lectures, and there was a certain assumption that you had a basic familiarity with things, which for me wasn't the case, and it was totally confusing. I think it is nice to kind of define things and then go to the historical perspective and values.

DR. GORDON: Wayne, and then Veronica.

DR. JONAS: I agree. I think we should world view shift as something --

DR. GORDON: I'm sorry, have what?

DR. JONAS: The shift in world view and what that is should be up front.

DR. GORDON: Before definition?

DR. JONAS: Yes.

DR. GORDON: Okay. Veronica, and then Linnea and Joe.

DR. GUTIERREZ: I support Tom's model myself.

DR. GORDON: Which one do you support?

DR. GUTIERREZ: The world view.

DR. GORDON: The world view first?

DR. GUTIERREZ: Yes.

DR. GORDON: Linnea, and then Joe.

MS. LARSON: Maybe I am back in organic

chemistry, but I really like those boxes that says here are the definitions, and then we will explain it.

DR. GORDON: Joe.

DR. PIZZORNO: It seems to me that we will have some kind of an executive summary to start out this thing. I think that there we will need to put the definition.

When we get into this section, I think it is much more important to start with the world view and principles, and such, and then show how we then arrived at the definition. So, I think we will achieve both needs that way.

DR. GORDON: Effie.

DR. CHOW: I go with what Joe has just said, that assuming that the definition is in the executive summary, and the world view is very appropriate to be up front here.

DR. GORDON: Let's hear from Jim Swyers. Will we have an executive summary, so we can see how it flows?

MR. SWYERS: Typically, you wouldn't write an executive summary until the report is done, but what we had envisioned was this definition section was not going

to be the first section of the report, but what I am hearing is that people would like the guiding principles put in the introductory section of the report. That will be done by December.

DR. GROFT: I think there is a format that we use in reports to Congress, and I think where you capture the most important parts are in the executive summary, which actually precedes then the full report.

MR. SWYERS: Typically, you wait until the full report is done, then, you write the executive summary.

DR. GROFT: We are capturing what you are saying as far as what are the important issues. I think as we go along, we will earmark those as to go into the executive summary. You will have a chance to read that shortly after the December meeting. Maybe we will even have a draft.

DR. GORDON: I think, Steve, we will need it. If we are going to resolve the issue on which a significant number of people want to have the principles first, others want to have the definition first, I think we have got to see how, and the proposition that Joe made was to see how it looks with the executive summary with

the definition, and then moving the principles.

I think we need to see it if we are going to make a decision about it.

DR. GROFT: We can prepare one. It would definitely be a draft, and based on what follows, then, at the December meeting. As far as the full report, there will be changes, but I think we could prepare one, but to have you keep in mind that it is very preliminary based on where we are on December 5th as opposed to December 8th.

DR. GORDON: Effie, do you have anything?

DR. CHOW: No.

DR. GORDON: Julia.

MS. SCOTT: I am just confused. Perhaps, Tom, you can tell me the difference. What are you thinking about in terms of the world view as different from the history?

MR. CHAPPELL: The world view is that section dealing with the guiding principles. It will have an opening paragraph that talks about the shifting paradigm. That is what we meant by a world view. History is walking you through the evolutionary stages.

DR. GORDON: My personal opinion is definition is better right up front. I think that, clearly, we have different opinions. I think what we need to do is to see the way you do it in December, to sort of refer this back to your group, see how you present it, see if you are satisfied with it, understanding that we are putting this up front.

It sounds like there is general agreement that this is what we want up front at the beginning of our report. Is that correct?

SISTER KERR: Jim, say "this" specifically, rather than "we want this," because I am getting confused on, are we going to do overview first or definition first.

DR. GORDON: I'm sorry, what, Charlotte?

SISTER KERR: When you say "this," say what you meant. Did you mean we agree that the overview should come first, or did you mean the definition should come first?

DR. GORDON: What I meant is that this whole section that we have been talking about, as I am understanding the general sense, is this is what we want

at the beginning of our report, together with the issue about the mission we have been given by Congress and by the Administration.

Is that correct? I can't read body language all together. I just need to know if we are on -- yes, okay.

MR. SWYERS: Jim, what I am hearing is that in the introductory section, people want to have the guiding principles included in that, and then, the next section could start with the definition of CAM.

DR. GORDON: That is what I am hearing, but I am not hearing that unanimously. I am hearing that at least several of us are saying the other way, that we want to see the definition first, but more people are saying they want to see the guiding principles first.

My sense of us is that we should give it back to the subgroup and let them show us how they are going to do it, and then set aside time for discussion of this in December.

Does that make sense to everybody? Okay.

I want to move very quickly through the second part of our discussion about the guiding principles.

First of all, again, there is something of a division here. The more general sense was that in the guiding principles, that wholeness and health and healing need to be absolutely up front and that evidence is second in importance, but very close behind it. That is the general sense of what I am hearing, with some people saying evidence should be first.

What Wayne and Tom then do is collect our preferences for how it should go, with what the order should be. My sense is, again, that this is something, and I don't think this is going to happen in every instance with every other group, but I think with this group in particular, because we are at an earlier stage, we are referring much more back to the group.

So, Wayne and Tom, my sense is that what we are looking for from you is to take what you have gotten from us, both in the discussion and in the written comments, and to reshape and re-present the principles in a coherent narrative order back to us including possible name changes for some of the categories.

Is that what everybody has a sense of? First of all, Wayne and Tom, is that your sense? And everybody

else agreeing with that? Again, we will be spending time, taking a look at that when we come back in December.

The second piece has to do with that there was a strong feeling, and I am just focusing on what we have said, that there needs to be more emphasis on partnership and relationship among all parties in the healing process than is currently here in the document. Okay?

The third piece is the issue of body, mind, and spirit, that somehow there needs to be some statements about that we don't want to get cumbersome or invoke something continually that begins to sound like jargon, but we want you to grapple with the inclusion of body, mind, and spirit, and then present it in a way that is not continually repetitive.

Is that right, Charlotte, does that reflect everybody's feeling about that?

There is also a strong sense of emphasizing, in the principles, safety, as well as efficacy, that that is an issue that needs to be addressed.

Finally, we want to relate our efforts to define guiding principles in particular to the IOM

report, and to indicate in a kind of generous way that even though there are differences between some of the principles or particular to what we are doing, that there is a kind of coherence with the larger movement of which the IOM report is a representation.

That is what I have heard from this discussion, and we are finishing right on time.

MR. CHAPPELL: Shall we have a break? That was well done.

DR. GORDON: It was well done all around. Thank you.

MS. CHANG: We do have a break. Please, please, please, I implore you to come back at 10:30.

Then if David Bresler, Tieraona Low Dog, and Corinne Axelrod could be at the front table, we can get started right away.

DR. GROFT: Just a thank you to Tom Chappell and Wayne Jonas and Jim Swyers for putting this session together. Thanks very much for your work.

[Applause.]

[Recess.]

MS. CHANG: This is actually Session II. I am

going to give you 15 minutes for the overview and then the workgroup around the table, and then we will start your discussion period for 75 minutes. I will give you a warning time just to let you know what the time checks are periodically.

DR. GORDON: Because you weren't here in the beginning, the more you can sort of focus on the issues that you need feedback about and where you are not hearing something you need to hear from people, address the question directly about what you would like to get back. That will make the task of figuring out where we go from here easier at the end.

Thank you.

Session II: Information Development and Dissemination

DR. BRESLER: We have been working on this section of our report together and kind of brainstorming, but we are very open to other ideas and suggestions from other commissioners, maybe some things that we hadn't considered.

Basically, we have many recommendations in this session, 10 recommendations that we need to go through, and we will go through them one by one. Again, the

emphasis doesn't need to be on wordsmithing at this point, but let's make sure that what we are recommending really reflects the consensus of the Commission, and let's make sure we are not missing something in our recommendations that we think is important to include.

Tieraona, have you got other comments?

DR. LOW DOG: Let's just get going.

DR. BRESLER: Yes, let's get going.

I hope that people have had a chance to look through this. Probably one of the real concerns we have had in our group is about information that is on the Internet. As most of you know, this is a bit problematic because due to free speech, people can say basically whatever they want to say within certain limits, make any claims and representations that they want, and they have a lot of protection under free speech to be able to do that.

As a result, there is a lot of misleading, inaccurate, or downright fraudulent information on the Internet, which we think needs to be addressed, and that is basically what issue 1 begins to do.

We also have concerns about access to the

Internet. Fortunately, through schools, a lot of children have access to the Internet, but approximately half the population probably doesn't.

That is going to be changing over time, as we know, but again, we have concerns about making sure that people have the ability to check the reliability of information that they are getting on the Internet, because some of it could be potentially hazardous to them.

In your report, there is one typographical error that I caught on page No. 1 of this section. It is the bottom of the first paragraph, "WebMD reports 4.7 unique visits," I am sure it is 4.7 million unique visits. We don't know what it is now.

Are people pretty much familiar with this, do we need to have more discussion? We have talked about this before, but let's look at the recommendations and see how people feel about it.

Our first recommendation that we have discussed is to form some sort of public/private partnership of a review board that can look at this information kind of like other standards boards are in place for rating

movies and the movie industry, a way of evaluating the accuracy of information, setting up standards, making sure that claims are evidence based and identifying when they are not, and so forth, and so on, and basically, being able to give like the Good Housekeeping Seal of Approval and an appropriate logo that is associated with that, to those sites that are in compliance with the recommendations of the standards board.

I don't think that it was so much our intent to have a rating system where Internet sites would be A, B, C, D, and so forth, but rather to develop certain guidelines for presenting information, for documenting the source of any claims or representations that are made, and hopefully, those sites that are in compliance with those guidelines will get this seal of approval.

