safety throughout this document, that people have the right to have safe products, but I'm not sure that I trust every manufacturer to have the safety data available in a file someplace.

DR. GORDON: Any other thoughts? Joe.

DR. FINS: There are two issues. I understand Tom's point and I think that it works fine when everything is fine, but when there is a problem and there is an adverse event, and a manufacturer is no longer in business, or there is a weekend and there is a tryptophan sort of story, and we are trying to figure out what the problem is, it would be nice if some of that information was on file and readily available.

So I think there are really two issues. I mean, I think the manufacturers should be required to keep a file, but there has to be a way of accessing it in a situation that is emergent.

DR. GORDON: Joe, do you want to provide some wording that might cover that?

DR. FINS: Well, I think that maybe it is complicated, and I think there are competing interests here. Maybe we should leave it as is at this point and

say, we recommend that the FDA consider mechanisms, feasibilities, working with industry to coordinate this process," or something.

In other words, not to say that it has to happen right now, but to figure out a way to achieve this end. I don't have language for you.

DR. GORDON: Joe, and then George DeVries.

DR. PIZZORNO: I think this is an incredibly important issue because we want to facilitate the public safety, but we also don't want to put barriers in the place of good quality products being available to the public.

I'm thinking about, we want to help the public and the manufacturers of high quality differentiate themselves in the eyes of the public and practitioners from those that are low quality, and that is a real problem right now, as I think we are all conscious of.

I wonder if we could have in this -- I'm kind of thinking out loud here -- some kind of a voluntary submission of safety data to the FDA that could then show up in some way on the person's label or package documents, so that they are showing to the public that

they really are taking a next step to being more safe and have higher GMPs in the development of their products.

I'm not sure how to word that, but it is a concept.

DR. GORDON: George, and then Dean.

MR. DeVRIES: I think the issue of safety is the primary issue here, and yet we are trying to come up with a mechanism. The mechanism that is being recommended, I hesitate on it also, and for some of the reasons that Tom has mentioned. I think it also places a great burden on the FDA. I am not sure they would see it has having the same value as maybe some of us would.

I am going to suggest, maybe, that we encourage a process such that the outcome is assurance of safety.

DR. GORDON: What would that process be? Because I think we have to come to some kind of conclusion.

MR. DeVRIES: Perhaps FDA and/or HHS task force to evaluate and to come up with a solution to ensure safety.

DR. GORDON: Okay. We can come back to specific wording.

DR. ORNISH: Well, we are not talking about efficacy, we are just talking about safety, and I think that it seems to me almost a given that if you -- it is like we are for world peace in a way, as David was saying.

I mean, who could argue against having safe things that say what is on the label? I mean, I am not sure why this is even controversial. If we are asking, and we may not necessarily want to specify it is the FDA or whomever, we should say an appropriate government agency should be responsible for making sure that these things contain what they say they contain, and that they are safe, period.

DR. GORDON: The recommendation here, though, is directed toward the manufacturers. So that has a different spin on it.

DR. ORNISH: Well, it is both. I mean, it is both the manufacturers, but it is also the regulation of the manufacturers. You can't have one without the other.

We are not asking this to be done voluntarily, and I think it is entirely appropriate that both the manufacturers be held accountable and that they be

regulated to make sure that what is in the product is what is on the label, and vice versa, and that it is safe. I can't imagine anyone would be against that.

DR. LOW DOG: I agree with you. There are a couple issues here. One is the GMP will take care of making sure that what is on the label is what is in the bottle, so that is covered under GMP.

Safety is a different issue, though. Trying to have adequate toxicology studies for acute and subacute and these kinds of things, most of them have not been done for these products, and so when you are requiring safety data, how much is going to be the standard and what kind of studies need to be done, what would have to be supplied by a manufacturer, because the Dietary Supplement Health Education Act of 1994 has put these into a different sort of category.

So I need to tell you that I don't argue against safety. I am absolutely for safety, but right now, we just seem hog-tied. I mean, we can't even come up with ephedrine guarana answers.

Maybe the best thing, at this point, is to require manufacturers to maintain records of this, and

that we have a recommendation that states that HHS or FDA, or collaborations of these agencies, create a task force to address the potentially serious problem here that we have with inadequate safety data and the fact that it is not submitted to the government.

DR. GORDON: I would like this, if we could, in the form of wording that would address these issues.

Tom.

MR. CHAPPELL: It seems to me, again, the burden needs to be on the manufacturer to establish safety. Now, I want to maintain flexibility for the manufacturer in so doing because there are many manufacturers that are responsible, and I want to maintain their flexibility.

The idea for me would be to simply publish that safety data to the FDA, to simply put it on file with the FDA. It is not getting permission, it is just filing its safety data with the FDA. So it would say: "Manufacturers should make available to the FDA their scientific information to substantiate their determinations of safety."

DR. GORDON: Tieraona.

DR. LOW DOG: My problem with that would be, what if it is basically a cell culture and that's it, and that's all we have determined as safety? It is a brand new designer drug that has never been seen on the planet before, and we have put it in as a dietary supplement, and there is no safety data available. What is the responsibility, then, of the FDA?

MR. CHAPPELL: There are other mechanisms to provide for that kind of scenario. First of all, the FDA regulates claims, so everything is claim-based. If you are making a claim that is hinged on an ingredient, then there is DSHEA, or there is a monograph, or there is the NDA route. Those are the avenues that you can go.

Now, you're shaking your head. I beg to differ with you.

DR. LOW DOG: No. All I am saying is, that claim doesn't have to do with safety, Tom.

DR. GORDON: Tieraona, let me just interrupt for a second. We can't solve the whole problem here. I think what we need to do is have an action step that is a step in the direction that we want to go.

MR. CHAPPELL: As this is written, I personally

would accept it as it is written, but I also think that we could push a little harder on this. It is simply to put on file with the FDA the manufacturer's safety data, and that is just an inventory of data.

DR. FINS: I mean, in a sense, we are asking for something here that is a kind of modification of existing statute, and we don't know what it should be. So we are asking you to file, but we don't know what the filing should be comprised of.

So I think what we need to do is say that, you know, we might say in the text or something that we recognize that this ultimately is what should happen and that the FDA should engage in a feasibility study to determine what should be filed in the safety documents, what the periodicity should be, and what the elements are, because this action item, in and of itself, will not lead to any action, but a recommendation for a feasibility study would be the first step towards the goal that we all share.

DR. GORDON: Okay. I want Julia, and then Tom.

Julia, you had your hand up?

MS. SCOTT: No.

DR. GORDON: No, you're okay?

Tom, go ahead.

MR. CHAPPELL: I think that is an intelligent idea, Joe. There are times when I prefer wisdom over intelligence.

[Laughter.]

DR. GORDON: And wit over brevity.

MR. CHAPPELL: So I do not want you, in this language, to tie the hands of the manufacturers. I just want you to hold them responsible for safety.

DR. GORDON: Tom, we need wording here.

MR. CHAPPELL: I gave it to you.

DR. GORDON: We need to come to a conclusion.

MR. CHAPPELL: I gave it to you. I gave it to you.

DR. GORDON: Let's say it again.

MR. CHAPPELL: "Manufacturers should make available to the FDA scientific information to substantiate --

DR. GORDON: Okay, and so on.

MR. CHAPPELL: Yes.

DR. GORDON: Okay. Let's talk about this

wording, let's see if it works. If not, Tieraona is also coming up with wording.

Comments? Joe first, and then George, Joe.

DR. PIZZORNO: So, Tom, a manufacturing question to you. Would it be of value to a manufacturer, or would it be too great a burden that those manufacturers submit information to the FDA, and the FDA approved their GMPs and safety data to be able to put on their label, "The FDA has approved the safety of this product"?

MR. CHAPPELL: I think it is up to the FDA to assess whether or not it has any concerns about the data that is submitted, and I think that is their domain to deal with. I don't think it is our domain. So I am not able to go beyond simply publishing the available safety data. They know whether we are dealing with something that is at risk here.

DR. PIZZORNO: Tom, you didn't quite answer the question I asked.

MR. CHAPPELL: Let me hear it again, then, Joe.

DR. PIZZORNO: It seems to me it would be a huge advantage for a manufacturer to be able to put on

the label that the FDA has approved the safety of this product.

MR. DeVRIES: You know, guys, we are really going outside of the laws that are in place. I think we are going way far afield, and I want to go back to suggesting what has been mentioned, whether it be a task force or a feasibility study.

I know Tieraona is working on some language related to a task force which I think can really help to narrow down a process, which I don't think, frankly, we are equipped to suggest the process that should be put into place today, but I think we can say there needs to be a task force that goes through these steps.

