

DR. FINS: "To coordinate federal policy with respect to complementary and alternative medicine." I just was beginning to revise it to incorporate this, "so that the American public has access to safe and effective."

DR. GORDON: Tom.

MR. CHAPPELL: I think the language should be, "create an office to coordinate and facilitate the safe and effective implementation of complementary and alternative health care practices and products."

DR. BRESLER: Again, we're okay with

integrating into our health system those practices that are determined to be safe and effective, are we not?

Okay. Then how about the language to say that it should create an office to coordinate federal CAM activities and to facilitate integration of those alternative health care practices and products into the nation's health care system that are determined to be safe and effective?

DR. FINS: Maybe that goes into No. 1.3 as an element.

DR. BRESLER: Yes, it could.

DR. FINS: Not No. 1.1.

DR. GORDON: I would like to get closure. I think we are all in agreement. I would like to just get some wording that we can agree to, and move ahead with this.

DR. BRESLER: What I am suggesting is that for the recommendation itself, that we clarify that it is to coordinate federal activities, and then, as those CAM practices are determined to be safe and effective, to facilitate the integration.

DR. GORDON: Okay.

DR. ORNISH: I can live with that. I can live with that.

DR. GORDON: You agree with that, Dean? Okay.

David, would you read that again, and let's see if we can go with that.

DR. BRESLER: "The President, Secretary of Health and Human Services, or Congress, should create an office to coordinate federal CAM activities and to facilitate integration of those alternative health care practices and products into the nation's health care system that are determined to be safe and effective."

DR. GORDON: Are we okay with this? Wayne?

DR. JONAS: Well, I mean, you can say that if you want. I'm not going to object, but I think it really is redundant. I think it's not necessary, it's not what is actually going to happen.

The office is going to coordinate federal activities, and that is all it's going to do. I think it narrows it down. There are a lot of things about integration that occur in medicine that have nothing to do with science or proven safe and effective, and will occur in this area just like they occur in regular

science. I think it should be kept simple, it is coordinating federal activities.

DR. GORDON: We have two proposals on the floor. One is the simple "facilitate coordination," and the other is to "facilitate coordination and integration of safe and effective."

Dean?

DR. ORNISH: Without trying to belabor it, Wayne, that is the very thing that I was trying to say in my memo, that just because a lot of allopathic things are used that aren't proven to be safe and effective doesn't mean that we should necessarily say that that is what we want to do with CAM.

DR. JONAS: I agree, and I don't think we should make another standard. I think we should just keep it simple and say this is coordinating federal efforts. Whatever those efforts may be is going to be determined by the office.

DR. GORDON: Now, we have two proposals. One is to facilitate coordination of federal efforts, and the other one adds the piece about integration of safe and effective. Can I get a sense? How many would prefer

just the "facilitate coordination"?

[Show of hands.]

DR. GORDON: That's, what, seven? Eight. Let's see that again.

[Show of hands.]

DR. GORDON: I think the simple wording has it. I think we can put in the text some of the issues related.

Will that be acceptable, to put those in the text, issues related to safe and effective, integration of safe and effective? Dean?

DR. ORNISH: The vote has been taken.

DR. GORDON: I'm sorry?

DR. ORNISH: Everybody has made a decision.

DR. GORDON: I can't hear you.

DR. ORNISH: I said the vote has been made. It doesn't matter what I think.

DR. GORDON: No, I am asking how about putting it into the text.

DR. ORNISH: I think that would be useful.

DR. GORDON: Okay.

DR. WARREN: I'm glad we had a consensus on

this before we started.

DR. GORDON: Okay. First of all, are there any issues about the text, any other issues about the text, that need to be addressed in this section? Then we need to take up the last issue that was raised, about where this should be positioned in the report.

Tieraona.

DR. LOW DOG: I just think you need to get rid of that whole "parents of children with attention deficit," blah-blah-blah, just narrow it down. You could say something like, "consumers, manufacturers, both CAM and conventional practitioners," or that, "We heard from a broad spectrum who testified about the need for," and then finish it. Then you could say, "This is consistent with findings of other groups as well, several national meetings," just make a nice segue. But I don't think it reads very well.

DR. GORDON: Okay. Any comment on that? Joe.

DR. FINS: I agree with that. On page 4 --

DR. GORDON: Let's deal with that one first, okay?

Are there other comments about this particular

change?

[No response.]

DR. GORDON: Okay to change it that way? Okay.

Thank you, Tieraona.

Joe, you have another?

DR. FINS: Yes. On page 4, we are talking about who might be on this council. In addition to the recommendation that somebody from the Office of Domestic Policy Advisor, from yesterday, that I suggested, I also think we should make some explicit mention of CMS.

DR. GORDON: Okay. Explain to everybody what CMS is, Joe.

DR. FINS: It is the HCFA, the new HCFA, which will have important implications for bringing safe and effective things to the reimbursement within the federal government, and that, I think, is a very important player to be in that loop.

DR. GORDON: Okay. Is that all right? Fine.

Anything else in the text that needs to be addressed? We did some of this yesterday, but if there is anything more. No? Okay.

The final issue with regard to this section was

the placement of the section. Right now, we have it at the end of the report. Yesterday, a couple people suggested it might be placed at the beginning, or elsewhere in the report. I would like to get some discussion and some resolution, if possible, about that.

David.

