other words, it is not that we are encouraging a partnership, we are actually talking about real money going to libraries in our communities to train librarians.

DR. GORDON: Let's check on that.

DR. GROFT: Yes, I think we want to check on that because I think some of that is already going on with the Library of Medicine. When Dr. Lindberg spoke at our session, he talked about --

DR. FINS: I don't think it was to local libraries.

DR. GROFT: Yes.

DR. FINS: We need more information on that.

DR. GORDON: Let's get some more information on that.

DR. GROFT: We will get more information for you on that.

DR. GORDON: No. 7 is as stands, and then the recommendation was that No. 10 go in this section. No. 10, if everybody looks at No. 10 on page 6, we are not just talking about protecting the constituency, we are talking more generally about educating those and other

constituencies.

DR. BRESLER: And also determining the needs of those communities, as well.

DR. GORDON: Right.

No. 8. This was accepted with just the understanding that we ought to provide a context and talk about globalization as we talk about No. 8.

No. 9. There was some concern about wording here. In particular, one of the issues had to do with not to focus on Spanish media, but I think Linnea said that we are talking about all media and all languages and that we needed to somehow tie in education here, as well, and that if we are talking about the FTC, that we have to make sure that the FTC understands the issues that are involved.

There was a suggestion that some of the wording that we used when we talk about the FDA might be brought in here, as well.

Is everybody following what I am saying here? The kind of information that the FTC needs in order to make these judgments, they may not have at this point, and that they may need the same kind of input that we

describe in a later recommendation about the FDA.

I think we can just bring that recommendation back with those additions. Does that feel okay to everybody? Okay. I will take silence for agreement.

Recommendation 11 was approved as is.

Recommendation 12 was also approved with the understanding that the issues, that this is simply a recommendation for making information available. This does not relate to the guidelines for licensure or credentialing, which will be dealt with elsewhere.

No. 13. There was considerable discussion about. There was general agreement, although some questions about mandatory registration. There are two issues here. One had to do with mandatory registration, and George DeVries in particular wanted to hear a little bit more from the group before we went ahead with that.

Then, there was a second issue, an addition of an (F) here to (A), (B), (C), (D), (E), and that Joe Fins was talking about, which I think there was general agreement about, about some kind of centralization of the functioning of monitoring adverse events and making information about them widely available.

My sense of this one is that to be absolutely sure, that we just want some of that background, Tieraona, that you were talking about gathering and presenting, and that you can bring it back to the group, but that there was a general feeling that the movement from voluntary to mandatory made sense, but just some questions about exactly what that might mean.

Is that fair enough? Okay.

MR. DeVRIES: Let me ask a question, though, because I think I was the one who voiced the question, and I am not sure anybody else did. I didn't actually sense a general feeling that -- I think that was more my question, is that right?

DR. GORDON: Right.

MR. DeVRIES: I think we can move ahead on this. I would just like to follow up maybe directly with you, if I can, and maybe talk with you off-line. I think that will be adequate.

DR. GORDON: Fine. Is that okay with everyone? Perfect.

No. 14. This one, both No. 14 and No. 15, goes back to the group, to the workgroup, for refinement, and

refinement particularly about issues both of benefits, harm, how we make decisions about what should be included, what should not be included, and then, coming into No. 15, what the whole issues are with standardization, and the subcommittee recognized those needed to be elaborated on.

DR. FINS: Jim, could I just ask, I think No. 14 is so critically important, I want to be a little more clear about what we think, if I could.

DR. GORDON: Sure, go ahead.

DR. FINS: If we can nail this down, because the specific question is whether or not we feel under the umbrella of DSHEA, whether additional information about the toxicity, the risk, the drug interactions, all of that information should now be included, not making the kind of claim for efficacy stuff which is clearly prohibited under DSHEA, but in the spirit of protecting the public, that we would recommend a consideration of that kind of information in the package insert.

I didn't hear people against that, but I just wonder if we could kind of get more clarity on that point.

MR. CHAPPELL: Well, at the present time, it is against the law.

MR. DeVRIES: I understand that.

DR. FINS: But we are here to recommend modification or reconsideration, again, trying within the spirit of the existing law, within the spirit of DSHEA, FDA might be able to make, not a statutory change, but a regulatory interpretation in the context of what is going on here.

DR. GROFT: When you get into your work in different areas, I think it is an area that we need to explore further, and I am never hesitant, and I think it is within our mandate that was provided in the Executive Order, for us to make administrative and legislative recommendations on what we feel is necessary to improve the access and delivery of CAM products and services.

To me, I think it is just something we have to look at in greater detail, and if the Commission feels that some changes are necessary, I think we have to be willing to go ahead and make those changes and recommendations to whoever is appropriate.