DR. GORDON: Okay. Joe.

DR. FINS: I agree with George, but I do want to close the loop very tightly here because I don't want this to look like we are just creating another task force. I would like that to be tagged to a report back to Congress to see whether or not there are any statutory changes that may need to be made based on that feasibility study.

In other words, this reporting mechanism

fundamentally raises the question of whether or not there is a modification of DSHEA, and I think that to just have a task force without a recommendation that it goes back to Congress is too open-ended.

DR. GORDON: Can we have George, Tieraona, somebody want to write some wording for this?

DR. LOW DOG: Well, we are trying. Let me just respond. I think, Tom, I think at this point, we would not want to recommend anything other if we were going to make this recommendation about manufacturers simply making available safety data.

In addition, I would like to make an additional recommendation that would say something like, "The appropriate federal agency" -- and I don't know who that would be; I would need your help, Corrine, in that -- "should establish a task force to evaluate the current reporting of safety information by manufacturer to FDA of CAM products to maximize and ensure public safety," something like that. I am on the spot.

Right now, the law is what it is. So I think that if we are saying manufacturers simply reported, the problem is a slippery slope on both sides. You could

have the FDA using that information to say that it is inadequate safety information in trying to remove products, which isn't our intent; and on the other hand, you may have manufacturers who are not taking that responsibility.

So I would either say that we could leave 4.4 the way it is where it is just simply a reporting, or we could remove it and you could substitute it. So you could add a Recommendation 4.5 about an establishment of a task force that is reportable to the Congress, or you could substitute it for 4.4.

DR. GORDON: Tom and George. We need to come to a closure on this. We have two more major recommendations in this section and we are already behind time.

MR. CHAPPELL: Okay. I think 4.4 is a very important action step and I would be highly opposed to removing it. I am not opposed to an additional 4.5 that tries to bring some standard to process or a process that establishes a standard for safety.

DR. GORDON: Okay. What about the 4.5 that Tieraona read the --

MR. CHAPPELL: Well, I need clarification from Tieraona.

Are you opposed in 4.4 to making reference that this be filed with the FDA?

DR. LOW DOG: Absolutely not.

MR. CHAPPELL: Okay. So manufacturers should make --

DR. LOW DOG: I feel very strongly about 4.4.

MR. CHAPPELL: Yes. So 4.4 would say, as it has been amended, as I was proposing the amendment, "Manufacturers should make available to the FDA scientific," blah, blah, blah. So that is where we are in our current process.

DR. LOW DOG: Can we accept 4.4, then?

DR. GORDON: Can we accept 4.4 as amended or not? Joe?

DR. PIZZORNO: I have a question about it. So we are having manufacturers submit the data to the FDA. What does the FDA do with it? Is it just archiving it?

DR. LOW DOG: They have it on file.

DR. PIZZORNO: Okay. A concern I have is what if a consumer has a reaction to a product that shows a

lack of safety? Can they then come back to the federal government and sue the federal government because the FDA had the safety data and didn't do anything about it that showed it was not safe? I am just wondering.

MR. CHAPPELL: For me, the recommendation to include the FDA here in 4.4, just filing, is a responsible step that this commission is recommending in view of the great concerns for safety in this area.

DR. GORDON: Okay. Can we agree to this?

Joe, having heard your concern, I don't think we have the answer to whether -- anybody can sue anybody any time. Whether they can win or not is another matter and really not our ultimate concern. Our concern is, are we willing to accept 4.4 here as amended? I don't mean to be short; I am just trying to move it along.

Yes?

MR. DeVRIES: Can we agree to 4.4 the way it is?

DR. GORDON: Just as Tom read it now.

DR. LOW DOG: It is exactly the same, but "make available to the FDA scientific information." That was the only amendment I heard. Is that correct, Tom?

MS. AXELROD: And are we leaving in the second clause in that? The second part is in there, "Current statutory provisions should be periodically reexamined." That is still in? Okay. Good.

DR. GORDON: Okay. George, are you okay with that? George DeVries.

MR. DeVRIES: It is a bit unclear. I mean, "should make available," does that mean upon request from FDA or automatically on an annual basis?

DR. WARREN: Shouldn't it be "filed with the FDA" so that they have a file on hand?

MR. CHAPPELL: Sure.

DR. WARREN: Instead of "making available upon request," have it a requirement that they file it.

MR. CHAPPELL: Sure. I will amend that. "Should file with the FDA."

DR. WARREN: "Should file."

DR. GORDON: "File with the FDA."

Where are you with this?

MR. DeVRIES: Well, I just think we are creating burdens for agencies and not giving them a role to say these are the ways to ensure safety. We are

saying we think this is the way safety be ensured, so go do it, and they might respond, you have just spent a huge amount of resources on our behalf, thank you, we would rather be spending it this way because we think we could do a better job ensuring safety this way. So I am just concerned we are --

DR. GORDON: I think if we cannot come to some kind of agreement --

MR. CHAPPELL: I am suggesting, George, that we fix 4.4 and then take up 4.5 to deal with the process question, George, okay?

DR. GORDON: But 4.4 will still stand, Tom. We are still saying, even if we going with the process, that the recommendation still says, give this to the FDA. We haven't asked the FDA if they want it and we have consulted with them about virtually all the other recommendations. So I think that George's point is well taken that we -- you know, we are introducing something that we have no idea whether it is wanted or not at this point, or needed.

DR. LOW DOG: Well, I think that the other alternative, then, is to propose the task force to

evaluate what is needed and what is required as a way of addressing these questions, because they may have minimum standards that they require.

DR. GORDON: That is fine. I am just saying -- I am just really sort of rephrasing what George said, is that we really have to think through the recommendations in terms of whether they fit and whether they are going to do any good.

Charlotte and then Joe.

SISTER KERR: I want to agree with George, though this is not my area. I think we have a clear intention of goodness and safety. What we are unclear on is that we are birthing a new baby in this country in particular, how to do it, and I think we need to be careful and not put burdens on people in case we won't get the outcome we seek.

So I would support this 4.5 concept, and really, from everything you as experts are saying to me, it sounds like that is only where we are, at the beginning of assessing what is wanted and needed to achieve the objective.

DR. GORDON: Okay. Joe?

DR. FINS: What I would suggest, and I think that ultimately it should go to the FDA, but I agree with George's concern, but suppose we did something like that? We made 4.4 "should file with the appropriate government agency," and then 4.5 is that we would respectfully ask the FDA to conduct a feasibility study to assess how this scientific information could be best provided to the government in order to ensure safety.

DR. GORDON: Is that okay, George?

DR. FINS: So 4.4 simply becomes "Manufacturers should file to the appropriate government agency scientific information to substantiate," blah, blah, blah.

MR. DeVRIES: How about, instead of "should file," because you have automatically created a tremendous amount of paper, huge amount of paper, you could say, "Manufacturers should make available upon request to the appropriate government agency." And if the government agency says, you know, that's a good idea, we want it from every manufacturer on every product, they can request it.

DR. GORDON: Okay.

MR. DeVRIES: If they are saying, it is not appropriate for us to collect all this, they don't need to ask for it.

DR. FINS: Okay. But then 4.5 should say that the FDA should conduct a feasibility study to determine how best to collect -- to determine how the federal government, because it may not be them, should --

DR. GORDON: Can help ensure the safety --

DR. FINS: Can help ensure the safety of these products, and specifically address issues of filing, registration, et cetera, so that these questions get played out in a sort of scientific way.

DR. GORDON: And let me say we need to move ahead, okay? So if we have a consensus on 4.4, which I think I was hearing that we had, I would like to get that clear, okay? So there was a wording I think, Joe, that you used that people --

DR. FINS: Yes.

DR. GORDON: Corrine?

MS. AXELROD: I just wanted to let everybody know that the FDA has reviewed this document and has not objected at all to this recommendation, so just, you

know, to put you at ease on that.

There is also an element of prevention in this that currently the manufacturers only need to submit a statement saying that the product is safe. So just even knowing that they must provide a little bit more information may act as some deterrent to the unscrupulous manufacturers who really don't have that safety data.

My other little comment is I don't think it is a feasibility study; I think we should just say study.

DR. GORDON: Joe, go ahead and read your amended 4.4.

DR. FINS: Okay. Four-point-four is that "Manufacturers should make available" -- we were going to say "upon --

DR. GORDON: "Upon request."

DR. FINS: "Upon request to the appropriate government agency" -- "to the FDA." Okay. We are back to the FDA. "Scientific information."

DR. GORDON: Okay. Are we okay with that? Good. Now, 4.5.

MR. CHAPPELL: Would you be all right, Joe, with "Manufacturers should have on hand and make

available upon request"? In other words, I want to establish the fact that their burden is to have it on file.