DR. BRESLER: Yes. Again, I brought this up yesterday where I thought it was backwards, but it started with Wellness and ended with CAM Central, and I think it should go exactly the opposite way. I think we should put our most important recommendations first.

Again, as Dean pointed out, I think that there are, maybe, two or three really key recommendations of all the ones that we are going to recommend, and I think that they should be strongly emphasized right up at the front of the report, and this is maybe the most important one of all.

DR. GORDON: I just wanted to make a point of information, that Wellness is not going to be at the beginning of the report. That is not the current plan, and I will just give the rationale for it briefly, and then we can go on. The current plan is to address the

mandate areas first, and then to follow with Wellness and CAM Central at the end.

So I just wanted that as a point of information.

DR. BRESLER: I understand. We even talked about the possibility of putting Wellness in as an appendix, too, since this goes a little beyond our mandate, but even though that was our mandate, I think the report shouldn't just necessarily follow what we have been asked to do, but it should emphasize what we think are the most important things to do first, and this is one of them.

DR. GORDON: Other discussion about this? Tom, and then Joe.

MR. CHAPPELL: Yes. I will just repeat what I said yesterday. I think putting CAM Central first is certainly license we can take, and I think it presents a very bold and powerful opening to the whole document.

DR. GORDON: Joe.

DR. FINS: I think what we might want to do is to finish going through all the sections, and then figure out how they sort out. I mean, arguments could be made

to put Research early on because everything, in many ways, follows downstream from that. I think it is premature to have the meta discussion before we go through the details of each section.

DR. GORDON: Does that feel fair enough to everyone? Okay. Let's make sure we get back to that at the end. Then let's close this discussion.

Tom, you had a point you wanted to make. Then I want to welcome George DeVries and give George a chance to say a few words, if you would like to.

Charlotte, you had something you wanted to say?

SISTER KERR: Yes. I'm not so sure about putting it first. I honor everything everyone said. My sense is that we need an organic process for the reader, or the evolutionary process, so that we bring them into the thinking and consciousness where it's really going to take a federal-level coordination to do this rather than, here we are; we want a big-time thing.

So that is my thinking, and I just share that with the group.

DR. GORDON: Thank you, Charlotte.

What I would like to do is defer, per the

discussion, defer the discussion of the order until the end, and then move ahead. Thank you.

Tom.

MR. CHAPPELL: I have completed the edits to the Education section. If everyone could go to the Education section. The task I was working on, with Steve's help, was to include the dentist and dental education as part of everything we are doing here. So if you open the Education and Training document, there are four very simple edits and they begin on page 3 with the heading "CAM in Medical School Curricula." I would simply like to amend that line, that header, to say "CAM in Medical and Dental School Curricula."

DR. GORDON: Okay. Why don't you go through all of them and then we can see where it all falls.

MR. CHAPPELL: They are all consistent. Two lines after that: "integrated into allopathic medical and dental school curricula." The next paragraph: "CAM taught in the context of conventional medical and dental education."

There is one more edit of that type, which I will find here in a minute.

DR. GORDON: All right. So the proposal is simply to add "and dental" to "medical."

Joe, and then Charlotte.

DR. PIZZORNO: Actually, we were going to say the same thing.

SISTER KERR: Yes. Go ahead, Joe.

DR. PIZZORNO: I think Tom has actually brought up a very good point, but why just medical and dental? Shouldn't it be conventional health care education, as what we are talking about? Because I think nurses should know about CAM, because they have interaction with the patients. I think we should broaden the language to everybody, just broaden the language.

SISTER KERR: I was kind of shocked that I just missed that. It absolutely should be all the health care schools and allied health care, and this is even part of the NCCAM money. I know nursing, in particular, got languaged in for the funding, and, in fact, it is being done. So right now, even our school is hooking up with the University of Pennsylvania. All the professional health care schools will be doing complementary medicine.

DR. GORDON: Any other comments on this? Do

you want to amend Tom's proposal? Julia, go ahead.

MS. SCOTT: I just want to make sure. If we are adding this in the text, then we need to have at least a line, or something about each of those, or not.

MR. CHAPPELL: If we could just make a decision on the language. There is one more line. I found it. It's in the paragraph, page 3, beginning with "Georgetown University" four lines down: "CAM and existing medical and dental schools."

Now, I am very happy to be more inclusive with the description, so I defer to the broader language. I just was concerned that "medical" had excluded dental.

DR. GORDON: Joe.

DR. PIZZORNO: Actually, if you look at Action Item 1.1 on page 7, we start out with "conventional health profession schools." So I think we just make sure the rest of the language is consistent with that.

DR. GORDON: Okay. Would that be all right with everyone, make sure it is conventional health professional schools, and not just restricted to medical school? Yes? Good. Let's move on, then.

Before we go into Information, George,

yesterday, everyone said a few words about their hopes and concerns and wishes. Dean spoke a little bit this morning. Welcome to you from the red-eye. Would you like to say a few words to the Commission?

MR. DeVRIES: Well, good morning. It's great to be here. This is obviously our last session together as a Commission, and I know there are still a lot of dynamics that we are working through, but out of the many, many recommendations -- there are so many of them -- there are actually a few of them that are so critical to the future of complementary health care.

So, as we delve through this, I think there is a real opportunity, even with the few critical ones, as well as the majority of the many, there are real opportunities to create a lasting impression and lasting impact on our field as we look to the future. So I am excited about that. Thank you.