So, basically, the first recommendation is that we establish a public/private partnership to develop voluntary standards to promote accuracy, and so forth, and to develop some sort of process to continually review Internet science and new sites as they come aboard, and those who do meet the standards of such a review board would be able to say that they do and to use some sort of

identification, perhaps a logo saying that they have met those standards. This is pretty much what the first recommendation is about.

Can we open it to discussion now, do people have any ideas, concerns, or thoughts about this particular recommendation? Joe.

DR. FINS: Yes, I think we should cite a parallel to -- I think it was called the Vancouver Agreement, that the leading medical editors of the journals use to have voluntary standards, that there is a precedent for that, and I would like to concretize Recommendation No. 2 more specifically and suggest that the National Science Foundation develop an RFP or some kind of mechanism for scientific literacy, which is critically important, and there may be also the National Library Association has some kind of partnership there, you might mention them later on --

DR. BRESLER: Yes, we do.

DR. FINS: But I think it is also relevant here.

DR. BRESLER: Other thoughts and comments?

Let's stick with the first recommendation.

Let's take them one at a time.

DR. GORDON: Just a point of procedure. Joe is addressing Recommendation No. 2, not No. 1, right?

DR. FINS: Both. We are on Issue 1, but there are three recommendations.

DR. GORDON: Right, but David has just mentioned the first recommendation.

DR. FINS: Oh, I'm sorry.

DR. GORDON: So, if we can focus on that one, that would be helpful.

DR. BRESLER: What we want to focus on now is this idea of public/private review board. As we have previously discussed, the idea would be to have people from academia, people from interest groups, people representing the public, consumer advocates, and so forth, and so on, just to basically set policies and procedures for identifying information and the source of any claims or representations that are made, and the extent to which people are in compliance with that, they would get that seal of approval.

Dean.

DR. ORNISH: As Joe was saying, there is a more

recent conference of medical editors that came out about a month ago, editors of JAMA, New England Journal circulation, Lancet, et cetera, that specifically address the issue of conflict of interest and how important that is to address. Particularly, they were referring to drug companies funding research on drugs and then suppressing the articles if they didn't show favorable findings, that kind of stuff.

So, I think, as Joe was indicating, to the degree we can cite other precedents that directly relate to this, it certainly makes it more mainstream and sees as the middle ground, as well as I think being a good precedent.

The other thing, though, is I think there are already some existing agreements. I know like WebMD has in terms of privacy and accuracy, and I know Dr. Koop took a lot of flak for those issues, and he has come up with some stuff, too.

I am not familiar exactly what they are, but it would be nice to include that in here, too.

DR. BRESLER: I want to table that for a minute because there is some concern about Recommendation No. 3

that we will discuss in a moment, but let's stick with No. 1, about this public/private review board.

Does this reflect the general consensus of the Commission, are we all in agreement that this would be an important thing to do, to have some sort of agency that has interest from both sides?

Joe.

DR. FINS: I think I actually made this recommendation at an earlier meeting, but I want to modify the idea just a tad, maybe with the preamble saying, "While recognizing the importance of freedom of speech, the Commission recommends," not in any way abridging, but just being clear that you can say whatever you want, but it may not be credible.

DR. BRESLER: We have always been clear that this is voluntary standards that we are asking for and that people, just like certification in any kind of agency, people can apply for it and be reviewed, and if they meet the standards, they get the seal of approval. It is a voluntary program. I think we have always considered it that way, but your point is well taken, that we need to emphasize that in no way is it our

intention to restrain the freedom of speech through this recommendation.

Other concerns about this? Does this generally reflect the consensus of the Commission, that we would like to see such a public/private review board to help give consumers some idea as to the accuracy of information that they are finding?

May I ask, does anybody have any objection to this recommendation? Can we move on?

Joe.

DR. FINS: Maybe there should be some reporting mechanism, of we come up with CAM Central or some idea down the road, what does this Commission do, and how does that information get disseminated? I mean what is the feedback loop?

DR. BRESLER: Again, I think our thinking about it was that an Internet site could apply to this commission or board, or whatever it is called, for their seal of approval, there will be a review process in which people will go and take a look at the information that they are providing.

There needs to be a way to update that and make

sure people would have to reapply or recertify periodically, like we do in continuing education programs. I mean, we don't want to give somebody certification that is good forever. So there does need to be a way of, not necessarily policing, but watching those people that have given the seal of approval and make sure that they continue to deserve it.

Again, these things, the mechanics of it, need to be worked out further down the line.

DR. GORDON: I think one thing about the mechanics is some of this will relate to recommendations later on, for example, for the Central Office, so that that may be the place out of which this comes.

I think we shouldn't focus too much, as we go through these recommendations, on figuring out all the mechanics and implementation because otherwise we will get bogged down, and we can come back at that later on when we have the whole picture in front of us.

MR. ROLIN: Just a comment. I am concerned about the fact that not all people will have the Internet. So definitely, I would support the idea of some type of report, and that can be worked out within

those mechanisms.

DR. BRESLER: Can we move on to the next recommendation?

The next recommendation is that the public really needs to know how to evaluate the information that is coming across the Internet, and this recommendation was to establish a public education campaign that teaches people how to evaluate information and again to look at it in partnership with schools and other educational institutions that use computers, that have an interest in the Internet, and basically to look at it as a set of fundamental skills in being able to get the information that you want and to be able to check to see if it is accurate information.

This is basically an educational campaign. That is what this recommendation is about.

Do people have comments or concerns about this recommendation? Joe made a comment that I think is very well taken, that we ought to look and see what the Library Association is doing, we ought to look and see what NSF and some of the other agencies are doing along these lines to increase literacy in terms of getting

access to health information on the Internet, and I think that that possibly should be incorporated into our recommendations.

Other comments or thoughts about this?

SISTER KERR: I know you addressed this with the library, teaching people how to use it, but have you thought, how would this look differently if we did not have access to the Internet, and are we considering carefully the population that will not? Particularly, who knows what is going to happen in the future?

But just to be sure it has been thought of, and then to say, but at this point in history we have got the Internet, so we won't, obviously, use billboards as much. Are we thinking about it enough?

DR. BRESLER: We are going to be coming to some of these discussions about access issues and ways of getting information to other people in Issues 2 and 3, but I think we could see the possibility that there will be industries developed to take information off the Internet and provide it to people that don't have access, that if people have a health care concern, there are probably going to be private sector businesses that

basically will do that, will do a search for you, will check things out, and so forth. I think this is probably going to be a growth industry that will enhance access, but we will discuss access more in the next issues.

Again, we are going to focus on the public education campaign to basically let people know how to get information off the Internet and how to check the accuracy of it, and again in collaboration with other organizations or institutions that have a similar interest.

Jim.

DR. GORDON: I have a procedure point and then a content point. The procedure point is one of the things that we should be thinking about is how we are going to order the recommendations. I mentioned this earlier, as well, whether or not, for example, the issue that you raised, Charlotte, should be combined here in this place. That is, making access more easily available to people who don't have access.

The content point that I would like to make maybe follows up on what Joe was saying. I think it is important that we say that it is all scientific

information, of which CAM is a part, and I think that this is the domain that we are working in, or we are stating right from the beginning the principles of evaluating should be similar.

DR. BRESLER: Which, again, makes a lot of sense to be working with other organizations and institutions who have a concern and are already probably working on this issue.

Joe?

DR. FINS: It also allows us to be funded by different sources of appropriations, everything from the Defense Department, if we are talking about misinformation about bioterrorism, all the way to the Department of Education.

So, it really is a tremendously generic problem, of which CAM here is a subset.

DR. BRESLER: Other comments?

Joe?

DR. PIZZORNO: I am not sure where this best fits in, maybe one of the earlier ones. I really like this because there is a lot of bad information on the Internet that we have to be careful about, but how do we

set this up in such a way that we facilitate, and not become simply a censorship body by vested interests?

Unfortunately, this happened a lot in our history as a nation, and unfortunately, I don't know how to do that, because we need to help people determine what is good information, but we don't want vested interests to keep out ideas they don't want to see come into the system.

DR. BRESLER: Tom?

MR. CHAPPELL: Thank you, Joe, for that comment. I have been noodling with that as we have been talking, and I do think that in your first recommendation, you are talking about developing the standards. I mean what that means to me is that by practice, you are going to have some standards. There may be some standards that are uniform to all practices, but I am still trying to make the link between the efficacy of the practice and the information that is being provided on a website here.

DR. GORDON: Speak a little closer to the mike, everybody, so you make sure that the audience can hear and we get everything recorded, too.

DR. BRESLER: Say a little more about it, Tom.

MR. CHAPPELL: Well, I am trying to avoid creating a censorship organization, too, because that is negative and controlling as opposed to promotion of information that is credible and efficacious.

I am wondering if you could give me an example of what a standard would look like. You have said to promote accuracy. I know I am back on No. 1, but it is related to No. 2, as well.

DR. BRESLER: That is okay. The way I think about it, I sit on the editorial review board of several professional journals. Those journals have standards which need to be met for articles that are submitted in terms of representations and claims that they make.

I think that our thoughts are, it is not to tell people what to put on the Internet or what not to put on the Internet. It is to look at the validity of claims and representations that are being made and how well documented the sources are that support those claims and representations are.

It is to establish the same kinds of standards for making claims and representations on the Internet as

we would in setting standards for what constitutes a random clinical trial, what constitutes peer review, what constitutes various other types of claims that you make on the basis of your research.

Those are fairly well standardized by these journals now, and my way of thinking about it is basically to establish standards and to put the seal of approval on those Internet sites that do that.

When they make a claim and they say there is no scientific basis, it is all anecdotal information, and there is not yet any published controlled studies to document this, but here are four case studies. Basically, to validate any claims and representations, and to provide the source or the basis that validates those claims, I think that is our intention.