DR. GORDON: Thank you. Yes, I feel the

mandate is not only there in terms of safety issues, Tieraona, I feel the mandate is also, is it possible to provide information if there is a meta-analysis of studies on St. John's wort; is there some way that we can make a recommendation that that information be made available.

DR. LOW DOG: What I think we would like to do is we would like to separate that recommendation into probably two parts, to two, one really looking at benefit and claim information, and the other looking at potential interaction and side effects, and we will work on that.

DR. GORDON: Joe, go ahead.

DR. PIZZORNO: I would like to second the issue about more appropriate language for making claims, because my concern is without being able to make appropriate claims, such as when there really is clinical evidence, that without being able to make claims, you kind of open up the door to anything being claimed, but if you have a good quality claim opportunity on the label of practice materials, then, people know they can write on this and they don't have to believe or consider the other stuff.

DR. GORDON: David.

DR. BRESLER: Just a point of information. Can a label refer people to an information source, can a label refer people to a book, an article, or an Internet site?

DR. GORDON: I think that what we need to do is explore all those questions. Again, we are taking this very seriously, as we should, but I think Steve's point is well taken, we can make recommendations.

Our job is to help the public be better informed and use these products safely and appropriately, and so I think we are in a position where we can make recommendations. The question is what kind of recommendations and how we should make them.

DR. GROFT: Just to bring up to date a little bit, one of the comments that were made when we received the Interim Progress Report we submitted for approval, one of the comments that came back from the FDA was the suggestion that perhaps we need to be more aggressive in recommending that or encouraging how we want to word it, that sponsors move products to a New Drug Application stage that Tom mentioned, as far as only then, to me, is

adequate information really available, that is looked at, is reviewed, peer reviewed, and then said this is the current state of knowledge.

But I think realistically, we are now in the Internet age, and information that years ago you only could go find way deep in the literature, is not up front on page 1. I think we have got to look at how people are retrieving information. We have heard how people are retrieving it.

I think we need to be rather aggressive in our stance of what we are saying that people need. I think that is realistic for us to do, as well.

DR. GORDON: So, this is an issue we really want, you take back, consider, listen, and all those who are interested in this group, please be in touch with Tieraona and David, and help them work on this issue.

Let's move along. Nos. 15, 16, and 17, we changed "purity" to "quality" and "safety," and there was general agreement about that. There was general agreement about the recommendations although there was some concern on No. 17 whether, if No. 16 were enacted, if GMPs were actually put forward, whether we needed to

mandate the domestic surveillance, as well as international. So, maybe you can just bring that piece of it back.

No. 18. There was concern with the FDA, that on the advisory board, there be the kind of clinical expertise that is necessary to help evaluate some of these approaches. There was agreement about the recommendation as a whole.

That was the only area where there was an additional feeling that it would be helpful, since there already is an advisory board, we don't need to make that recommendation, but that clinical expertise be included on the advisory board.

That is the recommendations, and it is time for lunch.

MS. AXELROD: There is another part to that last one, that Wayne had wanted the staff part to be deleted, the adequate staff part.

DR. GORDON: Right.

DR. WARREN: When we start talking about the labeling of these dietary supplements and all their possible interactions with drugs, I was just kind of

tipping the scale to one side. Shouldn't methotrexate have a label on it that says don't use it in combination with B complex vitamins.

DR. GORDON: Good point. Let's talk a little about that as a new issue, and then we can report back to this group. Let's bring that up again, if we can bring that up on Saturday. Thank you.

DR. GROFT: I would just like to remind you that after these recommendations are formulated here on the next three days, we are going to meet with the federal agencies involved and others to talk about what the Commission is thinking and to get their input into where things are currently and how might they be changed.

I think there are a number of federal agencies that would like to see changes, but until you get a legislative approach, things can't change because of the requirements. We will be doing some follow up on this meeting aggressively with the federal agencies.

DR. GORDON: This is great. Thank you everybody for being really on time.

[Applause.]

MS. CHANG: Lunch is in Conference Room A,

which is across the hall and down a bit. This room will be closed during our lunch break, so, visitors, you will have to go outside. You can leave your books and everything on the table, and we will reconvene at 1:30.

[A lunch recess was taken at 12:30 p.m.]

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A F T E R N O O N S E S S I O N

[1:35 p.m.]

MS. CHANG: We are ready to proceed.

Our facilitators are Dr. Wayne Jonas and Dr. Dean Ornish, and our staff lead is Geraldine Pollen.

So, if commissioners can take their seats and we can begin as soon as you all are ready.

Session III: Coordination of CAM Research

DR. ORNISH: I think we are ready.