DR. GORDON: Great. Thank you, George.

So let's begin. Turn now to the Information section.

DR. KACZMARCZYK: I would like to, as we make a transition to the next subject, thank Don Warren, Effie

Chow, Veronica Gutierrez, and Wayne Jonas for the contributions to CAM Central, and I have a little something to show our appreciation.

[Presentation of certificates.]

DR. WARREN: Thank you, Joe.

CAM Information Development and Dissemination

DR. GORDON: We are going to begin now with the Information section. For George and for Dean, the procedure that we have devised is to go through, recommendation by recommendation, to get a general sense that the recommendation works for us.

If it works for us, to let it go at that point and say it's a recommendation. If it doesn't, to work on it until it makes sense in some way, or else to say we are not going to make the recommendation. Once we have gone through the recommendations, then to go back and look at the text and look at all the issues in the text that may present problems that need to be amplified or clarified.

So what I will do is, I will read the first recommendation, then ask you all to read to yourselves the action items, and then we will go through them one by

one, starting with the recommendation and the action items, and we will have discussion on each.

So the first recommendation is on page 7 of the Information section, and it reads as follows: "The availability of reliable, useful, and easily accessible information for the public on CAM practices and products should be enhanced."

Then I ask you to take a minute to read through the action items under that, 1.1 through 1.4, and then we will begin to discuss the recommendation.

[Pause.]

DR. GORDON: Let's begin with a discussion of the recommendation. Tieraona, you have your hand up, and Don as well.

DR. LOW DOG: Well, I guess my question is just, is "reliable" the best word, or is "accurate" more powerful? "The availability of accurate, useful and easily accessible information"?

DR. GORDON: Let's continue. Don.

DR. WARREN: I like "accurate." Are we doing the actions yet?

DR. GORDON: Let's look at the recommendation.

If we can work with the recommendation first, that would be great. If we can't, we will go to the action items and work back.

Any other others on the recommendation itself?

Yes, Charlotte.

SISTER KERR: All along, in the recommendations, I had trouble with the fact that they weren't behavioral, and because we do 'shoulds' and get better and work harder, but when we have "enhanced," I'm like, what the heck is "enhanced"? It sounds like perfume or something.

So in this case, we want people to have more accurate, whatever, information. What do we want to say? The country should improve by 50 percent? We should have six more articles a year? How will we know if we achieved the objective?

It actually is a question I still have about our recommendations, of how they should be more behavioral, some kind of measurement.

DR. GORDON: So, do you have a wording that you think would be better and more action-oriented, so to speak?

SISTER KERR: No. I just said the dilemma. I mean, do we want something measurable: 50 percent; six articles; a new authority figure; a 911?

DR. BRESLER: How about something like, "The federal government should increase the availability of accurate, useful, and easily accessible information for the public on CAM practices and products"?

DR. GORDON: I would also add to that, after "products," "and their safety and efficacy."

DR. LOW DOG: Or, you could do: "The federal government should increase" -- however we come up with it -- "the availability of accurate, useful, and easily accessible information on the safety and efficacy of CAM practices and products," period.

DR. GORDON: Okay. How does that sound? Yes?

Don, what? I'm sorry?

DR. WARREN: Let's hear another reading of it, please.

DR. GORDON: Another reading, Tieraona.

DR. WARREN: Say it again, Tieraona.

DR. LOW DOG: "The federal government should provide accurate, useful, and easily accessible

information on the safety and efficacy of CAM practices and products," period.

DR. GORDON: Does that sound good to you? Comments on this?

MS. AXELROD: Jim, one of the reasons we did not put "safety and efficacy" or "safety and effectiveness" in the recommendation is that we don't want information to be limited only to those practices and products that are safe and effective.

DR. LOW DOG: That's not what it means. That's not what it means, though, Corrine. I would just beg to differ. When you're talking about the safety and efficacy, you're talking about, perhaps, the lack of safety, or you're talking about the lack of efficacy.

Talking about safety and efficacy does not in any way imply that it is only safe. You're just talking about safety as a category, and it may have a little safety or a great deal of safety, but I think people need to know the difference. So I'm talking about information on the safety and efficacy.

DR. JONAS: Why don't you just say "information, including the safety and efficacy." Then

it doesn't limit it.

DR. LOW DOG: Corrine, do you think that sounds okay?

DR. GORDON: Okay. Can we read that again and see if we are okay with this? Tieraona, do you want to read that?

DR. LOW DOG: Is this like a test? Let's see: "The federal government should provide accurate, useful, and easily accessible information, including the safety and efficacy of CAM practices and products."

DR. GORDON: I think Wayne had it the other way around: "for the public on CAM practices and products, including their safety and efficacy," "including about their safety and efficacy."

DR. LOW DOG: Well, Wayne, you read it.

[Laughter.]

DR. GORDON: Go ahead.

DR. LOW DOG: "The federal government should provide accurate, useful, and easily accessible information to the public on CAM practices and products, including their safety and efficacy." Did we do it?

DR. JONAS: Yes.

DR. LOW DOG: Okay.

DR. GORDON: "Including information about," to make it clear, because otherwise it is not quite grammatical. "Including information about their safety and efficacy."

DR. LOW DOG: There you go.

DR. GORDON: Okay. Are we okay with this? Okay. Great.

Let's go to the action items, then. Comments? Don.