MR. CHAPPELL: Thank you.

DR. BRESLER: We need to move on in a minute.

DR. FINS: Just to pepper the setup here, Jefferson said, "Democracy without education is impossible." So, we are not in any way constricting choice, but we want people to be able to make informed educated choices.

DR. BRESLER: Good. Any other comments about these because we are going to spend a little bit of time on the third one.

Joe, quickly.

DR. PIZZORNO: These are very well stated. I was thinking about when we had that presentation by the Berkeley Wellness Letter and by Goldberg's group. Both of them are publishing things, and they were both looking at the same information, and had totally separate conclusions, and I think both were on the extremes, and the truth was somewhere in between.

Again, how do we facilitate that we get the truth that is in between those two extremes, that we don't let either group dominate this process, so that when people are given advice on what is reliable and what is not reliable, that we are not too restrictive, but we are also not too inclusive.

DR. BRESLER: Well, what would make sense to me is that there are some issues in which there is evidence in both directions, and part of the standards are, in those kinds of situations, both sides need to be presented fairly.

Again, it is for this group, this public/private group, to establish those standards, and they are going to take some time to do it. It is not for us to establish those standards right now. We are making the recommendation that a group needs to be formed in order to do that.

Any further discussion about this one?

Again, the question that Tieraona raises is do we want to talk about transparency, potential conflicts of interest, full disclosure, and so forth. Again, I wouldn't get into the mechanics of what such a body might do. We are just basically recommending that a body be formed to do this.

Is that clear?

DR. GORDON: I think that the issue of transparency may be one that we want to talk about on Saturday morning. That may be a new issue that we want to bring to this particular area of information or maybe to all the areas. So, let's put that down as a possibility.

DR. BRESLER: Okay. Moving on, the third recommendation has to do with privacy and confidentiality

of information. As you will recall, we heard a lot of testimony about this from various people, and a large number of people are very concerned that when they go to visit an Internet site, that they are going to be tracked and that either the health insurance company, big brother, their employer, the government, whoever, is going to look at where they are visiting on the Internet and it is going to have an impact on health insurance premiums, things of this sort.

Now, the language in our recommendation is what I want to discuss for a few moments because in the recommendation we say, "The Commission recommends that the privacy of individuals using CAM Internet sites be protected by encouraging CAM sites to disclose if users are tracked and how that information is utilized."

The question that I have is I think we ought to put more teeth into this one. I would like to make that a requirement. I would like it to read, "The Commission recommends that the privacy of individuals using CAM Internet sites be protected by requiring CAM sites to disclose if users are tracked and how that information is utilized."

Can we have some discussion about this?

DR. BERNIER: How would you police that?

DR. BRESLER: Comments? How would we police that?

DR. FINS: I think that is addressed in Issue 2 about the FTC and all that. The point here is whether or not we would endorse such a thing.

DR. GORDON: It could also be in Recommendation 1 of this voluntary group, that that would be a condition of being a member of that voluntary group.

DR. BRESLER: Good point. Here is an opportunity also to look at what other agencies are doing. This is not a unique concern of people going on to CAM sites.

Joe.

DR. FINS: Did you guys come up with any information on HIPAA and how it relates to this, because there may be provisions in HIPAA that we are not aware of.

MS. AXELROD: The information on HIPAA is still evolving, but that is one thing that we want to just make sure that CAM is included, so that it is not like the CAM

Internet sites would really be treated any different than the other health information sites, but it is not clear to us at this point if those sites are included, so that is what we want to make sure about.

DR. FINS: It might be wise to mention that HIPAA, for instance, it is kind of evolving, any evolution or amendment to HIPAA consider the CAM-related issues. Now, HIPAA is a very complicated piece of legislation, but that is where a lot of this stuff is happening.

DR. GORDON: Joe, do you want to explain?

DR. FINS: It is about the confidentiality of the medical record and the exchange of information between providers within organizations, between organizations, and liability for disclosure.

Even the originating institution, as I understand, and I am not an expert -- it would be liable if I were -- passing between me and Effie, if something happened between George and Effie, I could conceivably be responsible for this. So there is a chain of responsibility.

Again, I am not an expert, but I think that we

need to envelop this in the context of major legislation on privacy and confidentiality that is out there right now.

MS. AXELROD: It is partly addressed in Part B of this recommendation because there is some other legislation that addresses this issue, as well, so we can add this to the background information that it is HIPAA and other legislation, and just make sure that CAM is included in those.

DR. BRESLER: I would like to focus for just a minute in how much teeth we want to put into this recommendation.

Are people comfortable saying that we want to encourage CAM sites to disclose if they are tracking people, or do we want to say that we require them, we recommend that they be required to disclose if they are tracking people?

SISTER KERR: I don't know the technology, but I would like to say "required."

DR. BRESLER: Other comments? Everybody is nodding their head. Is there any objection to changing the language from "encouraging" to "requiring"? Does

anybody have any concerns about that?

DR. ORNISH: I just think it needs to be clear that we are not saying this is something unique to CAM, as Joe was saying. I think that, here again, if we can not make this marginalized, or make this part of the mainstream, it has a double benefit. It makes the particular recommendation more acceptable, but it also makes it clear that this can be part of the mainstream.

DR. BRESLER: I think we are all in agreement with that.

Any further comments or discussion about this recommendation? Okay.

Let's move on to Issue 2. Issue 2 is regarding adequacy and accessibility of CAM information from the Federal Government. Does everybody remember this one? Basically, there is lots of agencies within the government that have interest in this in various ways, and I think we are still learning about other agencies in the government who already are fairly far down the line and nobody knew about it. Why reinvent the wheel? The idea is some coordination between all the federal efforts to provide information, to assemble information, sponsor

research, things of this sort.

The recommendation is for an interagency task force basically to identify what information we need that we are not getting, and also to develop strategies to stay up with activities of the government along these directions and to improve communication links.

We talked about Internet, too, but are people familiar with Firstgov.gov? I had never heard of it until I got it from this document, and I can only imagine what other resources might be lurking within the federal infrastructure that could be tremendously valuable to all of us interested in this.

Again, the recommendation is that an interagency task force be established to see what is going on, identify those gaps, and do something about it.

Jim?

DR. GORDON: Although I agree with that, I think that the whole recommendation is a little too tentative for my taste. I really feel we have to not only identify, but to develop strategies for remedying the gaps, I would say, number one, and number two, I think we need to indicate that we are responsive to the

questions that people are asking, which is basically does glucosamine work for my arthritis or not, what is the state of the evidence for all these various approaches.

I think the way it is worded here, it is too vague and it doesn't really deal with the central issue of what works, what doesn't, and where can I find people who are qualified to help me with it.

DR. BRESLER: Again, we are focusing on what is going on within the Federal Government.

DR. GORDON: I know, but they have been asking these questions right from the beginning. For example, in the early days of the OAM, 70 percent of all questions were from people with cancer and their families saying what else can I do.

I think that we have got to address those concerns and indicate that we want to remedy those concerns that people have, and give them the information that they want.

DR. BRESLER: Remedy them by telling them what activities are going on within the Federal Government that could be of interest to them?

DR. GORDON: No, no, remedying them by telling

them -- which is I thought we had pretty consistent testimony on that -- that people are saying we want the government, whether in partnership with private groups or not, we want the government to be able to provide us, as an impartial arbiter, and some of the government agencies including particularly NCCAM are trying to do some of this. What can you tell us about these approaches?

DR. BRESLER: Joe.

DR. FINS: I don't think that is my recollection of it, and I think Recommendation 1 under Issue 1 was to address it. In other words, I think everybody was uncomfortable with saying there was one site that said glucosamine worked or that was a definitive site. The idea was to have a plurality of sites that met a certain set of standards, and then with education that the consumer would have, they would be able to navigate that a bit.

I think they have a single voice about what works and what doesn't work. First of all, I don't think that is an answerable question. I mean does chemotherapy work in a particular cancer? Well, there is a lot of disagreement about the particulars.

DR. GORDON: But at least what you can do is you present the state of the art, and that is what people are looking for. Let's say, does chemotherapy, what is the nature of the literature, the research literature out there about X and Y, and we come to some of that later on when we talk about some of the meta-analyses or systematic analyses that we are looking for.

DR. FINS: As a clinician, when I have a question about what works, what I do is I go to the National Library of Medicine, and I do a search. I find articles that have reached a threshold and been indexed as NLM, so I think for No. 2, Issue No. 2, that I didn't see NLM mentioned, I know it is mentioned in Issue 3, but I think NLM is the leadership organization for this information kind of constellation.

I would also, just dovetailing about the cancer patient who is looking for a CAM modality, I would also link it up with NGOs, responsible NGOs, like the National Hospice Association, so a patient would have an idea about what are the options. It is not exclusively a government --

DR. GORDON: I hear what you are saying and I

think the linkages are good, but CAM already has a statutory responsibility to provide information, and I think we have to take account of that, as well, here. That is part of the authorizing legislation for the OAM, was that there be information made available.

All I am saying is I think we have to address the public -- what you are talking about has been significantly as researchers' or clinicians' concerns -- we have to really respond to the public need for information.

DR. FINS: The National Library of Medicine has Pub Med, which is a site specifically designed for the public. I think, getting back to what we were talking about this morning, the point is that there is this integrative continuum, so somebody might not know they are looking for CAM information, so they wouldn't go to the NCCAM site, but they might go to the National Library of Medicine and find glucosamine, because they were looking under nonsteroidals and arthritis, and they found a paper that said nonsteroidals versus glucosamine, they say, well, that sounds better, and I have got an ulcer, that might be a better choice.

DR. BRESLER: This issue, to me, is not about CAM Central and having an authoritative source within the government that can tell people what the status of information is, and so forth.