DR. GORDON: Okay? So let's read that once again to make sure --

MR. CHAPPELL: "Manufacturers should have on file and make available to the FDA upon request."

DR. GORDON: Fine.

DR. LOW DOG: That's good.

DR. GORDON: There is a recommendation for 4.5? Let's hear that, please.

DR. FINS: It is not drafted, but it is, "The FDA should conduct a study to determine how best to manage and oversee -- I mean, I don't have a wording here, but the filings or whatever. Tieraona, do you have --

DR. LOW DOG: Right, but can we agree? I would just like to have consensus on it and we can send it out. Corrine can certainly make a recommendation and get the words right.

DR. GORDON: Basically a recommendation to the FDA to look at how best to ensure safety of products.

DR. LOW DOG: Yes. Yes.

DR. GORDON: Okay.

MS. AXELROD: It may not be the FDA that --

DR. LOW DOG: It may be an appropriate agency.

DR. GORDON: Appropriate agency.

DR. LOW DOG: Yes.

DR. GORDON: Fine. Could you try to get that together and, if possible, even read it to us at the end of the day so everybody can be clear? If not, we are all in agreement about the general sense.

Joe.

DR. FINS: And then attach to that a report back to --

DR. LOW DOG: Congress.

DR. FINS: Right.

DR. LOW DOG: Right.

DR. GORDON: Okay. We need to move on.

Page 20, Recommendation 5. I am going to read the recommendation and then ask you all to read the action steps and ask everyone -- it was well spent, but we don't have the time to spend that kind of time on any more of these recommendations, okay?

"The public should have accurate information on the quality and safety of CAM products." And there are five action items. If everyone would read through them and if we could expedite the discussion of this.

[Pause.]

DR. GORDON: Okay. Let's begin now. Recommendation 5. Comments. "The public should have accurate information on the quality and safety of CAM products." Joe had a comment.

DR. FINS: Did we move on to the action or not?

DR. GORDON: Let's talk about the -- are we okay with the recommendation, at least provisionally, or do we need to address that first? Charlotte?

SISTER KERR: If I were being asked a question about Recommendation 4 and 5 in a public hearing, I don't see what -- first of all, the subject in both is products, and 4 is asking that they have good quality and consistency and 5 is asking that they have quality and safety. What is the difference here? Why didn't we put all of these in one recommendation, like safety, quality and consistency?

DR. GORDON: Well, Corrine may want to explain

this. Corrine?

MS. AXELROD: Maybe Tieraona or George wants to explain it.

[Laughter.]

MR. DeVRIES: I think Recommendation 4 is more about the quality and safety of the products themselves and 5 is dealing more with the information and the advertising and how those things are presented. So it is content versus presentation of the products. Is that good?

DR. GORDON: Are we okay at least provisionally with the recommendation and then we can move into the action items? Yes? Okay. So let's move into the action items.

Joe?

DR. FINS: I have one thing about this section. It seems to be, except for a little caveat in 5.2, exclusively about supplements, and I am wondering whether we want to be more specific in the recommendation or not, because it really is about supplements. But that is an aside.

DR. GORDON: That is what it is about.

DR. FINS: Yes. So I wonder if we should say safety of supplements versus safety of products.

DR. GORDON: Products is supplements. How do you --

DR. FINS: Supplements is a subcategory of CAM products.

SISTER KERR: We need to define products here because I don't know if we are talking about gadgets and --

DR. FINS: Right.

DR. LOW DOG: We could say dietary supplements.

DR. FINS: Well, I would say, you know, safety of supplements.

MS. AXELROD: No, 5.2 is more than just supplements.

DR. FINS: Well, I appreciate that and that is why it --

DR. LOW DOG: So you are probably going to have to leave "products," "CAM products."

MS. AXELROD: We could say "dietary supplements and other products."

DR. FINS: Yes. That is good.

DR. GORDON: All right. "CAM supplements and other products."

DR. FINS: Okay. Good.

DR. GORDON: You want to say "dietary supplements and other CAM products"? How about that?

DR. FINS: Yes, that is perfect.

DR. GORDON: All right. "Dietary supplements and other CAM products."

Let's move into the action items. Thank you, Joe, for pointing that out.

DR. FINS: I have an action item.

DR. GORDON: Go ahead.

DR. FINS: On 588, -89, one thing I think that we need to add in that last line, "so that consumers have truthful, complete and scientifically valid information on the benefits, appropriate uses of dietary supplements, and important drug supplement interactions on the product label at the point of sale."

DR. GORDON: Okay. Everybody got that, adding "and important drug supplement interactions." I would also add "hazards of the product" as well as "important drug product interactions."

DR. FINS: And "hazards." Okay.

DR. GORDON: "And hazards of the product and important drug product," and so if you are giving somebody ephedra, they need to know the potential liabilities.

DR. FINS: Maybe "risks," because "hazard" is maybe --

DR. GORDON: "Risks" is fine.

Tom?

MR. CHAPPELL: Well, I just want to say that the task of establishing scientific evidence of the synergies of dietary supplements with drugs is beyond what any manufacturer can do and it is a task that will take a decade for the government to do.

MR. DeVRIES: How about "significant and established"?

MS. AXELROD: Can I just make a point for clarification? This issue is actually dealt with in 5.3 and we separated out the appropriate use and benefits from the interactions, hazards, risks, because the mechanisms to do that are so different; and that in terms of the interactions and risks, that falls under the

caveat of material facts and that when those facts are known, the manufacturer must disclose it. There is no requirement that they do the research on it, but when they know it, it must be disclosed. So those are dealt with separately.

DR. GORDON: Corrine, I think if we are indeed going to deal with them separately, "material facts" has to be explained, because that is a technical term and not one that is accessible to people.

MS. AXELROD: It is explained in the text. Do you feel it needs to be explained in the action item?

DR. GORDON: It needs to be explained in the action item.

MS. AXELROD: That is not an easy thing to do.

DR. FINS: I understand what you are saying, but I also think that this is -- you know, 5.1 was kind of -- it is really a very consumer-directed action item, and they are going to see the label. You know, the disclosure is an upstream thing but the label is how it gets disclosed. So I really think the consumer needs to have -- it should be in 5.1 and --

MR. DeVRIES: Say, Joe, if that is needed, if

you look at the last part of 5.3, it says, "Public will know about known risks and well-documented and significant interactions." Can we take the phrase "known risk" and "well-documented and significant interactions"? I mean, if you want that in 5.1, that would be the phrase.

DR. FINS: I really want to say something. I want to specifically say, "significant interactions between drugs and supplements" or "supplements and drugs."

MR. DeVRIES: Well, it is not just interactions between dietary supplements and pharmaceutical drugs; it is also non-pharmaceutical drugs, OTC, tobacco, food, alcohol.

DR. FINS: Right.

MR. DeVRIES: I don't think you want to limit yourself.

DR. FINS: Okay.

DR. GORDON: Can we take that phrase that George has suggested and put that in 5.1? Yes? Joe, yes?

DR. FINS: Yes.

DR. GORDON: Okay. Let's move on, please. So you have that down, Corrine? So it would be, "on the benefits, appropriate uses and known risks and well-documented significant interactions" will be inserted on line 589.

Yes, Joe.

DR. PIZZORNO: So is that being removed, then, from 5.3 and just put into 5.1?

DR. GORDON: I think we can leave them in both places as well.

DR. PIZZORNO: Okay.

DR. GORDON: At this point. But let's put them in 5.1.

DR. LOW DOG: With 5.1, I need to get at what we are trying to really get. "So that consumers have truthful" -- well, that's already required by law. You can't make untruthful statements. The law requires they be truthful, and so the law would need to be enforced if you are looking for truthful. "Complete." "Complete" is defined by what? Including "significant interactions"? I mean, is that what we are looking for "complete"? And "scientifically valid." Well, there are already laws in

place for scientific validity and what you have to do to move through it.

So are we asking for -- I think if we are asking for more than what we are asking here, we need to be more specific, because right now, you have --

DR. GORDON: I am not sure what you mean.

DR. LOW DOG: We are saying right now that we should have further input followed by rulemaking, oversight, and legislative reform, so that consumers have truthful, complete and scientifically valid information on the benefits and appropriate uses.

DR. GORDON: Right.

DR. LOW DOG: Are you asking that we are revisiting the structure function in that?

DR. GORDON: Yes. That is the way I read it. I mean, the group that formulated this is the Information Group, but essentially yes.

DR. LOW DOG: Well, I know, I am on that group.

DR. GORDON: So that is what you are asking for.

DR. LOW DOG: But it has changed so many times. This actually was -- we had at-length discussions about

this and this has continued to change.