DR. WARREN: Yes. No. 1.1 is CAM Central, isn't it? No. 1.1 appears to be CAM Central and the advisory council on CAM Central. I think we probably strike it here.

DR. GORDON: Strike it here. We actually had a lot of discussion about this in our group and the reason that it is included here was, if CAM Central didn't go forward, or if it were limited in other ways, we wanted this issue addressed. It may get subsumed under CAM Central, but we think it needs to be handled one way or another, even if CAM Central doesn't become real. That was our thinking about it at the time.

MS. AXELROD: If I could also add that the task force is different than the advisory council, that CAM Central, if it exists, may convene this and make sure it happens, but the task force members are not the same people as the advisory council.

DR. GORDON: Are you clear on that, Don?

DR. WARREN: You are saying the task force is different, is an additional group.

DR. GORDON: I think, also, that the way things work in practice, is, if CAM Central happens, that function will be subsumed, almost certainly, under CAM Central, and the task force will be appointed by CAM Central. I mean, I think that's what will play out, practically. David's concern is if CAM Central is not created, that the function still needs to go ahead.

Other discussion about 1.1?

Yes, Charlotte.

SISTER KERR: Again, the words "to enhance," do we want it to say "facilitate the development and dissemination of CAM information" on the first line, in 1.1?

DR. GORDON: So that, the change would be from

"enhance" to "facilitate." Is that okay? Okay.

Anything else on 1.1? All right. We are okay with 1.1, then, with that understanding that David gave us. Let's go to No. 1.2.

David.

DR. BRESLER: Real quickly, let's take out the "all," just to keep it consistent with our other action plans.

DR. GORDON: In 1.2, okay. So let's look at 1.2. Comments about 1.2?

Tieraona.

DR. LOW DOG: I just wanted to add, Corrine, what do you think about, at the bottom, "safety and effectiveness of CAM products and services"?

MS. AXELROD: Okay.

DR. GORDON: Is that okay with everyone?

DR. LOW DOG: Or "practices."

DR. GORDON: "Practices."

DR. LOW DOG: I just didn't want to limit it to products.

DR. GORDON: "Practices." Good.

Anything else on 1.2? Any hands up? Okay. We

are okay with 1.2, then, with those two small changes: "all" stricken, and adding "practices" at the end.

No. 1.3. Charlotte.

SISTER KERR: Just a clarification. The American Library Association, the National Library Association, is that the working group? So that, we are actually affecting the working system of our library system?

MS. AXELROD: Yes.

DR. GORDON: Anything else on 1.3? Okay. We are okay with 1.3. Yes?

No. 1.4, any discussion on this one? Okay. We are all right with 1.4. Yes? Okay, good. Thank you.

Let's move on to Recommendation No. 2 at the bottom of page 9.

David.

DR. BRESLER: Again, to keep it consistent, along with Charlotte's concerns, I think we should say: "The federal government should improve the quality and accuracy of CAM information on the Internet."

DR. GORDON: This is Recommendation No. 2, at the bottom: "The federal government." What are you

suggesting, David?

DR. BRESLER: "The federal government should improve the quality and accuracy of CAM information on the Internet."

DR. GORDON: Well, let me read it the way it is, because that may or may not be the intent. What it is here is: "The quality and accuracy of CAM information on the Internet should be improved." You're making a suggestion that it is the federal government.

DR. BRESLER: It's tricky because we don't want Big Brother in this particular medium, for sure, but we want to make it an action-oriented behavioral recommendation.

DR. GORDON: Let me suggest, before we discuss the recommendation, that everybody look at the action items, and then figure out how the recommendation should be worded.

DR. ORNISH: I like the recommendation myself.

DR. GORDON: Dean? I'm sorry, go ahead.

DR. ORNISH: I like the recommendation.

DR. GORDON: You like the recommendation as it is?

DR. ORNISH: Yes.

DR. GORDON: Okay. Other discussion about the recommendation? Joe, and then George.

DR. PIZZORNO: I don't think we should put in "federal government," because there are already several independent agencies out there testifying to the quality of health-related content on the Internet. So let's have everybody responsible, not just the federal government.

DR. GORDON: Okay. George.

MR. DeVRIES: Yes. I wouldn't lead with the "federal government," because if the federal government doesn't do it, basically this still needs to be done, and as Joe said, there are a variety of organizations that are stepping up to provide that kind of oversight and accreditation.

DR. GORDON: David, where are you on this?

DR. BRESLER: I'm fine with it.

DR. GORDON: Okay. So the recommendation is all right as it stands?

SISTER KERR: A question.

DR. GORDON: Yes.

SISTER KERR: Again, it's not a big deal, but

people with better words than I might do this: "The quality and accuracy of CAM information on the Internet should be improved," and I wonder if we want to be more specific, like, "It should be accurate and up to date," words that may be a little more specific.

What would be something to indicate we are not going to do something?

DR. GORDON: Let me suggest, Charlotte, that we look at the action items and see if we want to take any of the wording in the action items and put them back in the recommendation or not. Let's look at the action items with the opportunity to go back and look at the recommendation again, in the light of the action items. Is that okay with you if we do that?

SISTER KERR: Yes.

DR. GORDON: So let's look at the action items, and then see if we want to revise the recommendation based on that, because I think a lot of the wording that you are looking for is in the action items.

So let's look at 2.1 first. Discussion about this? Any problems or concerns about 2.1?

[No response.]

DR. GORDON: Okay. No. 2.1, we are all right with. I need to get little signals, head signals or hand signals. All right, great.