This particular issue, the way that we have recommended it, is about finding out what is going on within the government and all the different agencies, linking it together, so that people know what is going on in the government, seeing what gaps are there that need to be addressed, and remedying them.

DR. GORDON: I hear you. I think then the issue becomes one of ordering recommendations, because the most important thing to the public is not all the things that are going on in the government. The most important thing is what do I do next. So, it is a different issue, and I appreciate the clarification.

I think we do have to look at the way we have ordered things in order to present it in a way that people will say okay, they are meeting my needs and here is another issue.

DR. FINS: There is a micro and a macro economic dimension to this. It is like what an

individual person encounters is based on these macro economic decisions about what the agencies are doing. So, they are related, and maybe when we set up the structure of this chapter, you might consider the infrastructure that would need to be in place to allow consumers and patients to make informed choices, and they are mutually reinforcing.

MS. CHANG: Just a time check. You have 20 minutes left for this section.

DR. BRESLER: I understand. I was just pushing forward and I was going to tell everybody the same thing. We have a lot of material to cover, so we are going to need to go relatively quickly.

Sticking with Recommendation No. 4, is there any further discussion or concerns about it? Effie.

DR. CHOW: Would you see this as being part of this other section, Coordinating and Centralizing Federal CAM Efforts, that this is one aspect of what we are recommending on the whole?

DR. BRESLER: Yes, and as you will see in Recommendation No. 5, we really address it more specifically. Let's stick with Recommendation 4. I

would like to get this one wrapped.

Any other concerns or comments about it?

DR. FINS: Does this relate to enforcement issues, as well, or is that in a different place?

DR. BRESLER: We hadn't considered that.

DR. FINS: Should we? I would really like to give the FTC authority to enforce --

DR. BRESLER: I think what we are trying to do right now is find out what the hell is going on, what agencies are doing what kinds of things, and who is doing nothing, where is the big gap, what agencies should be doing things that aren't.

That is really the intention of this recommendation: what is being done; how can we coordinate the efforts of these agencies, so that they are not duplicating efforts; and what things in the public's interest need to be done by the government that are not being done. This is the intention of this recommendation.

Corinne.

MS. AXELROD: I just want to add this is not just about the Internet. This is the Internet, this is

fact sheets, these are all information from the government that comes in all sources.

The government produces a lot of fact sheets, they have a lot of clearing houses, there is a lot of toll-free numbers, but if somebody is looking for information on arthritis or diabetes, there is FDA, there is CDC, there is HRSA. They all have their pamphlets, they all have their sources of information.

We want to get those agencies at the table to look at that and make sure that they have some CAM information in there. So, it is a way of bringing them onboard with this, identifying where the gaps are in the information they are producing, and enhancing the links, so that the consumer will have easier access to this information that is right now all over the place.

DR. BRESLER: Is everybody clear about this? Any further discussion? Five follows on it.

Effie?

DR. CHOW: I think this is very necessary, this recommendation. Do I see in there, after what you just said, that it is promoting agencies that don't have information to CAM, to include CAM information? I don't

see this in here. It should be included in here?

MS. AXELROD: Well, if you bring all these parties to the table and talk about the gaps in their CAM information, it is going to happen, and it is not explicitly in here. We can certainly add that.

DR. CHOW: Okay.

DR. BRESLER: Moving to Recommendation No. 5. It is basically once we have determined what is going on in the government with CAM, we would like to have one centralized place where consumers or other interested parties could go and find it out.

Any comments about this particular recommendation? We were going to establish a toll-free number and just as that information is assembled, it needs to be utilized in a form that can be helpful to consumers who are looking to find out what the government is doing in particular areas.

Don?

DR. WARREN: I like this. We are going to discuss this Saturday morning also.

DR. BRESLER: Good. Effie?

DR. CHOW: I wonder whether it is established

in DHHS, because I think in our other centralized CAM effort, we are questioning whether it is really good to be in DHHS or the Secretary's Office or elsewhere.

So, I don't know whether saying specifically DHHS, or it could say within government in this recommendation.

DR. BRESLER: Joe.

DR. FINS: I have no problem with having a place for information, but I do have problems with practicing medicine or anything over the phone, and I would hate this to be a kind of a proxy for --

So, I think we have to be very clear that we delineate the parameter of the activity, and it is just an information source, but it is not clinical advice.

DR. BRESLER: It is not even close, Joe. What we are saying is these are the activities of the Federal Government around this issue.

DR. FINS: That's right. I just want that on the record, and I don't think we disagree, but I think we have to understand that people will be calling up with medical questions about what is wrong with them, and whatever enabling legislation or regulation has to make

it very clear that this is just a generic information source, and not a clinical enterprise.

DR. BRESLER: It is information about what the government is doing, it is not necessarily information about what the consumer should do for their particular problem.

DR. FINS: But you know that is how people are going to use it.

DR. BRESLER: We know.

We need to move on quickly. Any further comments about this? Does anybody have any concerns about this? Wayne.

DR. JONAS: I think the last issue that was brought up is an important one to address, and that is, what is going to be the public value of this. If the vast majority of the public is calling to get clinical information, and they don't get it, then, it is not going to be something that is very publicly useful.

We found this at NCCAM. I mean there is a public clearinghouse specifically mandated at NCCAM to do that, and they do answer questions, but they don't give out clinical advice and clinical information, and when

people call there to try to get that information, they are not going to get it.

It may be that there needs to be, that the perceived value of this from our perspective may not be what the majority of people who are going to use this line would perceive as a value, so that has to be addressed in some say.

DR. BRESLER: Well, again, I think if such an agency were in place, I bet every one of us would learn about activities in the government that has gone on that we didn't have a clue about, and because of those activities, there needs to be some kind of centralization of those activities. That is what this is to address. Okay. And we understand your concerns that it not be to provide specific medical diagnosis or treatment, that is obvious.

Quickly, Joe?

DR. PIZZORNO: How much does this duplicate what is already being done at NCCAM?

DR. BRESLER: Do you have comments about that, Wayne?

DR. JONAS: Well, I haven't tracked and

followed the recent events, because I know they are actually growing that, and there are actually some representatives here who are involved in the clearinghouse, and we should probably get close with them to find out what they are doing, because it may be that they are doing a lot of this.

DR. GORDON: One thing we could do -- it is a long subject -- maybe Anita could talk with you about what is going on. Now, Anita Green, do you all know Anita Green, everybody?

Anita, do you want to raise your hand? Sure, come up.

DR. BRESLER: We don't have time now, Jim.

DR. JONAS: Chris Thompson is here, and she actually runs the clearinghouse.

DR. GROFT: We will get together with Chris. We have 10 minutes to finish the rest of our session. Let us get together with them and we will get the information for you.

DR. BRESLER: Is everybody okay? All right.

Issue No. 3 is about availability and adequacy of information, basically about access, the diverse

groups of consumers. We have two recommendations based on this. Number one, that in partnership with NLM and the American Library Association, that we provide specific information to librarians to help people find CAM information on the Internet and within the library system.

Comments about this one? Does anybody have any concerns about it?

The second recommendation that CAM information materials be at a level, at a reading level that the public can understand and utilize. We gave you some background information about that, and that specific information be targeted to specific groups.

Comments about this? Is everybody in agreement with this?

MR. CHAPPELL: I am wondering if this goes far enough in scope to accomplish the aim of informing particular groups. I recall at one point during the hearing process we discussed the sort of training tours, people going into communities to try to help make people more aware of what the possibilities are with CAM.

I am just concerned that again a source like a

library, as sound as that appears to be, whether that is enough to really communicate the benefits of CAM practices and products to particular diverse groups as opposed to going in like a public health issue, making this a public health issue and saying we are intentional about an education program that reaches very specific populations.

DR. BRESLER: A comment, Tieraona?

DR. LOW DOG: Yes, just as another person here. I felt that we have more of this under Issue 5, false and deceptive health claims on the Internet. Here, we talk about limited language skills, cultural isolation, poverty, and we make recommendations about bringing national and local leaders of communities, of special populations, together, and I am not sure why we have got under the Internet, because actually, culturally isolated people with limited language skills, they are not the biggest users of the Internet.

DR. BRESLER: Right.

DR. LOW DOG: I think that would actually fit better under Issue 3 where we expand and -- because I think this addresses some of your comments, Tom, about

local leaders of communities working with groups, bringing them together, and how do we get information to them, because the only thing we are talking about here is unnecessarily harmful or detrimental aspects of CAM, nothing potentially beneficial at all.

So, we fit it under this Internet, false, deceptive health claims, and I think it should be moved.

DR. BRESLER: For the sake of simplicity and time, can I make a recommendation? This particular recommendation is in regards to the library system, which is a major infrastructure that is in place in every city in America, and how we can work with that infrastructure and upgrade the skills of those librarians to make that an information source.

In addition, as a separate issue and recommendation, I like what Tieraona said, that perhaps we should get a consortium of interested parties together to discuss how we go into those communities and provide information, as Tom is recommending.

DR. LOW DOG: It's already here.

DR. BRESLER: It's in No. 10.

DR. LOW DOG: I am just suggesting that we move

it, that we move it out of False and Deceptive Health Claims on the Internet, and we put it under Availability and Adequacy of CAM Information, and include it under library recommendations, that's all.

DR. FINS: So, you are saying move 10?

DR. BRESLER: Yes.

DR. FINS: I just want to put a little more teeth into No. 6 just on that point.

DR. BRESLER: Go ahead.

DR. FINS: You are saying training materials be developed. I think we should say we should recommend an appropriation to build the infrastructure of local libraries and librarians by giving them training in assisting the public in educating them about access and health care information on the Internet including CAM.

I think the First Lady would probably be a proponent of that, so we should look for that alliance, being a librarian, and I think that again, this gets back and dovetails back with the scientific literacy questions and the fact that people don't necessarily start off their search looking for CAM information.