Good afternoon, everybody. Wayne and I are going to facilitate this discussion. I think the general context that a lot of these things fall under is something that we talked briefly about earlier, which is that, particularly in the area of research, we recommend strongly that CAM research be held to the same standard, not higher, not lower, as conventional or allopathic medicine is, in a variety of different categories whether it is research funding, publications and medical and scientific journals, presentation at scientific meetings, FDA approvals of new drugs or devices, et cetera.

The reason that we feel that way is that again, it defines the middle ground, it in a way marginalizes

many of the people who might criticize the work, because if we say, well, it should be held to the same standard, if they don't agree with that, then, they would be forced to say, well, no, we think it should be held to a higher standard, or we think it should be held to a lower standard, and, of course, I think those don't really gibe with the more American values of fairness and equity.

There are a number of recommendations in here, and we will go through them, but in the larger context, and I think the other issue that isn't really as clearly stated in this particular section as I would like it to be, is that a major compelling reason for increasing funding and making more research available in these areas is something that is self-evident to us, but may not be to many people who read this, which is that it is not whether or not people should be using CAM modalities, as Eisenberg and other people have talked about, the majority of Americans already are, and yet very little research has been done in these areas to either prove or disprove their safety and efficacy.

So, there is compelling need for research in the safety, efficacy, and cost effectiveness of these

various approaches, as well as for negative findings. I think this is something that virtually everyone that we have heard with few exceptions, whether it is the defenders of conventional medicine, the journal editors, or so on, or the people who are leaders in the CAM community, I think everyone agrees that we need more research.

I think this is one area in particular that we can held build consensus around and help to increase the credibility for the rest of the report.

There are a number of recommendations in here, and Wayne wanted to try to simplify and categorize some of them into more general themes before we get into the actual themes.

Wayne, do you want to pick it up from here or are you still working on that area?

DR. JONAS: One of the issues that came up in our committee discussions a number of times -- and Gerri did a heroic effort in trying to address those and condense the huge number of laundry lists of challenges, recommendations, strategies, et cetera, that we had in this -- was that we really needed to try to simplify this

and try to get it under a few categories where we could say, here is the primary recommendation, and then there are a number of examples of that or specific ways in which that could be implemented, et cetera.

If you think there is a lot of them in there now, you should have seen it before. She actually did I think a very good job of getting them condensed. Our feeling was we still need to do more of that to make them pointed and hopefully as effective as possible.

The suggestion was that we put them into kind of major categories and that the issue about the importance of research that Dean just mentioned, about the importance of holding these areas to the same standard as in conventional medicine meaning high quality, rigorous research that gives you information, the type of information that you need about safety, efficacy, mechanisms, et cetera, and the importance of it being relevant, so rigor, relevance, and quality.

That is the preamble really, that is kind of the background. That is an assumption that I think that we could assume that everyone on the Commission agrees with, that research is important and it should be done

well, as was elaborated. So, the thought was this would then go into the preamble.

Then, the recommendations fall into what I think are largely six categories although what we could discuss is whether these are the best categories or whether there are other categories or whether we even need this many, if these could even be condensed further.

The first set of recommendations really has to do with the importance of partnership and dialogue, that there needs to be an increased interaction between those both in the scientific field and in the complementary medicine field, in the public and among scientists, so that they can understand better what they are looking for.

The second category is I think the main category, and that is we need more research. I mean if you look through these recommendations, there is do research in this, do research in that, et cetera, et cetera, and a lot of that comes down to supporting more good research. So, I see that really as largely one recommendation under which a number of these things could fall, and that includes recommendations across all

agencies that are involved in research, and it includes making sure that they are done in a collaborative way to address pertinent complementary and scientific issues.

The third category was, in my opinion, what I think a lot of these fall into really has to do with the prioritization process, how do we go about prioritizing all these different things that we think need to be done.

One of the reasons I think that is important is because if you end up with a long laundry list of things, it dilutes out, I think, the power of what the recommendations are. If we just need more money and everybody should do it, and then you are just going to kind of list that, I think the question is how do you go about doing that. Several of these recommendations fall into the area of how do we go about prioritizing that, and there are some recommendations that the Institute of Medicine, the National Science Foundation, and perhaps other bodies get involved in helping us to work with public and practitioner and scientific input to set up a proper prioritization process for that.

There was several recommendations about the importance of ongoing review, systematic review and

evaluation, there are a couple of groups that do that, and the importance of maintaining that on an up-to-date basis and providing simple public language descriptions of the results of that review, so kind of an ongoing process.