No. 2.2 all right? Yes?

No. 2.3, the Privacy section. We are in agreement on this? Great.

Joe.

DR. PIZZORNO: I think, right now, the FTC is responsible for evaluating the accuracy and appropriateness of information on the Internet, and we don't seem to have supported them in that process.

MS. AXELROD: The FTC oversees advertising, and that would include on the Internet, but this is really about the content of Internet sites that provide information on CAM services and products, and other health information.

DR. GORDON: Okay. So are we all right, then, with 2.3? Yes? Okay.

I'm sorry, David. Go ahead.

DR. BRESLER: The question is, do we want to include little pieces of 2.1, 2, and 3 in the recommendation itself by saying how it should be

improved: "should be improved by establishing a voluntary standards board, public education campaigns, and actions to protect the privacy of," et cetera, just somehow include two or three words about each of these action steps in the recommendation itself, so it is not so vague, like "should be improved."

DR. GORDON: It would be easier if you could give us the precise wording. Then we could have a discussion about that.

DR. BRESLER: I can give it to you now, if you want.

DR. GORDON: Yes. Go ahead.

DR. BRESLER: Okay. "The quality and accuracy of CAM information on the Internet should be improved by establishing a voluntary standards board, public education campaigns, and actions to protect consumers' privacy."

DR. GORDON: Okay. Responses to David's follow-up on Charlotte's suggestion that we might want to be more specific?

Charlotte, do you have any response?

SISTER KERR: Taking it in, it sounds pretty

good.

DR. WARREN: What was the last part of that again, David?

DR. BRESLER: "Actions to protect consumers' privacy."

DR. GORDON: Dean, what is your sense of that?

DR. ORNISH: I'm not sure, if it is in the actions or the recommendations, that it really matters that much, but if it makes David comfortable, I'm all for it.

DR. BRESLER: Again, it was just our concern that a lot of our recommendations are sort of vague, and sort of like, "let's get world peace." Let's put something a little bit more specific with the recommendation.

MS. SCOTT: Quite frankly, many people are going to be pulling from this report, and many people won't pull the recommendation and the action. So I think, in that sense, it is just the addition of a couple more words that it makes sense.

SISTER KERR: My bias is just what Julia said. I think there will be the executive summary readers,

there will be just the recommendation readers, and I think our recommendations need to have a little more juice to them, like David is suggesting.

DR. GROFT: We are not planning to separate the recommendations from the action items in the appendix. They will all be included together.

The second part of that will be, the recommendations and action items will be highlighted, as far as the organization that is responsible for implementation, such as the department, such as the private sector. If there are specific ones towards FDA or NIH, they will be so identified.

DR. GORDON: Steve, okay, so you are saying that the recommendations cannot be pulled out.

DR. GROFT: Someone would have to remove the action items from the recommendation itself.

DR. GORDON: So, do you have any feeling about being more specific in the recommendation?

DR. GROFT: If you wanted to add those three statements there that follow, or the three phrases, it's okay to just continue on.

DR. GORDON: Okay. Tieraona.

DR. LOW DOG: Yes. Corrine, do you think that is okay? Because it is very brief and it just makes it more specific, I would support the additions.

DR. GORDON: Okay. David, read them once again so everybody can hear them.

DR. BRESLER: Recommendation No. 2: "The quality and accuracy of CAM information on the Internet should be improved by establishing a voluntary standards board, public education campaigns, and actions to protect consumers' privacy."

DR. GORDON: Okay. Are we in agreement with this? Do we feel this is something we can live with, want to live with? Yes? Okay.

Any problems? Great. Thank you.

Recommendation No. 3. Let me read this, and Corrine, you have that wording down. Great.

Recommendation No. 3 on page 11: "Information on the training and education of providers of CAM services should be made easily available to the public." Then if everyone would read through the two action items there.

[Pause.]

DR. GORDON: Okay. Discussion of the recommendation. Are people happy with the recommendation? Satisfied with it? Any concerns about it?

[No response.]

DR. GORDON: Okay. So the recommendation is all right. Let's look at the action items. Let's go to 3.1, "states require all persons providing CAM services to make information available."

Yes, Charlotte.

SISTER KERR: Again, it's almost like Action Item 3.1 should be the recommendation. It just says the recommendation more clearly.

DR. LOW DOG: Would you suggest something like "states should improve," something like that? Is that what you want in the recommendation? Because it's more than just the CAM services providers, it's also that they should maintain information on guidelines in that, et cetera.

DR. GORDON: It is more active, is what you are saying. It is more active, more specific than the recommendation. The recommendation is more general and

somewhat more in the passive mode.

Linnea, were you about to say something? Or, George?

MS. LARSON: This is something I still have not resolved myself, but I still have great difficulty when we tell states what to do, and there may be some way of rewording that or something, but to have that as the recommendation, states should do this, again, it comes back to my point of, we are trying to guide federal policy and then maybe give some support to states as they are carrying out some activities that we would recommend.

DR. GORDON: Okay. George?

MR. DeVRIES: I certainly understand the concern, but it is certainly reasonable and within the scope of this commission to make recommendations to states, and I believe that these are good recommendations to states and I actually think they are pretty well worded. So I think, in the context of our role, making recommendations like this is a good thing.

DR. GORDON: Can you help Linnea with her concern? You're saying it is within the role of this commission. Do you want to explain to her why you think

that?