DR. GORDON: This is your group.

Corrine, do you want to clarify this?

MS. AXELROD: Well, it hasn't changed since right after the last meeting when we did the revisions based on some comments from George, and then we had several conference calls and we worked it out. So, as far as I know, it hasn't changed.

DR. GORDON: This is what I have seen since the first revisions after the last meeting.

DR. LOW DOG: We had at-length discussions about DSHEA and we had -- because we had focused primarily on these other issues, and then it was brought to our attention that other commissioners really wanted to visit the scientifically valid information and structure function, and that is okay. I am just wondering if it could be more specific in the recommendation if that is what we are asking for.

DR. GORDON: If you want to make it more specific, could you do that? I want to move through these, Tieraona, because if we don't --

DR. LOW DOG: Yes. I am just saying right now,

it makes it sound, Jim, like right now the laws say that you can be untruthful, incomplete, and put scientifically invalid information on there, which is not true.

MR. CHAPPELL: Jim, this actually is not what the committee's subcommittee came up with. We didn't support this idea, just so you know. This is not a committee-based, this is something other than the committee. Am I right on that?

DR. LOW DOG: I was on all those calls and we discussed this at length. This is not what exactly we came up with in our group.

MR. CHAPPELL: If George, Tieraona and I agree to that point, you can rest assured we -- this did not come out of the committee.

DR. GORDON: So tell us, what are we going to do with 5.1?

MR. CHAPPELL: George, the process that we have in Recommendation 4, is that sufficient, or do we need a process -- that is really my only question of you, because you are the one that has been promoting the process here.

DR. GORDON: Let me just say, to take it one

step back, that there was considerable concern and discussion from the Commission as a whole that we wanted better information to be provided to consumers, and you were one of the leaders in that, as I remember.

MR. CHAPPELL: Yes, and we came up with language at the last Commission gathering that was not this language.

DR. GORDON: What I would like to do is, if you all are still having a difficulty with this language, I don't think we can take -- what we need you to do is maybe at lunchtime sit and come up with better language and work with Corrine, and with Steve, if you want, certainly with Corrine to do that.

We need to move through these, because what I am looking for is the deliberations of the subcommittees based on last-time's meeting, and if you are saying this isn't what you did, then let's move on and go to what you did, and we have to come back to this very quickly, though, okay?

So let's look at the rest of 5, 5.1, 5.2, 5.3, 5.4 and 5.5. I think the intent of 5.1 that I heard and I just want to make sure you address is that the

Commission as a whole wanted more information easily available to consumers about the benefits and risks. However you want to state it, that is the general intent and that is really --

DR. FINS: And also point of sale.

DR. GORDON: At point of sale, as Joe is saying.

Yes.

MR. CHAPPELL: I remember that was the Commission's intent.

DR. GORDON: Great. So as long as you have our intent in mind, go back and work out the wording. Meanwhile, let's look at the rest of No. 5.

MR. DeVRIES: One question, though. I heard you say earlier how much -- because as we worked through it on a committee, it was saying, yes, there needs to be better information but in the context of saying really the current laws really need to be reinforced, to be enforced. We are not talking about rewriting the laws.

DR. GORDON: Again, the Commission's concern, George, again, the Commission's concern is that better information be available at the point of sale whether the

laws have to be rewritten or not. That is your judgment as to how to best implement that, okay?

DR. LOW DOG: We are going to meet at lunch for a few minutes, our group, and we will get back to you right after lunch, okay?

DR. GORDON: Great. Thank you.

Let's move ahead with 5.2, 5.3, .4 and .5.

Yes, Joe.

DR. FINS: George, on this issue, I mean, I might have missed it, but where do we say that DSHEA should be fully enforced as an action item? That is kind of important. And that it should be revisited if it is found to be inadequate. That seems to be a major --

MR. DeVRIES: That was the core of the committee's discussion. All current laws need to be fully enforced because some aren't being.

DR. FINS: Right. And then, because that is a tease point, it should be, but we know it is not, so that is why we the reintroducing it again. So we need to have that language back, "fully enforced," and then go back and revisit it after a period of time and report to Congress.

DR. LOW DOG: To see if it is adequate or not.

DR. FINS: To see if it is adequate or needs to be revisited. Thank you.

DR. GORDON: Thank you, Joe.

Let's move ahead, please.

MS. AXELROD: Can I just point out that is in 5.5?

DR. FINS: We don't explicitly say that DSHEA should be fully enforced. I think we should explicitly mention DSHEA somewhere --

DR. GORDON: So mention DSHEA in 5.5.

DR. FINS: And then come back and say "fully implemented, enforced and funded," which is implied, and then say we are going to come back and then Congress should revisit the issue based on all of those resources --

DR. GORDON: Joe, are you suggesting that instead of it being 5.5, that there should be a separate recommendation, or are you content with the 5.5?

DR. FINS: It almost seems to me that this is -- the full implementation of DSHEA, its enforcement and its revisiting, is almost at the level of a

recommendation, not an action item, because everything else kind of follows in that context.

DR. GORDON: Okay. Is everybody agreed on that? Then we would like 5.5, which essentially is what you are saying, but it needs to be made explicit, right?

DR. FINS: As a recommendation.

DR. GORDON: As a recommendation.

DR. FINS: Not as an action item.

DR. GORDON: I got you. As a recommendation.

Everybody agree with that, that 5.5 would then become a recommendation?

DR. LOW DOG: Not 5.5. Please let us just take it at lunch. We will take the implementation and enforcement of DSHEA and look at that as making a recommendation, but there are other things in 5.5 that we are not going to include in the recommendation.

DR. GORDON: Okay.

DR. LOW DOG: Such as English language, et cetera.

DR. GORDON: All right.

MS. AXELROD: Jim, for clarification, will that replace the current Recommendation No. 5 or is that an in

addition to?

DR. GORDON: No. That would be in addition, is what I am hearing, or it may replace. I don't know. We have to see.

DR. FINS: And I would just argue that it should precede the current 5, I mean the first statement about DSHEA and about these issues.

DR. GORDON: All right. So what we would like from you all is for you all to reformulate this and come back to us, okay?

Now, does it make sense, then, to go through 5.2 through 5.4, or are we fine with those recommendations or those action items? Yes, Veronica.

DR. GUTIERREZ: One comment. It might be obvious under 5.2, Subsection 2. I would like to have it read "use appropriate CAM experts in the process."

DR. GORDON: Is that okay with everyone? Okay. Good. Anything else? All right.

So we are asking, Tieraona, you and George to go back -- excuse me, Tieraona? We are asking you and George to go back. There needs to be a recommendation that specifically addresses implementation of DSHEA and

there needs to be whatever rewording of 5.1 there needs to be to address the concern of the Commission that there be adequate information at point of sale.

DR. LOW DOG: We understand.

DR. GORDON: Okay.

Joe?

DR. PIZZORNO: Isn't 5.4 a restatement of what we are trying to create with 4.5, a new 4.5? I think that should be moved over there.

MS. AXELROD: One is before the fact and one is after.

DR. GORDON: Did everybody hear what Joe just said, that 5.4 is perhaps a restatement of 4.5?

DR. PIZZORNO: The new 4.5 we are writing.

DR. GORDON: The new 4.5. Yes? Okay.

MR. DeVRIES: We were just chatting that we would like over lunch the opportunity to look at 5.1 to 5.5, because that problem -- we were discussing 5.4 -- seems out of place now and 5.5 needs rework, 5.1 needs rework.

DR. GORDON: All right. Please do that. We will probably come back to it at the end of the day,

though, okay, because we need to move through the other sections.

MR. DeVRIES: Got it.

DR. GORDON: All right. Let's move on to Recommendation 6. On page 22, Recommendation 6: "The collection and dissemination of information about adverse events stemming from the use of dietary supplements should be improved."

Please read the action items under this.

[Pause.]

DR. GORDON: Okay. Steve was pointing out to me that already in the appropriation language additional funds have been provided to update and modernize the adverse events reporting system. Are we okay with these, Recommendation 6 and the action steps?

Joe.

DR. FINS: On page 23, 649, we have this elsewhere. We made this request that they file safety information, and that was not voluntary, and now we are saying but they should voluntarily register in the event that there is an adverse event. So I am confused about that.

DR. GORDON: Do you want to clarify that?

DR. LOW DOG: Yes. Actually, unless I misunderstood, I thought we had said that manufacturers will have on file and make available upon request. So they weren't just making the filing. And because you are going to have to mandate this -- I mean, we were just asking for voluntary until it could become --

DR. GORDON: Wait. But now you are confusing us again. You are adding something and now you are taking it away.