They look for information about what is wrong

with them, and they might end up in CAM, they might not, it depends, and it is a generic skill set.

DR. BRESLER: Jim?

DR. GORDON: I was just going to ask Joe, so, how would you amend that recommendation then?

DR. FINS: A new sentence. The Commission recommends federal appropriations for local librarians for training, to assist the public in utilizing health care information on the Internet.

DR. LOW DOG: Including CAM.

DR. FINS: Including CAM materials.

DR. BRESLER: Is everybody okay with that? Any concerns about that? We will take that back to our committee.

Any concerns about Recommendation 6 and 7? We are pretty much in agreement that it has to be in a language that is comprehensible to people. Any comments? Joe?

DR. FINS: For background, the AMA has a program on literacy that might provide helpful citations about this that could go into the background section.

DR. BRESLER: Anything else on this?

DR. GORDON: The other thing there is the issue that Tom raised, I am not sure where we are on that regarding No. 7. Does No. 10 take care of that?

DR. LOW DOG: Yes. On page 6 of this report, where we have, "Due to limited language skills," et cetera, et cetera, we have included that under Internet. We have suggested moving that under here, and moving Recommendation 10 under there. So it expands and fits.

DR. GORDON: The No. 10 statement is a kind of protective statement, and I think it needs to be also a more positive statement about educating and providing strategies of information.

DR. BRESLER: Does everybody follow that, we are moving No. 10 to 3, and taking Jim's comments? Any further comments about this? Tom?

MR. CHAPPELL: I would just like to point out that I think what this is all trying to serve is that CAM is a public health issue. I am not sure we are broadly stating it to have that kind of level of value and importance in our time.

CAM is as important as dental hygiene or nutrition. It is a public health issue, and I don't want

to lose that general overview of what is driving what we are trying to do about information and accessibility of that information.

DR. BRESLER: Well, would you be comfortable with us saying that because it is a public health issue, going back to No. 10, that we feel it is important to get a coalition of people that have interests in communities and public health within the communities, and so forth, and so on, and to frame it in that way? Would that be comfortable for you?

MR. CHAPPELL: Yes, that is fine for that specific piece, and I am making my comment in general in lots of uses, too.

DR. BRESLER: Good.

Joe?

DR. FINS: Just another vector of information, which I think goes in Issue 3 as a new kind of recommendation, we shouldn't forget the corporation for Public Broadcasting, PBS, and opportunities for disseminating more information. It is not just the Internet, not just libraries, so that is another very important site. We heard testimony from those folks and

other media outlets, but I mean those are ones that do receive, I think, still some federal appropriations.

DR. BRESLER: Other comments? Quickly because time is short.

Moving on to Issue No. 4, there is a tremendous amount of information and good scientific information being done in other countries and other research institutions that are basically unknown by researchers, clinicians, others here, and this is a recommendation that barriers to access to this information be addressed and this information be translated and made available.

Comments about this? Tom?

MR. CHAPPELL: Will this public/private interagency be awarding the seal of acceptance to international websites?

DR. BRESLER: Comments? If they apply for it and they meet the criteria, I see no problem with it.

Does anybody have any concerns about this? Joe?

DR. FINS: Just justification, recognizing globalization and the plurality of populations that have made America their home, we think this is even more

relevant and important.

DR. BRESLER: Any other concerns on the part of Commissioners, are we all in agreement with this recommendation?

Moving on, we have had a lot of discussion about false and deceptive health claims on the Internet. This is Issue No. 5. We have two recommendations, one, that we support the FTC in its efforts to identify false and deceptive advertising or health-related claims on the Internet, and to take action about those; to monitor various minority groups or other constituencies that we think are particularly vulnerable to deceptive claims in advertising. Again, an educational campaign for consumers and to help them identify deceptive and unsubstantiated claims.

Now again, this is a broader issue, and it relates to any health care information that is on the Internet. But again, a lot of this does focus down on CAM-related sites. So we want to address this.

DR. GUTIERREZ: I would just like to recount a chiropractic experience. We had a chiropractor who was sued by the FTC for some literature that he publishes for

the entire profession, and the FTC saw that as fraudulent advertising, and he was in the legal process for over six years.

It cost him many dollars, obviously, and if we are going to use the FTC at all, I think we should recommend that the FTC put CAM-type providers on their review board, so that when they look at it, they are not looking at it with their own limited perspective.

This chiropractor did win, but it was a horrific battle.

DR. BRESLER: Comments about this recommendation?

DR. LOW DOG: I would support that recommendation. It is not really if we want to involve the FTC, they are already are involved. They are there, and we have to deal with them. But the recommendation that they might include people that are experts in this area, I think is a good recommendation.

DR. BRESLER: I do, too.

SISTER KERR: I don't remember where now, but so much -- at least, one of the things I learned, and, I think, as a group we learned, is that we needed to be at

the level of decisionmaking and advisors as CAM people.

But my question becomes, in light of, particularly, what Veronica said, and as Tieraona just said, well, we are dealing with FTC whether we want to or not. What happens if they say, well, we can't get to that recommendation for 12 years?

It is a big deal. Can we say more than that? Can you put in a time? Is there anything else? Because I don't know that all these boards, and all, that we are recommending they put us on, whether it is insurance companies or HCFA, or whatever, are going to do it. It is a big deal.

DR. BRESLER: Comments? Joe?

DR. FINS: I think we have a very strong ally here. Senator Breaux had really remarkable hearings a few weeks ago, in the context of the elderly being taken advantage of by health fraud, and so I think there may be a real confluence here, and I just wanted, as a segue, say we probably should cite that testimony.

I would modify the recommendation regarding the FTC. I would say it is not our prerogative to suggest who gets appointed to FTC, but rather to say that the FTC

consult with its brother and sister organizations like NCCAM in the federal infrastructure to get appropriate information, but I don't think membership is necessarily our purview.

DR. BRESLER: To consult with other agencies that have expertise in this area.

DR. LOW DOG: Yes.

DR. BRESLER: Comments? Joe?

DR. PIZZORNO: I have two things. One is I really support the recommendation of including CAM professionals. Second is under the challenges, just a technical piece. I know that the number of successful actions taken now is 10, so just before we publish the report, staff should contact the FTC and see what the current status is, because there are a lot of cases ongoing right now.

DR. BRESLER: Good point. Linnea?

MS. LARSON: I guess I am already to the recommendation, the specifics, and it is just a clarification. I think it is problematic to have highlighted "Spanish-speaking." You know, it's English and all.

DR. BRESLER: Is everybody okay with that? Jim?

DR. GORDON: I think when we look at how we are going to make a recommendation for what the FTC should be including in terms of expertise, we can look at what Tieraona will be talking about very soon with the FDA, and I think we can make similar kinds of recommendations across the board for federal agencies. That will make it more consistent, and it will become clear as we move on to the next section.

DR. BRESLER: Okay. Time is tight. Do we have any other burning comments?

Moving on quickly, I think the next two are fairly straightforward recommendations. It is basically about disclosure of training, certification and qualifications of CAM practitioners to consumers to make more informed choices. We have two recommendations, basically that it is a requirement that health professionals clearly identify and post information. It explains the level and scope of training.

No. 2, let's take them together, that state and local governments make information about their

guidelines, requirements, and so forth, because it is tremendously diverse. In some states, even psychologists are not licensed and anybody can call themselves a psychologist. People in that state need to know that.

Joe?

DR. FINS: When we get to the education section, the group had come up with a kind of taxonomy or hierarchy, and there is also a little bit of that in the access and delivery, so I think this is really not the place where we really get into the detail, but it will need to be cross-referenced because it is probably addressed more fully elsewhere in the report.

DR. BRESLER: The only other thing that I would mention is it seems to me that information under challenges on page 3, where it talks about information on licensing and certification requirements, and different providers or different levels of training, and so forth, it seems like this paragraph would fit better under Issue 6 than under Issue 2.

Anyway, let's look at these two recommendations. Are there any further concerns or comments from Commissioners about these two?

Great. Thank you all very much.

DR. LOW DOG: Okay. Moving right along. Now we are sort of moving into the product side, if you will, of CAM, and adverse events, labeling, and that. We want to start with Issue No. 7 on page 7, and this is relating to adverse events reporting.

We all know that with the recent OIG report, that really said that this was inadequate, the system that is in place now, and one could argue that it is inadequate kind of across the board. It is a dinosaur of a system really.

So, we have the background and the challenges here, but I wanted us to focus on our recommendations here, and I want to clarify something in the recommendation because if you read it right now, it says, "The Commission recommends that the adverse event report system be strengthened by" -- and then it has "encouraging voluntary registration of dietary manufacturers, so that the FDA can identify and contact them if an adverse event is reported." This is a system that is in place in Europe, so that if there is a problem with a particular ingredient, that you know who you need

to contact immediately to notify them.

Then, if you go to C, it says, "mandating registration," so it looks like we have both. We just wanted you to know that we are going to rework that. That is just a wording issue.

We wanted to encourage voluntary registration until mandatory registration could be implemented, that we believe this actually should be mandatory, but this is an interim sort of step until that takes place. So, if you were confused by that, we apologize.

Then B, requiring dietary supplement manufacturers to report serious adverse events to the FDA, which is required of all other OTC medications, so if somebody is reporting something, you should be required to report that to the appropriate body.

D. Simplifying the system. To facilitate increased usage and easier reporting of adverse events, and increasing outreach activities to everybody really, health care professionals all across the board, really everybody, and also patients and consumers, so that they know where to go, but right now it's very cumbersome to try to go onto the FDA and report an adverse event, and

most people would become frustrated in the attempt and just stop. So, we wanted that to be made easier, as well.

Comments? Joe?