MR. DeVRIES: Well, you have 50 individual states who are making decisions on how to appropriately regulate health care and licensed health care providers, and ultimately those 50 individual states don't always see it on a national level, and that is the opportunity for this commission to give the states a reference point and recommendations, and that is going to be very helpful to them.

I do know, in talking with a couple representatives of state governments, that there is interest in having this commission make recommendations, and that is the way it is seen.

DR. GORDON: Okay. Other discussions about this whole recommendations to states issue? Yes, Veronica, and then Joe.

DR. GUTIERREZ: I'm not sure how you accomplish this, other than posting your diploma on your state license. How in the world do you make information more available, or easily available, to consumers? I don't know what this means.

DR. GORDON: Charlotte, do you want to respond

to that?

SISTER KERR: It's a little bit more muddying things, to me. There is a de-emphasis in this recommendation of the personal responsibility of the practitioner to say who they are, what they do, and there are some people who will not yet even be in registrations and licensure. It's back to the consumers being educated themselves to know what to look for, and the responsibility of a practitioner to say what the story is.

So mine is almost saying we want to say states and practitioners are responsible for making known their level of practice or experience.

DR. GORDON: Tieraona?

DR. LOW DOG: I would support states and practitioners making that. I just know that we don't live in an ideal world where everybody is up front about that.

Your point is well taken about the license and diploma here. I think this is really trying to get at more of an ambiguous category of people who are not licensed but who provide services, and the informed

disclosure-type of model where this commission has not taken the position to restrict their ability to practice, but that we feel, for public awareness and safety, that they should know who this person is and what their training is.

The problem will still be that if it says some school of healing or something up there, the consumer has no concept if that is a valid diploma or not. So it is still problematic, I recognize that.

DR. GORDON: So there are two issues on the floor right now. One has to do with whether or not there needs to be instruction to the states or whether the recommendation should be to all practitioners -- I'm hearing that nuance from you, Charlotte -- and Linnea's concern about instructing these states, and George's feeling that it is appropriate and asked for.

David? I'm sorry, Joe is first, and then David. I'm sorry.

DR. PIZZORNO: These are all great points, and I think Linnea and George raised very valid points. I think we have to be careful about that, where we draw that line. So I think that one area that is clearly over

the line is to say that the federal government should require states to do X. That is going over the line, but for us to recommend an action to the state, I think, is really appropriate.

So I think we should be careful about our language. I think "recommend" is very appropriate language. "Should" is language we must be very careful about. I wonder if there is some way we can modify it rather than just using "should," "should consider."

DR. GORDON: What about saying "The Commission recommends that states require."

DR. PIZZORNO: Yes. That kind of language would work.

DR. GORDON: Does that work? Does that work for you, Linnea?

MS. LARSON: Yes.

DR. GORDON: Do we want that as an action item, or do we want that as the recommendation?

DR. LOW DOG: Would you read your recommendation?

DR. GORDON: Just, "The Commission recommends that states require all persons providing CAM services to

make information regarding their level and scope of training easily available to consumers."

MS. AXELROD: Just for consistency, we have stricken "The Commission recommends" from all of the recommendations to avoid repetitiveness, so this would kind of stick out a bit, to word it that way.

DR. GORDON: Yes. We may want it, I don't know.

DR. GROFT: I think, in this case we are looking at states' rights, as opposed to federal involvement. Maybe this is one time when we can just go with recommending it, since every recommendation would not have that language in it.

DR. GORDON: David?

DR. BRESLER: I think our responsibility in our charge is to look at this from the point of view of the American public, and there are some things that the federal government regulates, there are certain things that the states regulate, but our mandate is to protect the American public, and I think in those situations where it is really the states' responsibility, I don't have any reservation about strongly recommending what the

states need to do to protect the American public. That is part of our charge, as far as I am concerned.

DR. GORDON: What we are talking about is making 3.1 the recommendation.

No? Leaving the recommendation as it is?

DR. BRESLER: Leaving the recommendation as it is.

DR. GORDON: The action item being the way I just stated?

DR. BRESLER: The way it is.

DR. GORDON: Okay.

DR. BRESLER: I wouldn't be concerned about telling the states what to do.

DR. GORDON: Are we all right with that, then? Okay.

Let's look at 3.2, then. We are in agreement the recommendation stays as it is? No?

DR. WARREN: You have confused me.

DR. GORDON: I'm sorry?

DR. WARREN: You have confused me on 3.1. Read 3.1.

DR. GORDON: No. 3.1 would be, Action Item:

"The Commission recommends that states should require," et cetera, et cetera.

DR. WARREN: Okay.

DR. GUTIERREZ: I would like "disclose information" rather than "make information." Disclosure, to me, denotes a little more honesty, maybe.

DR. GORDON: So it would read, "To disclose information regarding their level and scope of training to consumers."

DR. GUTIERREZ: Yes.

DR. GORDON: I'm sorry, "disclose information regarding their level and scope of training to consumers." Okay. Great.

Let's move on to 3.2. Do we want to reword it in the same way, or do we want to keep it this way?

DR. BRESLER: Again, I think we may all be more comfortable just recommending things to the state to say specifically that "the Commission recommends," and then take it out of everywhere else.

DR. GORDON: So that it would read something like, "The Commission recommends that states make information," et cetera, et cetera.

George?

MR. DeVRIES: Yes.