DR. LOW DOG: No, I didn't do anything. All I said was that on four-point-whatever-it-was, we had said that manufacturers will have on file and make available upon request, so that is something separate. That wasn't voluntary or mandated; we are just saying that they should have it on file.

DR. GORDON: Okay. What do you want to do here?

DR. LOW DOG: This one, I like it the way it is. I like it just the way it is. It says that you are going to register --

DR. GORDON: Okay. But Joe doesn't like it the

way it is.

MR. CHAPPELL: Okay. Well, Joe, this is adverse events and that is different from the larger picture of safety data.

DR. FINS: Maybe really in 6.2, I think we would want to mandate reporting of adverse events, whereas, you know -- because 6.1 is that you are voluntarily registering as a manufacturer. In the event that something were to happen, they could find you. Six-point-two is that we are asking them to report adverse events to the agency, and that it is a requirement. So I think we are covered. I think that works.

DR. GORDON: You think it is okay.

DR. FINS: I think we are okay.

DR. GORDON: Julia? Okay. So we are okay. There is not a problem.

Effie.

DR. CHOW: In 6.1 or 6.2, should consumers come in there or does that assume that, reporting to the manufacturers, that the consumers are going to be notified right away of adverse events? So in 6.1, on

page 23, "so that manufacturers and suppliers and consumers can be promptly notified if a serious adverse event is identified."

DR. LOW DOG: Yes, I understand what you are saying there. The way this is written is that the reason we are asking manufacturers and suppliers to register is so that they can be promptly notified if there is a contaminant, adulterant, or concern. Obviously, if there is a concern, the FDA would need to make that known to the public, if there is an adverse event.

DR. GORDON: Effie, are you asking if that needs to be in here?

DR. FINS: It is in 6.3. It is in 6.3, Effie, line 661. They mention consumers.

DR. GORDON: Okay.

DR. FINS: Jim?

DR. GORDON: Yes, Joe.

DR. FINS: On 6.3, I would like to include -- I have said this a thousand times -- CDC because it is not here, I don't think.

DR. LOW DOG: We had had that before.

DR. FINS: Okay. "Provided to FDA and CDC."

The reason I say that is an adverse event, once it is known to be attributable to a drug or a supplement, is under the purview of FDA, but if children are having rashes in the schools, it is the EIS that is going after and trying to figure that out, and it may be a supplement or it may be --

DR. GORDON: Okay. Are we okay with that, adding CDC?

DR. LOW DOG: Yes.

DR. GORDON: Okay. Good.

DR. FINS: And the other thing is, I would add on No. 3, "an increase in outreach activities and education to consumers" and all that, et cetera, but I also want to make explicit resources available, and we mentioned poison control centers and to emergency medical services. They need more than outreach and education; they may need some real resources. So I don't think outreach will meet the need for the training and the information that they require.

DR. GORDON: What are you suggesting adding?

MS. AXELROD: Ken just reminded me that this section is on information, it is not on education and

training. So we just need to keep that in mind in terms of going out to train other people.

DR. LOW DOG: Right. And that first line is "additional resources and support."

DR. GORDON: Okay. I would like to get agreement on this. I think we are really in an incredible time bind and I need to let everybody know. We should have been through two sections by now. We are only through one.

I want to get a reading from people. How many people will be here until the end of the day?

[Show of hands.]

DR. CHOW: What is the end of the day?

DR. GORDON: End of the day is midnight. No. End of the day is when we finish, because we need to finish this today. There are no ifs, ands or buts about it. If everybody wants to be here to finish it together, everybody has to move faster, okay? I can't do it myself. We have to be completely mindful and only focus on what is most essential.

Don.

DR. WARREN: It seems like in this 6.1,

whatever it is, we are setting a higher standard for the adverse reporting system for nutritional supplements than we have for vaccinations. It does not make sense. Are the manufacturers of supplements liable for suit and the manufacturer of immunizations aren't? What are we doing here?

DR. GROFT: No, there is a vaccine injury compensation program already available. It is federal dollars.

DR. GORDON: And vaccines have to register.

DR. GROFT: And licensed.

DR. GORDON: They are registered and licensed.

DR. GROFT: They need to be licensed and adverse events must be reported as part of the licensing process.

DR. GORDON: Tom.

MR. CHAPPELL: The issue that you are -- I don't see the equation here, so I think our language is fine as it is.

DR. GORDON: Are we okay, then, with 6 as it is, and action? Any major issues with the text? Minor issues, please contact Corrine outside of this meeting.

Joe, go ahead.

DR. PIZZORNO: Page 10, line 287. I don't like quite the way that is written and I would like to suggest that after "for example," in front of "naturopathic," maybe if you put the word "lay" there, that would help make that work better; and on line 288, after "naturopathic physicians," cross out "may."

DR. GORDON: Is that all right with people?

DR. PIZZORNO: Line 287, after "for example," insert before "naturopathic" "lay," the word "lay," l-a-y; and on line 288, after "naturophatic physicians," cross out the word "may."

DR. GORDON: Is that okay with everyone? Okay. Anything else on the text?

Okay. We are going to take a ten-minute break and then we are going to come back with Access and Delivery and we are going to finish it by 11:45. We will be beginning with Wellness and then we will Access and Delivery right after lunch. So thank you for your indulgence for this necessary change.

[Break.]

DR. GORDON: A couple of points. One is Public

Comment will be at the time that it was scheduled. There are seven people signed up, seven or eight people signed up for Public Comment. Each person will have three minutes. They will be in panels and we will have an opportunity to talk with them after each panel.

The Commission will adjourn here at about 10 of 12:00, and then commissioners are going to be getting together over lunch and having discussions, sort of figuring out various things. Then we will come back here at 1:00 promptly. We will begin again, we will go up to the time of Public Comment, and then we will continue after the Public Comment.

It is entirely possible that the meetings will continue until 6:00 or 6:30 this evening. It's just necessary for us to get through the business we have at hand. I would suggest, and I know a number of you have begun to do this, if you could reschedule flights so that you can be here until the end. We really want everyone here, even Don. We want to make sure Don is here, too. This is our last meeting and we want to make sure that everybody has input into all the sections.

So let's begin now. Thank you, and thank you

especially, Corrine, for your indulgence in doing one session right after the other.

CAM IN WELLNESS AND HEALTH PROMOTION

DR. GORDON: Let's begin with the Wellness session, and I want to remind everyone that the current order would have the Wellness session just before the CAM Central section, which is at the end of the report, okay?

What I am going to do once again is to read the recommendations.

Yes, Joe?

DR. PIZZORNO: I think it may be more appropriate to discuss now where it is going to be located and then get the recommendations, because it may change the character of how we go through this process. If that is okay, I would like to put on the table that this be an appendix, not be one of our sections.

DR. GORDON: That is a recommendation put on the table. Tom?

MR. CHAPPELL: I think wellness is so much a part of the world view that that would be disvalueing the work. So I would argue that we keep it where it is presently intended.

DR. GORDON: Other comments? Julia?

MS. SCOTT: I really would like us to press forward on the recommendation. The placement of any of this, I think we can do later, but it is very important while everyone is here that we get consensus on the recommendations or the need to make changes. The placement in the report is important, but not as important as getting us while we are here to agree on the recommendations.

DR. GORDON: So can we move forward with the recommendations, then, and defer any discussion? Okay.

Let's look at Recommendation No. 1 on page 7. It reads, "Safe and effective CAM practices should be utilized to help achieve the Nation's health promotion and disease prevention goals and to promote wellness throughout the life span." And then there are several action items and six action items, so if everyone could take a little time to read through the action items, please.

[Pause.]

DR. GORDON: Dean, do you want to begin?

DR. ORNISH: Yes. First, let me thank you

again for the scheduling.

I am not going to repeat everything that was in my memo yesterday, but I want to just highlight one part of it which I think is, to me, among the most important, and that is that many if not most of our recommendations are not about specific modalities, they are about CAM, and CAM -- we made a joke about it a moment ago, but almost anything passes for CAM. So it concerns me when we talk about here again CAM practices, CAM practices. What are we referring to?

So at a minimum in Action Item 1.1, I would like to see "CAM practices that have been proven to improve nutrition, promote exercise"; in other words, add the four words "have been proven to" in that one, at least to help to narrow it down a little bit.

DR. GORDON: Dean, do you want to also, while you have the microphone, say if there is -- that is a quite clear recommendation there. There are a number of recommendations that talk about CAM practices throughout the different action items here. Do you have a general kind of way of looking at it that you want to outline?