Then, there were several categories that fall under the area of infrastructure and training. One might say this is really in the area of do more research, you could perhaps put it as a subset underneath do more research, but our feeling was that it should be addressed specifically, that the importance of dual-trained individuals who understand both complementary medicine, as well as conventional science are important and that there needs to be a specific recommendation about infrastructure, that there needs to be a support of infrastructure, and a number of these recommendations have examples that we would put under here in terms of how infrastructure is currently supported in research, building core clinical sites, building basic research sites, building demonstration projects, and that should be done also in complementary and alternative medicine.

The sixth category, which I kind of threw

everything else in, but I called it Methods in Epistemology, which has to do with addressing methodology issues, because there is always ongoing, and should be ongoing, discussion about what is an appropriate methodology for answering particular questions, how could you go about doing that, and also, are there assumptions that come from many of the complementary medicine systems that are not readily addressed with straightforward standard research models, things like energy medicine, which was mentioned here frequently, how do you go about looking at whole systems -- holism is one of our guiding principles -- how would you go about doing that, relationship issues, spirituality, that type of thing.

So those types of things that are really epistemological, but then have implications for how we go about doing research methodology, and so recommendations that address that specifically, methodology and epistemology would be another category.

Anyway, that is kind of our thinking or at least some of my thinking. Some of those categories are already there and have been lumped underneath that, but my suggestion is that as we go through these

recommendations, that we think about trying to condense them further and if a recommendation is simply saying, for example, do more research and do it in this agency, then, hopefully, if we can agree on these general recommendations, then, we can say, yes, that will go in there and it is part of that.

Did you want to say anything, Dean, or are there any comments on that?

DR. ORNISH: No, I think that was very eloquent. I also just wanted to acknowledge the other members of this working group, George, Effie, Veronica, Bill, and Tieraona, and also to second your praise for Gerri and the other staff people who worked on this.

Do you want to now just go through each individual recommendation or how do you want to proceed?

DR. JONAS: The issues, yes.

DR. ORNISH: Well, the first issue is increasing dialogue, cooperation, and collaboration among conventional and CAM practitioners, clinicians, and researchers.

Rather than just reading it, I think you have all seen this. The long and short of it is, as Wayne

said, we think that we should increase dialogue, cooperation, and collaboration among the conventional and CAM practitioners, and gave examples of what some people are doing, just that, people who have testified before the Commission.

The challenges are the lack of dialogue and the lack of mutual respect, and whether there is a willingness to enter into a dialogue. I think that although in 1(A), on page 2, we talk about that the lack of dialogue impedes the progress and building knowledge about CAM, I think it might be worth making it reciprocal, as well, and saying that it also, I think, works to the disadvantage of conventional medicine, too.

I wasn't quite as clear about 1(B), which are the cultural taboos that can affect the evaluation of research applications. I was wondering if maybe --

MS. POLLEN: That was actually a quote from Marvin Cassman, who is Director of the Institute of General Medical Sciences, at the first research meeting in October of 2000. He was just recognizing that there are cultural taboos in conventional medical circles that do impede the dialogue, and also when applications come

in. It is probably not only for CAM. I mean there are other areas where this happens, as well, but he is looking for more openmindedness when he was saying this.

DR. ORNISH: Okay. Cultural taboos, I mean needs just to be a little bit -- because we are talking about, it sounds like child incest or something, you know what I mean. It is more of a prejudice or bias.

The second one is developing research. I think it should be clear that it is research grant applications of sufficient quality to compete.

IRB familiarity is No. 3.

No. 4 is including CAM professionals on advisory and review committees and in discussions. I think it also should be and vice versa. Again, it should be reciprocal, that we need to include conventional or allopathic people on CAM advisory boards and schools, research committees, review committees, and advisory committees.

So, the two recommendations that are here, Wayne, do you want to just go through those?

DR. JONAS: Yes. I think the first one is what I had outlined as the major category, and it is part of

this major category, and that is to strengthen emerging dialogue between conventional medicine and CAM by developing way to enhance cooperation. Then, it lists researchers, clinicians, research centers programs, et cetera.

My suggestion is that we make this stronger by actually saying that we suggest that a series of ongoing meetings, conferences, to foster and develop collaborative research projects and discuss various issues in CAM be supported and sponsored.

DR. ORNISH: Under whose auspices?

DR. JONAS: Under whose auspices is the question.

MR. CHAPPELL: Well, that gets it by thought, as well, and by the way, I just think you have done a wonderful job, your committee and Gerri, thank you.

As it relates to No. 19, you are beginning to get at what I am looking for, is there some operating idea of how this will be advanced forward rather than it just being lifted up as we need, can we become more specific in this paragraph and later language about whether you are recommending annual conferences or some

organization of a body, but I do think we need to evolve to that specificity with a recommendation.