DR. GORDON: Yes.

Dean?

DR. ORNISH: This is not important enough to me to spend a lot of energy on, but, as Corrine said, in every recommendation is implicit the statement "the Commission recommends." I'm not sure why this is different. It doesn't change anything. It's just redundant, but I don't really care.

MR. DeVRIES: I would just add, I think Stephen made a good point, which is, we can err on the side, on this one, which says, "the Commission recommends" because we really truly are, just on this, recommending to the states a course of action, and erring on that side is probably prudent on our part.

DR. GORDON: So, in a sense, what you are saying is, we are taking our function as a recommender, we are not violating states' rights, and that is why we are putting in the "recommend" here and not elsewhere. Is that correct?

MR. DeVRIES: Yes.

DR. GORDON: Okay. Joe.

DR. PIZZORNO: One is, I don't know if we should change "information" to "disclose" on this one because the state, we are assuming, is open.

However, I have a concern. Do states have the legal authority to make public disciplinary action against health providers?

DR. LOW DOG: They do.

DR. PIZZORNO: They do?

DR. LOW DOG: They do for conventional practitioners. It is the wall of shame.

DR. GORDON: Okay. No. 3.2, anything else on that?

[No response.]

DR. GORDON: All right. We are fine with 3.2, with that amendment of "The Commission recommends that."

Let's go on to Recommendation No. 4 on page 14.

MR. CHAPPELL: Jim?

DR. GORDON: Yes, sorry.

MR. CHAPPELL: I would like to speak to the recommendation.

DR. GORDON: Which recommendation?

MR. CHAPPELL: No. 4.

DR. GORDON: Let me read it, and then let's give people a chance to read the action items first.

MR. CHAPPELL: Okay.

DR. GORDON: Recommendation No. 4 on page 14: "CAM products that are available to U.S. consumers should meet or exceed minimum standards of quality and consistency."

Then if everyone could read the action items, and then, Tom, you will be first to speak on this one.

[Pause.]

DR. GORDON: Okay. Tom, you wanted to speak to the recommendation.

MR. CHAPPELL: Yes. Thank you.

I would like to add the idea of safety to this recommendation for two reasons. Safety is expressed in Action Item 4.4, and safety is the number one concern that surrounds this whole subject. We have not been able to embrace the notion of safety in any of the other recommendations throughout the document, and it seems to me this is the place to do it.

To talk about quality and consistency falls

short of the concern that has been expressed throughout the hearing process for safety. So my language change here would be very simple: "CAM products available to U.S. consumers should be safe and should meet standards of quality and consistency."

DR. GORDON: Okay. Thank you.

Let's have discussion. Dean, and Tieraona, and Ming.

DR. ORNISH: Yes, I agree with Tom. When you think about it, "should meet the minimum standards," I mean, that is a pretty low bar. I think we can do better than that.

DR. GORDON: Tieraona.

DR. LOW DOG: I would agree about the safety, products that are safe. I think consistency is problematic at this point for crude botanicals. Because of the variability of constituents within them, having consistency can be tough depending upon how you are defining that.

So I would say "should meet quality standards." I need to work on the language, but I think "consistency" is going to need to go, only from a technical point of

view because of how you are going to define "consistency" from one product to another.

DR. GORDON: How are you with the safety issue?

DR. LOW DOG: I am absolutely in support of safety and products that are safe. Again, that needs to be determined, because safety for many of these products hasn't been determined. That is what we are trying to get to in the items.

DR. GORDON: Ming.

DR. TIAN: I think safety and quality will be enough. We don't need consistency because that is part of the quality. In No. 2, I don't like the "minimum." What is a minimum standard? I think there is only one standard for both. It doesn't matter if it is pharmacy or food or dietary supplement.

DR. GORDON: So, how would you say it, then?

DR. TIAN: Well, just "safety and quality, to meet the standard."

DR. GORDON: "Should meet standards of."

DR. TIAN: Right. Right. There is one standard. We don't want to have two standards.

DR. GORDON: Okay. George DeVries.

MR. DeVRIES: I would support the recommendations related to inclusion of "quality" in the recommendation, as well as eliminating "consistency" for the reasons stated, and basically say: "CAM products available to U.S. consumers should meet or exceed standards of quality and be safe," or, as Tom said, either way.

DR. GORDON: Okay. Yes, Joe?

DR. FINS: I mean, I think you could have quality products that, in isolation, would be quality products but they may not be consistent from batch to batch, and as you think about adverse events, consistency is very, very important. We are going to get to that.

So I think consistency is an element that we might want to maintain.

DR. GORDON: Tieraona.

DR. LOW DOG: Yes. I would like to just respond to that. It is like saying that every apple has to have exactly the same constituents from apple to apple. You are just never going to get it, because depending upon when the apple was harvested and what the environmental conditions were, it is going to influence

how many of the constituents -- and there are hundreds of them in an apple. It's the same thing with botanicals.

Now, when you are talking about a dietary supplement, it is much easier to get consistency, but even a product that is standardized, for instance, if you standardized it to a marker compound, other constituents will vary greatly within the plant. There is just no way to completely control complex mixtures in that way.

DR. FINS: If I could respond here, and maybe you guys changed this when I was out for a moment, but you are using the phrase "CAM products." Maybe that is too vague a term, because the argument for consistency is good for supplements, but it is not good for other things.

DR. LOW DOG: That's correct.

DR. GORDON: Joe.