DR. ORNISH: Well, short of revising the whole

document, no. I mean, that is part of the problem. It is not just in this section, it is in all sections. When we talk about CAM, it is one thing if you are saying -- I mean, you may be talking about CAM or David Bresler might talk about CAM and say, well, that is acupuncture because that is proven, but if you look at Table 1 in the very first section of the document, not this chapter but the document itself, it can include, you know, coffee enemas, it could include all kinds of stuff that -- sitting under a crystal pyramid to some person is a CAM practice.

So I know that there is an ethos that goes through this document that when we talk about CAM, we tend to think of those modalities that we have the most experience with, that we have seen clinical efficacy of even if they may not be proven in randomized trials. But I think we need to also wear the filter of someone saying, well, that could also include almost anything, and that is why I keep coming back to safe and effective as just one shorthand way of trying to limit the scope of it, but even that really doesn't address the issue fully.

DR. GORDON: Okay. Well, let's try to go through the specific action items keeping that in mind

and addressing it in a way that feels like it is appropriate.

Yes, Tieraona.

DR. LOW DOG: Can I make a comment on the recommendation?

DR. GORDON: Yes.

DR. LOW DOG: I would opt to change that "CAM practices and products should be evaluated to determine what role they may have in improving the Nation's health and disease prevention goals."

DR. ORNISH: I like that a lot, actually, because it completely addresses the issue that I have, which is this ethos of presuming that these things are beneficial and just finding out how we can implement them.

DR. GORDON: Let's read it again, please.

DR. LOW DOG: "CAM practices and products should be evaluated to determine what role they may have in improving the Nation's health and disease prevention goals."

DR. GORDON: And you are leaving out "and promoting wellness"?

DR. LOW DOG: I just sort of figure that's part of the health promotion. And you can add that, I am not attached to anything; I am just trying to find --

DR. GORDON: I think that is a distinct thought.

DR. LOW DOG: Fine.

DR. ORNISH: I would add that since it is part of the chapter.

DR. LOW DOG: That is fine.

DR. ORNISH: But I completely like what you are doing.

DR. GORDON: Okay. So we have a recommendation for the recommendation on the floor.

DR. ORNISH: I recommend that you accept the recommendation about the recommendation.

[Laughter.]

DR. GORDON: Okay. Are there any other recommendations about this or discussions about this? I think this is very important that we discuss it, that if people have concerns about it, that we enunciate it here at the beginning, because this is going to help shape all the other recommendations.

Yes, Joe.

DR. FINS: I really resonate with what Dean said and Tieraona's suggestion, but if you think about it logically, it is really a research question, it is not a health promotion question. I mean, the question is that we need to study whether or not this stuff causes decreased morbidity and mortality and promotes wellness.

So it really is logically a research question, and I think that the tone of this section has a proselytizing quality to it which is anti-scientific. I think it undermines the entire rest of the report. This is the implicit question in so much of what we are doing, and I think you are basically undermining the seriousness with which this report would be accepted.

DR. ORNISH: I don't quite follow you. Are you saying that the act of saying that we need to do research as well as promotion undermines the credibility of the report?

DR. FINS: I am saying what you said before in a slightly less clear way.

[Laughter.]

DR. GORDON: I appreciate less clarity, Joe.

DR. FINS: I am agreeing with what you said before about making claims for the imposition of vague modalities yet to be proven and established, and just agreeing that whether or not these interventions will impact the public health in decreasing morbidity, mortality, is a question to be determined.

DR. ORNISH: I agree with you, but I think that the nature of this chapter is it overlaps a lot of other chapters.

DR. FINS: Right.

DR. ORNISH: I mean, I was arguing against having this chapter in from the very beginning. Now that we have it, though, I think that we need to make the best of it, and so given what we have, I think adding Tieraona's qualifying language to me makes perfect sense.

I also would like to say that some of the narrative could come out as being a little more balanced and a little less as an advocate. I think there would be some value in that, too. We don't have time to go into that line by line now, but as a general --

DR. GORDON: We will have time. I want to get some other thoughts about this discussion that we have

here on the floor.

Charlotte.

SISTER KERR: I need to say this recommendation again from Tieraona. Complementary practice -- "CAM practices and products should be evaluated to determine their role in achieving the Nation's health promotion and disease," da, da, da.

Now, I think this conversation is really good, though. It is a challenge, because I think Joe's point is important in terms of is it a research question, and this feels like it is going to be one of those ones of not making the enemy -- perfect the enemy of the good.

By saying as it is, "safe and effective CAM practices," we are resting upon almost all our other chapters that we are requesting; for example, the last work we just did with guidelines on adverse reactions. We are resting upon the fact that we are recommending many things in research, so that this recommendation comes to say, yes, indeed, only those things that we know at this point that are safe and effective we want to include in schools, and I think to do it as Tieraona is saying is to totally drop out of the whole

recommendation, really. It is kind of like, let's do a study on so-and-so, and then after we do that, we will decide whether or not we want to do anything. And if I have not understood this, then I am open to --

DR. ORNISH: Tieraona, if I understood you correctly, you were saying that, "CAM practices and products should be evaluated to determine their role in achieving the Nation's health promotion and disease prevention goals and to promote wellness," blah, blah, blah, and that those that are safe and effective should be implemented. You are not saying we don't make any recommendations about implementation, but that we qualify by saying that we also need to evaluate them.

DR. LOW DOG: I am saying that right now, right now, practices without products, first of all, because I think products need to be in here, that if you are just relying on those that have actually been shown to prevent disease, you are going to have a very short list of implementation because -- I mean, you are. And I think that you want to set the stage here that we want to evaluate and we want to determine what role and for what populations and to whom.

This is a big area. It is not just an adult group found this if you are suggesting it is going to go to kindergartners. I mean, I think that you have to have some serious thought. If you really want to make an impact on the Nation's health, you have to evaluate the data that is there, and that will help drive research questions.

I am not asking for research here; I am asking for an evaluation of the data that is out there to determine what role and for whom this may play a role.

SISTER KERR: But we did delete "safe and effective," correct? Okay. But then if that statement would become the recommendation, I think we would have no actions because you are stopped at we are going to evaluate.

DR. ORNISH: In other words --

DR. GORDON: Please, let Charlotte continue, okay? This is not argumentation; this is learning from one another about what our positions are. So please, let's allow Charlotte to speak and then if others want to speak, please feel free to speak. Dean, you can respond.

DR. ORNISH: No, I am not arguing with you at

all; I am just trying to clarify that we are not taking that out, we are only adding the other. In other words, it wouldn't take out the part about that we want to utilize those that have been found to be safe and effective. That stays. It is only adding that we also want to evaluate the data that is there.

SISTER KERR: I didn't hear that. When Tieraona read hers, she didn't leave that line in, or did I misunderstand?

DR. LOW DOG: We can just include at the end "those that have been proven safe and effective should be integrated" or "should be put," whatever words you want to put in there.

SISTER KERR: So then let's read it as we are saying it because that is not how I understood it, and if that is the case, it may be very fine.

DR. ORNISH: This is what I was reading. I was trying to clarify. Again, I am not in any way trying to be argumentative, at least not at this particular point.

"CAM practices and products should be evaluated to determine their role in achieving the Nation's health promotion and disease prevention goals and to promote

wellness throughout the life span. Those that are found to be safe and effective should be utilized to help achieve these goals."

DR. GORDON: So that is the recommendation.

DR. ORNISH: That is the recommendation.

DR. GORDON: Okay. I agree with Charlotte. I didn't hear that in the beginning.

DR. ORNISH: Okay.

DR. GORDON: Okay. So that is the recommendation as amended. Are we okay with that?

MS. AXELROD: Can I make a comment, Jim? The way that it just read makes it sound like you are evaluating it for safe and effectiveness, when, in fact, you are evaluating these things to see their applicability to the goals and objectives that are laid out in H.P. 2010 and 2020.

So I think we need to clarify that we are not looking to evaluate safe and effectiveness here; we are looking to see which ones -- we are evaluating which ones that have been shown to be safe and effective apply to the goals and objectives.

DR. GORDON: That is a different question.

DR. ORNISH: I mean, you are saying they are -- I mean, in some ways the data would be evaluated to see if they are safe and effective and then to further evaluate them in the ways you are describing.

DR. GORDON: Tieraona.

DR. LOW DOG: That was actually a good distinction. I guess you could say that -- I don't know how to get around that, because at this point, you are needing to determine the effectiveness. Safe and effective CAM practices and products should be evaluated, but if you had done that, then they are effective, you already know, though you still may not know for the specificity for what groups that we are talking about.

DR. GORDON: Joe.

DR. FINS: They have to be safe. Whether or not they are effective for this purpose is the question, right?

DR. ORNISH: Can you explain, again, Corrine, what you are saying? I don't quite follow you.