DR. ORNISH: I agree with what you are both saying, and maybe that could be done under the auspices of the NCCAM or the Institute of Medicine. I think that by putting it under those kinds of organizations, it provides the credibility and the ability to draw people, because of the cultural taboos that you mentioned, that Gerri mentioned, it would be easier to get people to come to a meeting under those auspices than if it were just done ad hoc, I think.

DR. JONAS: Certainly, one of the possible ways is to dovetail this with CAM Central, which we are going to talk about a little later, which is an office that coordinates this, the various activities that we have been talking about, and one of their duties could be to put together or facilitate with various agencies, ongoing collaborative dialogue meetings in particular areas. So, that would be one specific way.

I wouldn't want to make that the only way and maybe what we could do is then have several examples including that one as perhaps the first one and then

Institute of Medicine, then, NCCAM-sponsored conferences, and this type of thing as examples as to how it could occur.

DR. ORNISH: Joe.

DR. PIZZORNO: Two things. One, I would still like to see Wayne's I think brilliant triangle diagram of the different kinds of research and what is appropriate be submitted to the Commissioners and considered for inclusion in this document, because that is really quite, quite good.

The second is a little technical change, but I think it will help. On the third line, where you have "collaboration among conventional and CAM," I think there should be a colon there, because I want to ensure that conventional and CAM relates not just to research of clinicians and practitioners, but also research centers, programs, institutions, professional leadership organizations.

MS. POLLEN: A colon after researchers?

DR. JONAS: A colon after CAM.

MS. POLLEN: I see what you are saying, yes, okay.

DR. JONAS: So, that applies to all those things. Now, that does not apply, of course, then to federal and state research and health agencies, so it will have to be separated as a separate clause.

MS. POLLEN: Right, we can do that.

DR. ORNISH: Other comments before we move on? Jim.

DR. GORDON: I think it would be helpful, when you mention the specific coordinating agencies, CAM Central, IOM, NCCAM, to mention them as part of this paragraph. If everybody agrees, then, we can move ahead with it and omit a step.

DR. ORNISH: Great. Joe.

DR. FINS: I don't know exactly where this goes, but since you are talking about the relationship and the coordination between conventional and CAM research, I am just wondering -- and I have looked through this -- if this is the place where we discuss the issue of global budgets, are we robbing Peter to pay Paul. I don't know if it is another issue for Saturday, but relative allocations.

If we are talking about there is $20 billion to

spend, how does it get spent? Someone might be losing if CAM is gaining. Have you considered that relationship?

DR. JONAS: I think we addressed that under research support actually, and where the big bucks go. I agree, I think that is an important issue to address.

DR. ORNISH: Well, it is a critically important issue because if people think we are going to take money away from them, they are going to fight tooth and nail.

On the other hand, since we don't have a budget surplus anymore, if we recommend that more money be allocated for that, then, it is going to come out of some else's budget. Maybe it is not NIH's, but it is going to be some other program. It will be harder to define whose it is, but it is going to make it more difficult.

So, there is really a strategic question, is whether it is better to highlight that or just let it be a subtext.

DR. FINS: Because I think a corollary issue is how things get labeled, like, do you go in under CAM research, or do you go in under allopathic research if you have a funding strategy.

DR. ORNISH: Right.

DR. FINS: I don't know where this goes, but --

DR. JONAS: It goes actually under Recommendation 21, so when we get to that, let's readdress this, because I think it is very important.

Recommendation 20 is, I think, fairly straightforward. As Dean mentioned, we ought to make sure that it is a reciprocal balanced recommendation, so it is not simply that CAM practitioners ought to be sitting on one board, but there should be mutual membership on various advisory, journal, regulatory, advisory boards from the different professions.

DR. WARREN: You mentioned here licensed CAM professionals. You are assuming that licensure is going to be a requirement?

DR. JONAS: Good question.

DR. ORNISH: I think we are actually.

DR. WARREN: I don't agree with that.

DR. FINS: How about appropriately credentialed because we are going to address it more robustly later?

DR. WARREN: I think that is much better than licensed.

DR. ORNISH: So, we will be dealing with the

issue of licensure versus credentialing at another time, I presume.

DR. LOW DOG: I think that there is only a few places where that would be relevant, but I can tell you from New Mexico, that especially in areas of research, bringing in traditional indigenous healers, Navajo and Pueblo, involving them in the research, because you can't do research in those groups without their being there, and they have a lot of sort of restrictions on what they are going to allow us to do.

So, I think that if we are just talking about license without including some specific areas where research is essential, and the inclusion of their healers would be important.

I am in favor of licensure and training, but I think you need to be inclusive there. I am only thinking of all that goes on in our own state, but there is no licensure in those groups, and yet they are intimately involved in our research process.

DR. FINS: Why don't we cross-reference the other sections?