DR. PIZZORNO: I think we can handle this by putting in the term "appropriate" instead of "minimum standards." That way, with dietary supplements, clearly we want much more consistency, where, with botanicals, we realize there is going to be some variation, and that is appropriate.

DR. GORDON: So, can you give us a wording?

DR. PIZZORNO: Okay. "CAM products that are available to U.S. consumers should be safe and meet appropriate standards of quality," period.

DR. LOW DOG: Say it one more time, Joe.

DR. PIZZORNO: Okay. "CAM products that are available to U.S. consumers should be safe and meet appropriate standards of quality."

DR. LOW DOG: That's good, because consistency would be a part of quality for many products.

MS. AXELROD: Well, I'm just wondering, if we have the word "appropriate," if it would be okay to leave "consistency" in. I'm looking back at the text where we have really gone to great lengths to describe the problems with consistency. If you look on page 12, line 335 and down, for instance, it is a big problem, and I think it is something, if we have the word "appropriate," that would give a little bit leeway. What is appropriate for one may be different than another.

DR. LOW DOG: Corrine, I think you are absolutely right on leaving that in. I just want to point out again that if you are using a marker compound

and you've stated that you have a certain amount of that substance, your quality standards will guarantee that you have that. But I could live with it either way. If you are using "appropriate," I could leave "consistency" in.

DR. GORDON: Where are you?

DR. PIZZORNO: I don't think we have to put it in there, but if people prefer it, I'm okay with it.

DR. GORDON: Okay. Would people like to have "consistency" in, modified by "appropriate"? It sounds like they would. So let's read the amended recommendation.

DR. PIZZORNO: Okay. "CAM products that are available to U.S. consumers should be safe and meet appropriate standards of quality and consistency."

DR. GORDON: Are we all right with this? Great.

Let's move on to Action Item 4.1. Any discussion on this?

[No response.]

DR. GORDON: Are we okay with this? Good.

Please, I am just going to move through these, so everybody pay close attention. If there are issues,

this is the time to discuss them.

No. 4.2. Charlotte.

SISTER KERR: Sorry. Back on 4.1, I would recommend on the third line, "Reference materials for dietary supplements should be improved and accelerated." "Enhanced" is just not a word that I think says a lot.

DR. GORDON: Are we okay? Instead of "enhanced"? Is that all right with everyone? Yes? Okay.

Let's move on to 4.2, then.

MR. CHAPPELL: Jim, Tom here.

DR. GORDON: Tom, sorry.

MR. CHAPPELL: I think the last sentence, the word "complex" is really unnecessary to use in the text. Delete it.

DR. GORDON: Is everybody okay with that? Anything else in 4.2?

Thank you, Tom. That is one of those places where we unnecessarily make things more complex, right?

Anything else with 4.2?

DR. FINS: Jim?

DR. GORDON: Yes.

DR. FINS: The proposal concerning GMP, is it a specific proposal here? I mean, I know what it refers to, but it looks like it is "the proposal," and I'm not sure if it makes sense to the reader, in isolation.

Could we specify a little more?

DR. GORDON: Corrine, do you want to say what the proposal is? Or, Ken is here.

MS. AXELROD: Well, it's a proposal and it's pending, so I'm not sure what your confusion is.

DR. GROFT: Or, would you want to add "the proposal to establish good manufacturing practices"?

MR. DeVRIES: I think Tieraona suggested "the proposed good manufacturing practices," which made it clearer.

DR. GORDON: Okay. Are we okay with that emendation? We are okay with 4.2 as it is? Fine. We are eliminating "complex," and saying "the proposed good manufacturing practices."

No. 4.3. Any issues regarding 4.3?

[No response.]

DR. GORDON: Okay, No. 4.4. Yes, Tieraona.

DR. LOW DOG: Corrine, to whom, and how, should

manufacturers make available scientific information? "Manufacturers should make available," but we don't really say to whom.

MS. AXELROD: I think this was intended to the FDA.

DR. LOW DOG: Should we be more specific here?

MS. AXELROD: Yes.

MR. CHAPPELL: Jim?

DR. GORDON: Yes, Tom.

MR. CHAPPELL: I think this is a burden of responsibility of manufacturers to have in their files when they are creating new products. I'm not sure I am comfortable making those manufacturers accountable to the FDA to present that. I think it should be available on request by any regulatory agency.

DR. GORDON: Can you explain why you are saying that, Tom? It might help people understand better.

MR. CHAPPELL: Well, if you make the manufacturers accountable to produce this safety data to the FDA, you will wait and wait and wait and wait before you can produce a product, and a lot of the safety data is very readily available as secondary research

information, number one.

So it fulfills the responsibility, in my opinion, to require manufacturers to have this data on hand and on request, but it poses a whole different burden to make them accountable, or for the FDA to approve.

DR. GORDON: Okay. Tieraona.

DR. LOW DOG: I'm not sure that we were looking for approval here. I am sensitive to the problem here, and I am open to more exploration, but I think that the problem here is that because safety data is not required, we end up, then, back-pedaling when there is a problem, and that the reality is that safety data information is not available for many of the botanicals. You have in vitro data, but that is it. There is no safety data, other than we have used it for a long time.

So I don't know if there needs to be a review of this, maybe, before we make the recommendation that manufacturers do this. Maybe there needs to be a recommendation for a review of how safety data is made available.

I think that, right now, we keep talking about