MS. AXELROD: I think that what we want to look at are safe and -- CAM products and practices that have been found to be safe and effective should be evaluated

to determine their applicability to the Nation's goals and objectives for health promotion/disease prevention.

DR. LOW DOG: Say it again.

DR. GORDON: That is a different recommendation because that doesn't -- the recommendations that follow may or may not fall under that one, right? Everybody see there is a bit of a -- I mean the action steps may not fall under that particular recommendation.

MS. AXELROD: I am just building on what Tieraona had suggested about doing an evaluation, but that we need to be clear this is not research, we are not researching whether CAM products and practices are safe and effective. We want to look at the CAM products and practices that are safe and effective, how they can be utilized to help achieve the Nation's health promotion/disease prevention goals.

DR. ORNISH: I was only really talking about changing the Action Step 1.1; in other words, to -- I am okay with the Recommendation 1. I was referring to, when you get into things -- particularly when you are talking about kids where it is a real red-hot button for a lot of people, what you teach my -- what are you going to teach

my kids in the school? You are going to teach them about coffee enemas? You know, it is easy to distort this, very easy.

I am just saying I am only arguing something that seems to be pretty reasonable, which is that CAM practices that have been proven to be safe and effective -- excuse me -- that have been proven to improve nutrition, promote exercise, et cetera.

DR. GORDON: I think we are okay with that. I think, Dean, we are still on the recommendation, though. I think 1.1 is a separate issue, and we haven't really had discussion on that, although I suspect that your addition is fine. The question is, what about the recommendation as a whole?

SISTER KERR: I would like to respond again. I think, again, I think leaving the recommendation as it is and adding Dean's thing in 1.1 is a reasonable compromise in the attempt to be more specific to protect people and to just restate we want safe and effective. You cannot get this, I think, perfect.

DR. GORDON: Joe.

DR. PIZZORNO: Another potential wording would

be to leave the current wording in Recommendation 1 as written with this following addition. That is, "Safe and effective CAM practices," insert "when appropriate should be utilized," or "appropriate safe and effective CAM practices."

DR. GORDON: Is that okay as an addition?

DR. ORNISH: I think that is great. So it would say, "Safe and effective CAM practices, when appropriate"? Is that your recommendation?

DR. GORDON: Julia first.

DR. PIZZORNO: "When appropriate."

MS. SCOTT: It looks like there is going to be consensus on new language. I just wanted to say, I think what has been suggested really addresses our concerns. "Safe and effective CAM practices and products should be evaluated to determine" -- not for safety and whatever because we are assuming they are going to be safe and effective -- "determine their role in achieving the Nation's health promotion and disease prevention goals and to promote wellness throughout." I mean, I think that says it pretty specifically.

I also feel, after reading the actions, that

those actions are still appropriate to that recommendation and I would second Dean's addition to 1.1.

DR. GORDON: Where are we? Charlotte, where are you with this?

SISTER KERR: I heard two things. One, for myself even, and again, this is just thinking, leave the recommendation as it is, not with Tieraona's addition or anything; and the second thing I am hearing is make Recommendation 1 with this additional concept of evaluating, determining their role, so forth, and just stop there before we go into action steps. But I thought we were kind of going back to leaving Recommendation 1 as it was because safe and effective took care of it.

DR. GORDON: Joe? Joe is next, and then Tieraona.

DR. FINS: I think the confusion might be that a CAM product or service can be safe and effective on an individual basis for a person, but the question is whether or not it has an impact on a population, and Healthy People 2010, 2020 is health services, broader public health issues. So I think clearly, you know, it is like aspirin is safe and effective; does it decrease

the morbidity from heart disease in a population?

So that is sort of the analogy, and I think that needs to be clearer because I think we are confusing safe and effective for an individual versus its impact on a population vis-a-vis the articulated goals of the U.S. Public Health Service.

DR. GORDON: Charlotte, I want to get a sense of where you are with this, because Joe is addressing it to you, and then Tieraona, if you want to add something.

SISTER KERR: Was I clear in the distinctions I made, that there are two suggestions for recommendations?

DR. GORDON: Yes, there are two suggestions. One has to do with evaluation and the other has to do with leaving it the way it is.

SISTER KERR: Right.

DR. PIZZORNO: And mine, which is the third, would be "when appropriate."

DR. GORDON: And the third would be "appropriate." Thank you, Joe.

SISTER KERR: See, I think we are unclear. Appropriate, to me, was under Action 1.1. So Wayne's suggestion under Action 1.1 is appropriate CAM practices.

DR. GORDON: One-point-one, we already -- let me just suggest that under the action step in 1.1, on the floor is Dean's addition, which was "CAM practices that have proven to improve nutrition," et cetera, et cetera, et cetera, should be included.

DR. ORNISH: Can I make a suggestion that would combine everything?

DR. GORDON: Let's go back to the recommendation, though, if we could, okay, and get that cleared up.

DR. ORNISH: There are actually four things on the floor and I just want to suggest something as a compromise that might meet everybody's needs just in the spirit of moving forward and just tell me how you all feel about this.

It would be something like, "CAM practices and products should be evaluated to determine their role in achieving the Nation's health promotion and disease prevention goals. Those that are safe and effective should be utilized," you know, just the way that it reads right now. It would just be a sentence before that, and then the second part of it would be just as it is.

DR. GORDON: Does everybody understand? Wait. Before we go any further, does everybody understand what Dean just said? Okay.

Tom, you have not had a chance to speak. Please go ahead.

MR. CHAPPELL: I think we accomplish what I am hearing we are striving to do with the existing recommendation edited only by changing the concept of "utilization" to "evaluation." I do think that that is not asking for research, just discernment, and so "Safe and effective CAM practices and products should be evaluated to help determine their role in achieving the Nation's health promotion and disease prevention," et cetera.

DR. GORDON: What about the second sentence? Dean says bring back --

MR. CHAPPELL: No, I don't think you need the second sentence. Then you go into 1.1 to be edited --

DR. GORDON: Okay.

DR. ORNISH: I mean, I think that is fine; it is just that some people thought there should be inclusion about utilization, but that may be implicit in

the actions that we are recommending. So I can live with that, too.

DR. GORDON: Wayne, you have your hand up.

DR. JONAS: I think that is fine; however, then I think there should be, under the action statements, there should be an item that specifically says who is going to evaluate it or at least emphasizes the evaluation component. There should be a federal panel or there should be members of a task force that specifically looks at Healthy People 2000, et cetera, to accomplish these goals.

A lot of the other action steps under here really are about utilization, and so if you drop the utilization out of the overall recommendation, then they don't kind of make sense under --

DR. GORDON: There is a 1.5. That action step is there.

DR. JONAS: Oh. Sorry. Okay.

DR. GORDON: I understand your point.

Tieraona, go ahead.

DR. LOW DOG: I think part of my problem with the utilization was that they have not been appropriately

evaluated, and I think you need to evaluate before you utilize. So I feel strongly that the recommendations should include an evaluation so that we can determine what and to whom it is going to be, and maybe we could move the -- if you think that is sufficient, the Healthy People Consortium, or if you think that should be something else, that that maybe should be moved up to 1.1 so it is the first thing that you read, is who is going to do this.

DR. ORNISH: So, Tieraona, are you comfortable with Tom's recommendation, then?

DR. LOW DOG: Yes. Absolutely.

DR. ORNISH: Okay. Can we all agree on that and move forward?

DR. GORDON: All agree on what, Dean?

DR. ORNISH: On what Tom recommended, which was simply to say that "Safe and effective CAM practices should be evaluated to help determine their role in achieving the Nation's health promotion," blah, blah, blah.

DR. LOW DOG: Since it is a little confusing, let's read things specifically out, because we are going

to perhaps have a question on "utilization" inclusion. So please read it exactly as it was stated, please.

MR. CHAPPELL: "Safe and effective CAM practices and products should be evaluated to help determine their role in achieving the Nation's health promotion and disease prevention goals and to promote wellness throughout the life span."

DR. ORNISH: And implicit in that, because you have a lot of these action steps, is that there is -- you know, it doesn't just include evaluation, it includes utilization is what we are recommending.

DR. JONAS: Then you have to eliminate about half the action steps underneath there.

DR. ORNISH: No, no, no, I wouldn't eliminate them; I would just say you don't have to necessarily spell it out in the recommendation, because implicit is that we are talking utilization as well as evaluation.

DR. JONAS: I think they are going to have to be reworded, then.

DR. GORDON: I would like to add that second sentence, because I think it is important, that you left in, Dean. "Those have been proven safe and effective

should the utilized." I think it is necessary and that it helps --

DR. ORNISH: I am okay with that.

DR. GORDON: -- to move things forward.

DR. ORNISH: That is fine with me.