DR. ORNISH: Because this area is going to be

debated in a different subcommittee of whether licensure should be required, whether certification should be required, whether there is some groups that should be, as long as they disclose what training they have, they need to be neither licensed nor trained.

I think we are in a way getting ahead of ourselves, because we haven't really resolved that issue. I mean we could just say whatever we resolve that as, then, we will put here.

DR. JONAS: Gerri recommended at least for this wording, "appropriately qualified," which may vary depending upon what the topic is, and this type of thing.

DR. ORNISH: Okay.

DR. GORDON: So, it would read essentially, "include appropriately qualified CAM professionals and traditional healers on research," et cetera, et cetera.

DR. ORNISH: Well, "traditional healers," could mean Native Americans, or it could mean Arnold Wellman [ph], I mean I am not sure what traditional healers means.

DR. GORDON: I was just trying to get the word that you want here.

MS. POLLEN: I think just "appropriately qualified."

DR. GORDON: Just "appropriately qualified."

MS. POLLEN: And not "traditional," just leave "appropriately qualified."

DR. ORNISH: What I was saying before, though, is it should be reciprocal, it should be both CAM and conventional, if we are using the term "conventional" for non-CAM, for allopathic, or whatever, so that it is clear that it goes in both directions.

MS. POLLEN: Yes.

DR. GORDON: I just want to get something clear. So, you are saying that on the board of an acupuncture journal, there should be an M.D. who doesn't know anything about acupuncture?

DR. ORNISH: There should be an M.D. who has some experience with --they don't necessarily even need to know about acupuncture, but there should be somebody who has experience with experimental design, biostatistics. Those kinds of things don't require knowledge of acupuncture to make good research.

DR. GORDON: I thought that is what you were

saying. I just want to make sure that people agree to that before we move on.

DR. ORNISH: I also think again, in the larger context, it makes it much more defensible and marginalizes people who would criticize. You say, well, yes, we think that it should go in both directions. Then, you have to argue about why it shouldn't be, and that tends to get people on the extremes.

DR. GORDON: This is a small question, but potentially a knotty one. I just want to make sure everybody agrees. If everybody agrees, that is fine.

DR. ORNISH: Knotty or naughty?

DR. GORDON: I think it is knotty because some people may say, well, look, here we are, we are this fledgling little group of people, if you put on an M.D. who is a qualified research in methodology who is a skeptic, he is not going to let us publish anything.

DR. ORNISH: Well, the fact that somebody is on a commission doesn't keep people from doing things, but I think that is exactly what people need, are a few skeptics on there, in both directions. I think that is the whole nature of science, is to have skepticism.

Just so you know where I am coming from, just to put my own biases on the table, what concerns me about both conventional and many CAM practitioners is a lack of skepticism, such a strong belief in the efficacy that there is a reluctance to submit it to more objective analysis.

That is the kind of thing that I think that people on both sides could benefit from.

DR. GORDON: I wasn't talking about skepticism with a small "s," I was talking about it with a big "S" as a profession.

DR. ORNISH: As a cultural taboo.

[Laughter.]

DR. ORNISH: Tieraona.

DR. LOW DOG: For one, I don't think that if you are a small fledgling acupuncture magazine, that you would hire an M.D. skeptic, so we are not saying which one would have to be on there, but I mean you could argue the other way, what would a massage therapist really know about invasive cardiology.

I think that the door swings both ways. I think that it is a good recommendation, Dean. I think

there should be inclusion, and by including, and I think it needs to go both ways, I really do, so I support that.

DR. ORNISH: We could just say "appropriately qualified." "Appropriately qualified," I think covers a lot. Again, we are not dictating to anyone, so it is not like these recommendations have the force of law, it is more of a general principle.

Effie.

DR. CHOW: I think one of our big debates has been that people don't understand the principles of what is being called research. I know that there are solid protocols, but protocols can be adjusted and still be good quality research, certain considerations to a particular practice.

If someone doesn't know anything about it, someone with a big "S," they are going to be close-minded about the nuances, which perhaps makes it successful or not successful. That doesn't mean fudging the results, nor fudging the guidelines or protocol.

But I think it is really important that people are involved, and people, also, who know research protocol, that they should have some innate experience

and knowledge about the particular CAM practice. I think that has been a big discussion all this time.

DR. ORNISH: In the interests of time, would you be comfortable if we said "appropriately qualified?" Does that give you enough room to cover the point that you are making?

DR. CHOW: I think, not really. It depends on who reads the appropriate qualification, who defines it. I think it should be stated that they should have knowledge, working knowledge with the particular practice that is being researched.

DR. ORNISH: Well, see, that is why we disagree, because I think that there are people who have experience in biostatistics and experimental design, who can help provide meaningful input into studies that they may not know very much at all about the intervention itself.