DR. PIZZORNO: Again, excellent recommendation. I wonder if under the last one, D, if we should include in there the people who actually sell the dietary supplements, like health food store employees, because they are kind of a separate category, and yet they are selling a lot of these things to the consumers.

DR. LOW DOG: Pharmacies, retailers. Again, I think it needs to be a campaign for everybody. Yes, I think everybody.

Is there any disagreement with that? Joe?

DR. FINS: I want to add a section F or something. This is all reporting of what happens. It presumes that things that happen get reported.

DR. LOW DOG: Surveillance.

DR. FINS: So I would like a surveillance function exactly, and I think that CDC should be involved in that, and those kinds of activities and any kind of citations by FDA that pose a real public health threat

should be reported in MMWR, so that everybody who is not necessarily in the FDA loop will hear about it, who were just the rank and file practitioners.

DR. LOW DOG: I think that is a good recommendation.

DR. GORDON: I am not clear what you are saying because you are saying surveillance and you are saying reporting, so can you clarify that a little?

DR. FINS: If there is an epidemic or something, the CDC is involved in tracking and identifying it, and then characterizing it and reporting is. It is part of a containment strategy, and I am looking for some sort of parallel language.

If something were out there that posed a threat to the public health, like the tryptophan story a few years ago, how would that get disseminated, how would that get identified, because it is really an epidemic, because it is really an epidemic. It looks initially like an epidemic of a new disease that has to be figured out, and it may not be apparently a supplement or drug interaction or causal relationships.

DR. LOW DOG: Right. I think it is important

that if there is not one central place, what normally happens now is it is reported in so many different places that it would be very difficult to see if there was any kind of pattern.

So, I think the point of this is to try to have, one, make one central area where adverse events are reported, and then to have somebody that sort of oversees that and makes accessible that information if there looks to be a real health problem.

DR. FINS: Just maybe to clarify, but a word like epidemiologic surveillance versus a recipient of information to know what is going on and to help to characterize it, but maybe Joe K. and Corinne can help us with the public health language here.

DR. LOW DOG: We can take this back, and if there is anybody that really has an issue with that, I mean I would like to leave some of those things to the group to try to re-present to everybody with our working on it.

DR. FINS: There is another mechanism that actually came up in my own hospital, where the consideration was, if we want to allow supplements into

the hospital, how does a hospital deal with that question in the context of an established hospital formulary system. We are talking here about a macro, sort of a national system, I think -- adverse monitoring within organizations -- and how institutions would begin to integrate this stuff into their setting.

It is something I think may be really ripe for an RFP. How do you integrate a conventional formulary with a supplemental inclusion, do you limit it to certain manufacturers, certain drugs, do people bring in their own drugs?

DR. GORDON: I would like to say that this is a new issue.

DR. LOW DOG: I think that is a great question for Saturday. Would somebody keep track of those things for Saturday?

DR. GORDON: Yes.

DR. LOW DOG: So, I would like to leave that for that discussion, because I think that is important, Joe. Is everybody pretty much in agreement with this recommendation No. 13 under Issue 7?

DR. GORDON: Tieraona, I would just like to get

a clearer sense of the voluntary to mandatory, a little bit more about the background on that, and just make sure that everybody is --if you could explain it a little bit more and then get a sense whether everybody is in agreement and if you see any down side to it, too, so we could discuss that.

DR. LOW DOG: I think that it will probably require some sort of legislation to make a mandatory registration, so obviously, that may or may not happen, right, I mean because of that, but we do feel that there should be at least an attempt. We believe that that is where we should move, our group did, but we would strongly suggest that there be a voluntary registration at this point until legislation could be enacted, and whether that happens or not, I think there needs to be something in the interim.

Now, they do this in other countries, and you are supposed to clearly put What is in your product on your label, so this shouldn't be something hidden from view. You don't have to get your formulas or your recipes, you just have to provide what are your major ingredients, what are your ingredients that are in your

product, so if there is some sort of adverse event, manufacturers could be notified immediately.

We do not have that system in place, and if we did have a bad batch of something in this country, if there was a contaminant, et cetera, that came in, there would be very little way of trying to go back and figure out who we needed to notify.

DR. GORDON: My point is that this is potentially a very strong recommendation, and I just want to make sure the Commissioners are aware that this is strong, this would require legislation, that it is well backed up with documentation by your group.

DR. LOW DOG: I think we can get the information. If you think we need to strengthen that, we certainly can. We can also bring in how they do it in other countries including Europe, their system, which they are a little more advanced in some ways of following this, and if you think that would be important, we could do that.

DR. GORDON: I do, and I also wanted to make sure that everybody is on board with this one, because it is a major recommendation and does have legislative

implications.

DR. LOW DOG: Does anybody not agree or strongly feel that we should not be recommending for legislation for mandatory registration?

SISTER KERR: Why wouldn't we recommend it?

DR. LOW DOG: Well, that is what I am asking.

SISTER KERR: What is the coaching on that? The other one is what does it mean to report serious and who decides what is serious?

DR. LOW DOG: Well, a lot of things end up getting reported that may be just a tummy upset, or things like that. Serious adverse events tend to be ones that are more serious and may require hospitalization, or enough that you would have go visit somebody, a practitioner.

So, those are already laid out what constitutes serious adverse events.

DR. FINS: It is in the OIG report.

DR. LOW DOG: Right. But I guess I would like to know, is there anybody that dissents on this or do we have an agreement on going towards mandatory?

MR. DeVRIES: I am wondering if we have enough

information to really make a good decision. I guess what I am questioning is, we have a recommendation. Have we really gotten some outside input, whether it be in terms of legislation, what it is going to take to get the legislation done, or in terms of regulation, what it is going to take to regulate, and what the perceptions are, and the input of people outside of this commission who maybe are more directly involved and have perhaps a level of understanding that would help us in formulating a recommendation.

I feel like I am somewhere in the middle, I can neither support it nor oppose it, because I just don't have enough information right now.

DR. LOW DOG: Joe?

DR. FINS: I think the issue is that if, god forbid, something were to happen, and the manufacturer was not registered, you cannot fix that after the fact. We are just saying register. We are just saying know how to reach you so we can get additional information about the formulary and what was constituted in the supplement.

So, it is really, I mean I don't think it is all that stringent, and it seems to me it is common

sense, and it is good public health, and it would be a good preventative strategy, and I don't think it is going to adversely affect that marketplace in a way that would be anything other than that.

It is sort of like -- and I think Tieraona's idea of having it as initially a voluntary thing -- that we encourage that. People could say they have voluntarily registered, which, as a consumer, I would be more likely to buy that product, that one that didn't choose to voluntarily register before there was any legislation.

MS. AXELROD: I just want to mention that the OIG report addresses this in depth, and they recommend mandatory registration. Just for the sake of the length of the document, we didn't include everything from the OIG report, but we can put a little bit more in if that would make people more comfortable.

DR. LOW DOG: I think doing that, but also I am saying, with a lead-in sentence, similar to mechanisms that are in place in Europe where dietary supplements are available and widely used, so that it is consistent also.

MR. CHAPPELL: Item C. So, if a company has

300 different products, they are going to list the ingredients and formula of all those products?

DR. LOW DOG: They are going to list the ingredients, right.

MR. CHAPPELL: Some kind of order of importance.

DR. LOW DOG: Exactly. You don't have to put your formulas in.

MR. CHAPPELL: You run into this in your profession as do I, and it is not the ingredient, but it is the adulterant. How are we going to discern between the adulterant and the ingredient itself?

DR. LOW DOG: I think that's a great question. I mean part of this will be implemented when GMPs are implemented. I mean so part of that, we will take care of. If it is an adulterant or a contaminant in a product, but we trace it back to like with plantain, in 1996, if we know that the plantain was actually contaminated with fox glove, we have a way then to get to all the people that are selling plantain, so that they know that we have had contamination, and we can inform them of batches that we believe were contaminated.

Everybody should be keeping lot numbers and all of that, so they should be able to test, but if you have no way of knowing, and that is what happened in '96, there was no way to know who to contact who may have even purchased the contaminated plantain.

MR. CHAPPELL: Perhaps then this recommendation ought to be including language that cross-references to GMPs in that regard, because I think is an important feature.

DR. GORDON: Come closer to the mike, please.

MS. CHANG: Tieraona, this is a time check. Fifteen minutes.

DR. LOW DOG: All right. So, Tom, we have got that, too. We move on to Issue No. 8. We are going to rework this a little bit as far as wording goes. We would like actually Issue No. 8 to be Issue No. 9. We are going to move quality control up front, ahead of labeling, just for the way it flows, just so you know that.

So, I would like to look at Issue 9 first, if you just would, quality control of dietary supplements to assure consumer safety. Here, again, we are going to

tweak the language a little bit, but I would like us to look at the recommendations here.

"The Commission recommends that the FDA's Good Manufacturing Practices be implemented to help assure the purity of dietary supplements."

Is there any dissent on that? Ming?

DR. TIAN: I have a question for you. You talk about purity. What does that mean?

DR. LOW DOG: I had a little issue with purity, too. Be implemented, I think to help assure either safety, or just the Commission recommends that the FDA's Good Manufacturing Practices be implemented to help assure the safety of dietary supplements."

DR. TIAN: Can we say quality instead of purity?

DR. LOW DOG: Quality?

DR. TIAN: Yes, and also you talk about the GMP. That is special GMP procedure for dietary supplement, it is not for pharmaceutical company.

DR. LOW DOG: Right.

DR. TIAN: Because if I understand, a lot of dietary supplements are not purified. It's naturally get

extract. We don't even know more than 100 of few hundred components in it.

DR. LOW DOG: Right.

DR. TIAN: All right.

DR. LOW DOG: And we can be more specific actually in the dietary supplement. These have been agreed by industry, and we are just waiting. They are just kind of held up right now.