DR. GORDON: So if you could read that fully as you had it before, and I think that will satisfy us, and then we can move ahead.

DR. ORNISH: Julia wants to say something pretty badly.

MS. SCOTT: No. I had a recommendation how to incorporate both of them. "Safe and effective CAM practices and products should be evaluated to determine their role in achieving the Nation's health promotion and disease prevention goals. Those found to be safe and effective should be utilized to promote wellness throughout the life span."

[Applause.]

DR. GORDON: All right. Excellent. We are all agreed? All right. Thank you.

DR. JONAS: Just a minute. Wait a minute.

DR. GORDON: Wayne?

DR. JONAS: I like that very much, except now you need to cut out the first "safe and effective" because you are talking about evaluate. So the very first one, you just have "CAM products and practices" and use it in the second half.

MS. SCOTT: Okay. I am all right with that.

DR. LOW DOG: I move that Julia read the corrected amended version and that then we move to accept it.

DR. GORDON: Right. Julia.

MS. SCOTT: That is what happens when you open your mouth.

"CAM practices and products should be evaluated to determine their role in achieving the Nation's health promotion and disease prevention goals." Second sentence: "Those found to be safe and effective should be utilized to promote wellness throughout the life span."

DR. GORDON: Okay. Are we okay with that? Charlotte?

SISTER KERR: Yes.

DR. GORDON: All right. We are fine with this?

Great. Let's move on.

One-point-one. Dean has an amendment on the floor for 1.1.

DR. ORNISH: Right.

DR. GORDON: Do you want to read that, Dean?

DR. ORNISH: Yes. Selected, inspected, rejected and dejected. I just added four words. "CAM practices that have been proven to improve nutrition, promote exercise," blah, blah, blah.

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

MS. AXELROD: Can we say "have been shown"?

DR. GORDON: "Have been shown"? Okay. Do you accept that amendment to the amendment?

DR. ORNISH: I didn't hear that part. I'm sorry.

DR. GORDON: "Have been shown" as opposed to "proven"?

DR. ORNISH: Sure. What is the difference? Fine.

DR. GORDON: "Have been shown." Okay.

Let's move on to 1.2, please.

DR. ORNISH: One-point-two I have a problem with just because, again, it just said all these things should be incorporated in CAM practices. Which CAM practices? For whom? You know, again, it is way too broad for me.

DR. GORDON: How would you like to amend it to make it --

DR. ORNISH: You know, the same way that we had before. "CAM practices that at a minimum have been safe and effective." I don't know. Anybody -- "or should evaluate and -- you know, I like the same pattern that Tieraona is talking about.

DR. GORDON: One at a time.

DR. ORNISH: Okay. So I think "Federal agencies such as," blah, blah, blah, "should evaluate CAM practices and those that have been found to be safe and effective should be utilized" or "should be incorporated into national guidelines on wellness."

Tieraona, does that work for you?

DR. GORDON: All right. That is an amendment on the floor. George, did you have something to say? Tieraona?

DR. LOW DOG: I think we are close, but again, I would say that these agencies should evaluate CAM practices to determine their role in wellness and prevention for children or whatever.

My concern with this whole thing, and I just need to state it right now, is that, to me, it sounds like, when you read that, we are just going to incorporate all these CAM practices into wellness and prevention practices, and we just haven't a clue, especially in pediatrics, what is going to affect wellness and prevention.

DR. GORDON: Okay. I think we have all accepted that. What we are looking for is the specific wording, and what you are saying has to do with evaluation, so I would like you to repeat it.

DR. LOW DOG: "Should evaluate."

DR. ORNISH: Tieraona, I completely agree with what you are saying, so why don't you say how you would like it to read.

DR. LOW DOG: "Federal agencies such as Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the Department of

Agriculture, should evaluate CAM practices and products," I guess, "to determine their role in enhancing wellness and" -- is that "disease prevention in children"?

DR. GORDON: The issue here, I think, and Corrine can correct me, has to do with national guidelines. So I think that is what needs to be addressed.

DR. LOW DOG: Well, yes. I mean, you need to --

DR. GORDON: "And should evaluate their relevance to national guidelines."

DR. ORNISH: "To evaluate their effectiveness in order to determine their role in national guidelines."

DR. GORDON: Is that okay?

DR. LOW DOG: I don't like the recommendation. I think it is premature. I think that you need to go through the very first recommendation, which is the evaluation of these and how they fit into promotion and disease prevention, and then you start thinking about national guidelines.

DR. GORDON: I think the issue here, and I want

to try to make it clear -- maybe Corrine can clarify it even more -- is that there are things that are underway, and the evaluation is a perfectly legitimate step, but we are trying to indicate -- I think the thrust of these recommendations is to say, okay, there are efforts that are underway, how do we get these approaches, those that are safe and effective, considered for inclusion in these activities that are underway?

DR. ORNISH: What activities are underway?

MS. AXELROD: That is correct, Jim, and I think this recommendation reflects the very strong sentiment that has been expressed by the Commission to address the children, the obesity, the eating habits, the influence of everything that is going on with children, and that there are existing guidelines -- this was described in detail in the text -- that the Health Resources and Services Administration has developed. They are actually working with the American Academy of Pediatrics right now. The Centers for Disease Control and Prevention has guidelines that are used in every single school in this country.

So the idea here was to not do something

completely out of, you know, what is existing, but to build on that to incorporate where things have been, you know, shown to be safe and effective, may be applicable, and should be looked at to see if they can be built into the existing guidelines.

DR. GORDON: Conchita is next, please.

DR. PAZ: Then what we might say is to evaluate and then incorporate those to be determined to be beneficial into the national guidelines.

DR. GORDON: Other comments on this? Yes, Wayne and then Tieraona, okay?

DR. JONAS: I have a suggestion that might help manage this a little bit. If the overall recommendation involves this two-part aspect, "evaluate and those proven to be safe and effective," or whatever the terminology that would be used, "should be then utilized or incorporated," then the first action step really should be how do we want to evaluate that?

We talked about 1.5 doing that, although I think it needs to be reworded to do that. But the Healthy People Consortium now incorporates all of these agencies that we just talked about. They are involved in

developing this plan.

So if we move 1.5 up to the top and said, "The Healthy People Consortium should evaluate the role of CAM" or "the potential role of CAM for the 10 leading health indicators and develop strategies for the use of proven CAM practices in this areas," and then in the subsequent action steps in which we are saying incorporate, incorporate, incorporate, put "proven" in front of "CAM" every single time so that it is contingent upon what comes out of the evaluation component that is number one. Then that follows from the original recommendation which has the two parts. It says where we want the evaluation to occur -- within Healthy People Consortium -- and then the rest of that is all contingent upon whether what they had discovered may be useful in that.

Anyway, end of suggestion.

DR. GORDON: Thank you.

DR. ORNISH: Wayne, I like your suggestion a lot. At the same time, I do think it is worth being a little redundant by putting under each action step that we evaluate and then those that have been found to be

effective are implemented because these may be taken out of context and I think it is just useful to be a little redundant here.

DR. JONAS: Okay. I have no problem with that if we can figure out how to do that in an expeditious manner.

DR. GORDON: The question is, can that be formulated right now, or do you want to take some time at lunch to formulate the correct --

DR. ORNISH: I think it is pretty simple, really, I mean if I understand Wayne correctly, and, Tieraona, if you are comfortable with it. Basically Action Step 1.1 would be to take 1.5, move it up to the beginning, and then how would you strengthen 1.5, Wayne?

DR. JONAS: This again is saying strategies to encourage the use of CAM practices, and what we want to say is Healthy People Consortium should evaluate the role of CAM's potential for the 10 leading health indicators and develop strategies for the use of proven CAMs or --

DR. ORNISH: I think that sounds great. Tieraona, what do you think?

DR. JONAS: Or you could even eliminate the

strategy issue if you just want to be clear about -- take the Healthy People Consortium and ask them to do an evaluation component. Then that becomes your standard for determining what has been demonstrated to be useful, and then that is inserted into each of these subsequent recommendations.

DR. ORNISH: I think that is great. Tieraona, how do you feel about it?

DR. GORDON: Let me tell you, the only concern that I have, immediate concern relates to 1.1, which I don't want to wait for the -- 1.1 as amended is "CAM practices that have been proven to improve nutrition." I think this is one that is important to me, it was extremely important to Bill Fair, and I feel it is very important to the Commission that we begin to move ahead with this right now and not wait for the Healthy People Consortium.

DR. ORNISH: I am okay with that.

DR. JONAS: The Healthy People Consortium, I mean, we are not asking them to prove it; we are asking them to evaluate it. So this actually wouldn't take that long in the scope of things. One could say --