I understand the point you are making, but I would be reluctant to limit this to say that they have to be. Otherwise, if we are going to CAM people on conventional research journals, are we going to say that they have to be experienced interventional cardiologists

and know how to do angioplasty before they could be part of a cardiology review board? I mean I don't think we would take it on that side either.

I think that everybody brings a dimension of expertise that can be useful, and I think like the blind man and the elephant, the more different dimensions you get, the closer to truth you get. Even if one person isn't expert in all aspects of that particular discipline.

DR. CHOW: Well, I think that is moving so, maybe not specifics about cardio angioplasty, but acupuncturists, which were not required to know Western medical anatomy and physiology, is now being required to know anatomy and physiology from the Western standpoint, and also analysis and diagnosis by Western methods.

So, they are being required as part of the training, and so I guess maybe not right away, but hopefully, that that is in the future, and in the near future, that researchers, if they want to do research in acupuncture -- well, let's use another -- in homeopathy, et cetera, that they must also have some training in that.

I guess that goes with education of professionals.

MS. CHANG: With all due respect, I'm sorry, Dean and Wayne, you are way over your allotment on this particular topic.

DR. JONAS: What we could do is elaborate a little bit on what "qualified" means in terms of methodology, expertise in particular areas including complementary and the conventional areas on that, and then we will bring this back to you all. I will bring it back to the committee and that type of thing.

DR. ORNISH: Can we move on now to Issue No. 2, Wayne? Are you okay with that?

DR. JONAS: Yes.

DR. ORNISH: Issue No. 2 is conducting high-quality CAM research, prioritizing types of research needed, and assuring public input into the process.

I will put my two cents' worth in. I think that I would like to see something right up front about safety, efficacy, and cost-benefit before we get into too much of the specifics, again for all the reasons we have talked about, but other than that, I thought it was very

well described.

I have a few other minor points also as we get further along, particularly on page 4, the second paragraph, where it says, "Its the view of some CAM researchers that the requirements for CAM," I would say "were often higher than those for conventional research." That paragraph, I think might be moved closer to the beginning of that section just for the very reasons we have been talking about.

MS. POLLEN: Moved forward.

DR. JONAS: Yes, moved forward.

This category lumps several of the things that we discussed, and I think what we will do is maybe split them out, because it's huge. As you will see in the recommendations, we have gotten 21 A to Z almost, and there is really the issue of support, doing more complementary medicine research, and then there is the issue of prioritization and obtaining public input.

I think we would like to kind of massage these out a little bit, and we can adjust that, but I would like to go to the actual recommendation, if you will, which is on the bottom of page 5, No. 21, which really is

the primary recommendation that there be more support.

"The Commission recommends that all federal agencies with research or health-related responsibilities increase as relevant to their mission, support in a more proactive manner clinical research on the safety and efficacy of CAM practices and products, basic research on underlying mechanisms, and health services research to improve CAM use within the health care system."

Any feedback or comments on this?

DR. ORNISH: Well, the first one is do you want to comment at all here about whether those a new dollars or whether those are reallocation of existing dollars, or is it better not to address that question at all?

DR. JONAS: I think we should. Any comments on the general recommendation in terms of whether we should be more specific about that? David.

DR. BRESLER: Yes, I would like to see some language including an addition to safety and efficacy, indications, contraindications, precautions, complications, I would like to have a fairly broad view if they are going to do this research.

DR. JONAS: You don't see that as falling under

safety?

DR. BRESLER: It is not just safety, but I think indications of contraindications, too. We have had a lot of discussion about interactions of CAM modalities with other kinds of modalities, and I think we have to stay vigilant of this if we are going to encourage this type of research.

DR. ORNISH: Good. Who else? Joe.

DR. FINS: I have two points. I don't think it is strong enough overall. I am not sure it is strong enough on the HRSA side, the health services dimension, it gets buried. I know it is here, but it is not as prominent. I think all of these things that are embedded in No. 21 perhaps deserve their own bullet because I think they are all different.

I think that as I read through the later part of the report, there is a lot of redundancy and a lot of nitpicking kind of mechanistic kind of approaches, which I may not necessarily be a recommendation, but sort of background, but I think that we really want to identify these various areas.

The other issue about the prioritization

question is, it seems to me, Congress appropriates money and decides what the balance is between the various constituencies, disease constituencies and professional organizations, and the like. So it is really their prerogative to set the standard.

But what I was sort of hoping to see was some mechanism to help provide Congress with some guidance into knowing whether or not, in the context of a global budget, what the relationship, what the percentage should be, and I don't know how we can help them there, but I think it would be helpful if we could sort of characterize that somehow.