DR. TIAN: They have different standard. We don't want, also, it is impossible to improve that quality up to the pharmaceutical standard. There are two standards. We ask too much, we will kill everybody.

DR. LOW DOG: We are just looking for the ones, and we will be more specific in our language of the dietary supplement, Good Manufacturing Practice, that have already been agreed to including industry member representation. It is not pharmaceuticals.

DR. TIAN: Okay. Thank you. And page 10, second paragraph, No. 15. You mention limited to the products with industry-approved standards. What does that mean?

DR. LOW DOG: Where are we?

DR. TIAN: Page 10.

DR. LOW DOG: Did I skip something?

DR. TIAN: Yes, but this is the same question.

DR. LOW DOG: I would like to come back to that. That is under Issue 8. Let's come back to that. We will, I promise, get to that.

DR. TIAN: Okay. Thank you.

DR. LOW DOG: Do we have consensus with changing also from "purity" to "quality," which I think is a better word, and we are going to make sure we include the proper GMP, so everybody knows what we are specifically talking about? Do we have consensus on this? Tom?

MR. CHAPPELL: I believe I heard safety and quality.

DR. LOW DOG: Quality and safety being a relative term, safety. 17. The Commission recommends that the DHHS, USDA, Environmental Protection Agency, U.S. Custom Services, and other appropriate federal departments and agencies work with manufacturers and importers to monitor the quality of imported and domestic dietary supplements and identify and prevent contaminated

or adulterated products from entering the U.S. marketplace when possible. And then DHHS, USDA, EPA, and others work with the WHO and other appropriate international organizations to establish guidelines to help assure the purity, or quality, I guess, or herbal ingredients and, where possible, set international standards for consistency.

Questions? Comments? Issues?

And also just supporting for initiatives that we mentioned somewhere here about AOAC, USP, NSF, other groups that are setting standards, that we probably want to move that into this section. That is just a technical -- never mind, forget it. Technical thing for us. This goes there.

Any questions or problems with that recommendation? Basically, that we have had some issues and problems with contaminants and adulterants in a number of the raw botanicals and formulas, prepared formulas that have come into this country, so there has been a desire to try to get a handle on that.

Tom?

MR. CHAPPELL: Yes, thank you for that

reference. I am wondering why we include domestic in this?

DR. LOW DOG: Is there a reason you would not include domestic of our raw botanicals and raw materials here for adulteration and contaminants, which we have known to be a problem for many, many, many, many years, echinacea being a prime example of substitution with parfineum and tegra folium.

So, I mean we have issues of substitution, adulteration, and contaminants here in this country, as well. It is not just foreign material.

MR. CHAPPELL: I guess I just would like to ask how manufacturers would proceed under normal circumstances with this recommendation.

DR. LOW DOG: I think this is more of an issue of trying to get some of the agencies involved to help in this whole big arena. As long as manufacturers are pretty much following GMP, they are going to be doing the best that they can. I think that we need to perhaps involve some of the other agencies to look for ways of identifying quality and ways of helping to assure that we are identifying adulterants and contaminants when

possible. It is a big task.

MR. CHAPPELL: I appreciate that. I am just wondering is that covered in 16 for domestic companies. I guess what I don't want to do is accomplish 16 and then put on additional encumbrances and bureaucracies that prevent domestic companies from proceeding in an orderly way to get their products to market.

DR. LOW DOG: So, your issue is with the word "domestic" here.

MR. CHAPPELL: Yes.

DR. LOW DOG: Because you believe that if they are in compliance with 16, 17 naturally follows.

MR. CHAPPELL: I think 17 really deals with imports.

DR. LOW DOG: We will take that and work with that. That's a good point, Tom.

DR. FINS: The other thing is whether or not there is a role under 17 with the appropriate state agencies, as well. It is not a purely federal problem, but there are state departments of housing, environmental protection, et cetera.

DR. LOW DOG: Any other comments? Those were

good comments. Anything else? Joe?

DR. PIZZORNO: One piece left out here, and it may actually be a totally new issue, but I would just like to raise it for the committee to consider, is we haven't dealt with the Environmental Protection Act about some of these botanicals being well crafted, being endangered species.

It seems to me that this would be an appropriate place somewhere in this section to discuss that.

DR. LOW DOG: Threatened and endangered, working with groups like United Plant Savers, working on that. Okay. New issue.

DR. GORDON: That would be a new issue, right?

DR. LOW DOG: Make sure we write that down. That's good.

Anything else? Is there sort of general agreement about this? We can tweak it a little bit and add some things, look at the domestic issues and GMP, sort of look at that and bring it back to you all. But is there general consensus?

DR. FINS: Is there a role for DEA in any of

this? There is some herbals that would be under their jurisdiction.

DR. LOW DOG: Yes, but they are not being sold at Wal Mart.

I am going to move to 8 kind of quickly here, Issue 8, that we skipped over. This was about labeling, adequacy of labeling. Part of what we are going to do here, part of this has to do with labeling, but part of it has to do with quality control.

So, if you say that your St. John's wort has 0.3 percent hypericin, and it doesn't actually have it, is that a labeling issue or is that a GMP issue? I mean did you not meet your label claim because of your analysis, your analytical method, or your quality control.

We are going to take that and tweak that a little bit and re-present that to you, okay, because we think we can make it clearer for people that are reading this.

Our big thing with labeling is the issue about structure/function claims, drug claims, some of the issues that were raised by a number of people who

presented here. This is what we wanted to address, safety, people putting what is known if there are safety risks on their potential interactions, and also the issue, then, of benefit, structure/function.

So the recommendations that were made, where the Commission recommends that the availability of consumer information of dietary supplements be increased through improved labeling, package inserts, and information at points of sale, inclusion of information on possible interactions with prescription or OTC meds, foods, or other health products, and I think we should put "when known" or "when established," because a lot of it is very theoretical right now, and theoretically, anything could interact with anything, so I think we need to tweak that a little, and inclusion of information on possible risks to vulnerable populations, such as children, elders, pregnant, nursing women, and those with certain health conditions that compromise the immune system.

Basically, if we know that there is somebody who shouldn't be taking this, should it be on the label.

Joe.

DR. GORDON: Tieraona, here, I think that the recommendation needs to be much more specific about the whole area of what kind of information we feel should be on there. You present it in the section on Challenges, and also just in discussing the issue, but the recommendation just says "improved information," and I think this is an area where we can make -- I am not saying we have to do it in this next few minutes, decide what to do -- but I want to hear from the Commissioners.

My personal opinion is we need to provide more of the available information about what we know about the utility of these substances that are being marketed.

DR. GORDON: All right. Joe, and then Tom.

DR. FINS: It is sort of along the lines of what Jim was suggesting, we have a little more specificity. Another area which I don't think you have covered is the issue of dosages and toxicity. In other words, if people take one vitamin C, it is one thing, if they take a tremendous amount, they get kidney stones, so I mean I think we want to have people aware of what a safe dose is or what the recommended dose is, so they don't get toxic by taking too much.

DR. LOW DOG: Tom.

MR. CHAPPELL: I think it might help you to begin -- the doorway here is either a DSHEA claim, it is claim based, it is either a DSHEA claim or an over-the-counter drug. If it's an over-the-counter drug, there is a monograph that requires certain dosages that you must adhere to, the language of the claim must be adhered to.

If it's a DSHEA claim, there is strict language about what you can say, and then if you have knowledge of the biological activity of any one ingredient in there, that doesn't fall under either DSHEA or OTC, you are really required to apply for a New Drug Application, because it's a drug and you are not claiming it to be.

I think we have to ask how are our aims going to mesh with the regulatory world today, which is claim based. That is the starting point in improving information, and if we think we have the liberty of adding information to the label, believe me, we do not. The FDA will absolutely slam us for saying, oh, in addition to the zinc citrate that we have in this toothpaste that is going to help your gums, we have chamomile in there, too.

Well, good luck. If you have got clinical evidence to show that chamomile is helping the gums, then, you will be invited to do a New Drug Application, but this is so structured that I just want us to be aware we don't have the liberty of providing a lot of information to consumers that we might like to, but we are very much constrained by the regulatory world here.

DR. LOW DOG: One could divide this really into two pieces, one which is benefit, and the other which is risk, because much of this right now is -- because it's really two parts, isn't it -- one is the structure/function claim or drug claim, and the discussion of soft claims and somewhere where that might be in there.

The other then is potential risks -- I hear you, Michele -- is the potential risks, which is then about adverse effects or risks for certain populations or interactions with particular drugs. So, we have two pieces.

This one really focused on or our attempt was to really focus on Recommendation 14, on potential interaction, harm, side effects, that aspect of the

label. Do you have any concerns about that?

MR. CHAPPELL: Only to say that the whole world wants to know about interactions.

DR. LOW DOG: No kidding.

MR. CHAPPELL: I am just wondering where the burden has to lie here for providing that information.

DR. GORDON: Just a point of procedure or order. We will take 10 more minutes, because I think this is really important to focus as much as we can on this.

MR. CHAPPELL: There are a whole world of pharmacists. May I speak?

DR. LOW DOG: Yes.

MR. CHAPPELL: There are 110,000 pharmacists out there that would like to know more about drug interaction. As you say, we need to tweak this, but since there is so much analytical information required here, and further study on interactions, that I am concerned that we may be setting up a hope here that we can't deliver on.

DR. LOW DOG: Right. I think it is an excellent point. We are going to work on the language.

We have discussed this on when it is known, when it is clearly established. Certainly, we do know for some things, where it has been clearly established and there is consensus, but we want to work on this a little bit and bring it back to the group.

Joe.

DR. FINS: This gets us back to what we do with DSHEA. I think we have all sort of agreed that that is a huge thing and it is probably not something we can really modify at this point, but I do think, my understanding, in a sense, DSHEA was written, not to make claims that were too grandiose, but it really didn't address the toxicity or the risk side.

I think the way to carve it out, and we are providing more information about interactions, about toxicities, about vulnerable populations, all of that is protective and, if anything, it doesn't enhance the desirability of people wanting to take these entities, it is not an inflated kind of claim.

So, I think that in the spirit of the public health, given all the testimony that we have heard and the interactions that we have been aware of, I think we

are really operating under the spirit of DSHEA, but we are providing absolutely necessary information that would allow people to maximize their utilization of these products in a safe and efficacious manner.

I think we have to, as you were beginning to suggest, it is about the toxicity, it is the down side that we are providing more information on, and not necessarily the up side. I don't think that is inconsistent with what was the legislative intent.

I think the other thing I would couple in here is that we should track this information, the FDA should track this information, and there could be a possibility of revisiting this legislation in a more formal way down the road, that there should be a report to the Secretary in five years based on if our recommendations are implemented, because I think that this remains an open kind of question. It is not a question we want to open right now, but there should be some future revisiting of these concerns.

DR. LOW DOG: Dean.

DR. ORNISH: Just to emphasize again, I think it is really important to add issues like this. I know

it is going to be, as more research is done, more side effects will be known. There is an article coming out next month in The New England Journal showing that antioxidants interfere with statin drugs, for example. So, I think addressing this issue now will be important now and even more important later.

DR. LOW DOG: Thank you, Dean. Thank you for all those comments. We are going to work on that a little bit, and we will bring it back.

DR. GORDON: I have one more, which I believe is a new issue, which we raised several times in the course of the hearings, which is should there be some kind of education for health food store employees.

DR. LOW DOG: Put that for Saturday.

DR. GORDON: Thank you. That is what I wanted to do. I just wanted to raise it now, though.

DR. LOW DOG: Yes. Put that on our agenda.

Recommendation 15. The Commission recommends that claims of standardization be limited to products with industry-approved standards.

That, we need to go back and rework, who is the industry, what standards, which products. So, we would

like to beg your forgiveness and sort of go back and rework that a little bit and re-present that to the group.

Finally, in our last one, Issue No. 10, on page 11. Federal oversight to assure public access to, and safety of, dietary supplements.

Recommendation 18. The Commission recommends that there be adequate staff of professionals within the FDA and NIH with expertise in dietary supplements especially areas other than vitamins and minerals, plant, animal, et cetera.

This could include hiring people with these specific skills and/or providing training to current staff, and may require increased staffing levels or funding. Many of the biologics and the plants are extremely different than looking at vitamin and mineral metabolisms. They bring their whole set of issues and sometimes we feel that maybe these organizations might need increased funding to be able to enhance their staff for people that have special expertise in those areas.

Joe.

DR. PIZZORNO: Another good recommendation. I

would also like to suggest that after the "adequate staff of professionals," say "and an advisory board, which includes amongst others, CAM professionals experienced in clinical use of these agents."

DR. GORDON: Excellent.

DR. LOW DOG: Corinne. Go ahead, Corinne, you can speak.

MS. AXELROD: I think there should be a little bit of discussion on that because we don't want to be telling FDA what to do. Part of that is just their management, if they choose to have an advisory board or not. I think there are a lot of implications.

So I would just like to be aware that advisory boards are not just casually assembled and have a lot of implications that, maybe, we should discuss.

DR. LOW DOG: Thank you, Corinne.

David.

DR. BRESLER: I want to talk about this point, too, because there are lots of people that have academic information about biochemistry and physiology of some of these products and supplements, and so forth, but have no experience clinically whatsoever in their utilization.

I do think this is an important point. Maybe the language we use is to encourage the FDA or something like that, but I think it does need to be addressed. Clinicians with clinical expertise need to be involved in decisionmaking at this level, I think.

DR. GROFT: Tieraona, if I may add, that there is an advisory board already in existence for dietary supplements at the FDA.

DR. LOW DOG: You are so good. Thank you, Steve.

Tom.

MR. CHAPPELL: I am really not sure what I want to say, but I am having trouble with this. As I have been sitting here for a year and a half, the concern is about safety more than efficacy on these products. As I speak as a company involved in herbal products -- I didn't say a professional, because I am not a professional -- I know that we don't know enough about the mechanisms of action of these individual herbs to understand what to use for a marker to establish a standard.

For us to be seeking standardization of, let's

say, a DSHEA-type claim product, we really need more knowledge than we know today. On the other hand, if we are talking about standardization of an OTC item, the OTC has a benchmark. We know what the drug is that is accomplishing the effectiveness.

The OTC, that already is set up, so we are really talking about DSHEA items here, and there is so little known about the individual herbal mechanism of action that I would think we ought to be encouraging, not claims of standardization, but rather more knowledge on the bioactive ingredients.

DR. LOW DOG: Tom, I hear exactly what you are saying. That is why we didn't go through 15. You are back on Recommendation 15. We are on Recommendation 18.

MR. CHAPPELL: I beg your pardon. I thought we were talking about 15.

DR. LOW DOG: No, we left that one. We said we would like to beg your forgiveness, because that needs a tremendous amount of work. We are real aware of those issues, so we don't like Recommendation 15. We would like to rework it with your permission and bring it back.

MR. CHAPPELL: Okay. Well, you didn't have my

permission to take it away yet. I wanted to comment on it.

[Laughter.]

DR. LOW DOG: We were out of time, that's all, we were aware of the issues.

DR. GORDON: Procedurally, Tom, what might be most helpful is if, Tom, if you worked with Tieraona and that committee on No. 15.

DR. LOW DOG: He is on now. We realized all the pitfalls with that one, so we wanted to come back to it.

On 18, anything else on Recommendation 18? Ming.

DR. TIAN: I think the advisory board is very necessary, very important, and the advisory board, I would suggest to have some subcommittees for different CAM products or subjects, because the qualification to be an advisor, to understand all the 31 CAM, we are talking about the definition, who could do that, understand everything? I am afraid not.

I think it is very important. We must have a subcommittee and also to hire the qualified person to be

advisors. I don't feel shy to recommend this to the FDA, and as we all know, and you can't ask FDA officers to understand everything.

DR. LOW DOG: Thank you.

DR. GORDON: It is time for us to come to a close here, and then we can come back to where we are on all these issues as we go over them.

DR. LOW DOG: If they could keep their comments very brief, could we hear from Wayne and Effie just real quickly? They were waiting.

DR. GORDON: Sure, go ahead.

DR. JONAS: I had a very short thing. I assume you are going to change this about staff, adequate staff. I would not include that. I think that was along the lines -- I wouldn't word it that way, I don't think we should be dictating how much or what kind of staff that particular federal offices should have. That is really in their purview of management.

The collaboration aspect, the importance of having input from experts in particular areas including clinical experts is important, but I wouldn't say you need to hire more people.

DR. LOW DOG: Okay, leave it out.

Effie.

DR. CHOW: I would like to confirm what Xiaoming said, and in addition, that it is not just people from institutions, but individuals, because at some point we mentioned include institution, but individuals who don't belong to institutions and are known as excellent practitioners should be considered as part of advisory, subcommittees or whatever.

DR. GORDON: We have minutes. I am going to move through it again pretty quickly. Thank you very much, Tieraona and David and Corinne. This is really a very nice job of making recommendations and taking us through it.

I am just going to go through the recommendations one by one.

Basically, No. 1 is approved as is. If you have a problem, I think the best way is if there are issues with my summary, raise your hand or turn on the mike and let me know or let us all know.

No. 1 is approved as is.

No. 2. The issue had to do with we want to

find out what other kinds of education campaigns are going on. We are talking, not just about CAM information, but information about science and medicine more generally.

No. 3. There was a strong sentiment for changing "encouraging" to "requiring," and there was an issue raised here about the whole transparency of the process. I think this is a larger issue that all of the groups need to take into account as we go back and formulate both issues and recommendations. It is not just one that applies here.

Recommendation No. 4. There was a recommendation that -- go ahead, Joe.

DR. FINS: Point of order. You are obviously going through this, not mentioning everything that was covered.

DR. GORDON: Right.

DR. FINS: But things that were said that were agreed upon are still on the table, like, for example, the relationship to HIPAA is just an example in No. 3.

DR. GORDON: Right, exactly. I am not giving every detail, but I am trying to deal with the

recommendation, and that is sort of filling in.

No. 4. One that did come out strongly was to find out what is going on with NCCAM as we make that recommendation.

In No. 4 and No. 5, we sort of ran into some confusion because this is really about letting people know what is happening in the government. This is not necessarily about providing definitive information. It became clear that as this is presented, the distinction between the provision of information and providing, in a sense, information about information has to be made.

No. 6.

DR. BRESLER: Back up one second.

DR. GORDON: Go ahead, David.

DR. BRESLER: Go ahead, Corinne.

MS. AXELROD: I just want a clarification on Recommendation 4, what the disposition is, please.

DR. GORDON: The understanding is that we need to find out what NCCAM is doing and include that as part of our background information and as part of our understanding and statement about what is going on. If that reshapes the recommendation in any significant way,

that needs to be brought back here, otherwise, it is all right as stands.

Is that okay? Did you have something on that, Corinne?

MS. AXELROD: My understanding was that that was approved and that we can certainly add the background information.

DR. GORDON: That is my understanding, as well, unless there is some way in which it changes things materially.

DR. BRESLER: We will bring it back to you if it does.

DR. GORDON: On to No. 6. Here, there is an emphasis on providing other kinds -- on working with local librarians and other media other than the Internet needed to be included in No. 6, in that recommendation, but that otherwise, the recommendation was as stands.

DR. FINS: Didn't we want to put an actual appropriation?

DR. GORDON: I'm sorry, what?

DR. FINS: An actual appropriation for infrastructure building and training of librarians, in