DR. JONAS: There is recommendation actually along those lines in terms of requesting that the IOM establish some prioritization approaches which then, of course, would go to a variety of individuals including Congress.

DR. ORNISH: I was just going to say that it may be that we simply -- I mean it would be hard for us to say, as a commission, for example, whether they should be appropriating new money or reallocating, because a lot of that will have to do with changing budget

requirements.

You know, we had a budget surplus this last year. This year, we are already in deficit, but at the same time, it may be worth mentioning just what is self-evident, that it would be easier to effect this if there were new dollars coming in rather than reallocating existing dollars, or we may just want to remain silent on that.

DR. JONAS: Let's talk about the budget issue since it keeps coming back and hitting us in the head. Does the Commission feel that there should be an emphasis that there be new money, set aside money, or support, because we are making all these suggestions that there needs to be more research, and the natural question is how to do that, and are we suggesting there be appropriations for that?

DR. ORNISH: I would like to suggest that we make a recommendation that increased funding be available for research in these areas, in safety, efficacy, health services, cost-benefit, whatever. We might even just say, very explicitly, that, absent that, it will be very difficult to convince existing agencies to reallocate

some of their current research budgets for these areas.

I think certainly people in Congress will get that very easily, and it is just stating what is true, and then we are not really saying how much more it should be, but just the general principle gets outlined.

DR. GORDON: I think there is a real question here that we are sort of coming toward, and do we think research priorities ought to change, or do we simply say we want more money for this approach.

If we say the latter, it is the safe thing to do.

DR. ORNISH: I don't understand that.

DR. GORDON: Let me just finish.

DR. ORNISH: I just want you to clarify, when you say research priorities should be changed or this, this is asking for research priorities to change. I am just trying to understand.

DR. GORDON: What I am saying is there is a fixed amount of money basically. I mean we can act as if there is going to be infinite amount of money, we know it is not true. Do we want to make a statement about research priorities should shift in this direction as we

make a statement a little bit later on saying that we ought to begin to shift some of the research priorities toward those things that can't be patented, for example?

My answer is yes, but I want to put that out as a question for us to address, which is really in response to the issue that you raised, how do we look at budget.

MR. CHAPPELL: I agree with Jim that we ought to be looking at a shift in priorities at a minimum.

DR. GORDON: What Steve is saying, quite rightly, is this may be something we want to focus more on, on Saturday morning, because we have a lot of recommendations here, so I think that is a good idea, but I do think it is something we are going to have to grapple with.

DR. ORNISH: Well, then, if that is the case, then, shall we limit now discussions away from that area into the other recommendations themselves?

MR. CHAPPELL: If I could just finish my point. You have been using the language safety, efficacy, and cost-benefit, and I didn't think that cost-benefit needed to be a qualifier, in fact, I would rather it not be a qualifier. It is not in the language currently, so I am

seeking clarification, is it your intent to put it in, if so, I have a problem with that.

DR. ORNISH: It is my idea to put it in, and the reasons is, is that I do think that one of the advantages of CAM, in our work, for example, we found that almost $30,000 were saved per patient by teaching them how to change lifestyle and diet rather than having, say, bypass surgery.

It is something that can really appeal to people across the political spectrum to show that it not only is medically effective, it is also cost effective. So, it doesn't mean that something has to be cost effective before it could be implemented or used, but it is simply studying that aspect of it, because many CAM modalities I think will be found to be more cost effective than their conventional counterparts.

So, I am interested in why you have concerns, for why you would be opposed to that.

MR. CHAPPELL: It's on principle that I think we ought to be looking at it from a needs-based orientation, and not a calculation of which money is going to be invested for which greater gain.

DR. ORNISH: Anytime that Congress decides, like Medicare, decides to cover a new modality, it always goes to the Congressional Budget Office. They do a cost-benefit analysis, and if that information isn't available, the CBO will almost always say something costs a lot of money.

So, in a way, having those kind of data looking at cost-benefit can really advance the field in terms of getting the kind of widespread adoption and coverage that I think many of us are looking for.

DR. GORDON: Let me make a procedural point here a minute. Michele is reminding me we are going to be coming back to some of these issues under coverage and reimbursement. We have a large number of research recommendations that we got to get through and hear people's comments about.

So, if we can postpone that discussion to coverage and reimbursement, I think it will simplify things.

DR. ORNISH: Okay. Joe.

DR. FINS: A quick point on that because it is something that we depend upon research being conducted on

cost-benefit analysis to make access and reimbursement and coverage kinds of arguments. So, we have to keep it in here for the cogency later on.

DR. ORNISH: Okay. Thank you.

Do you want to move forward?

DR. JONAS: Yes, I think so. I don't want to go through all the sub things even though I recognize that some of the subcategories underneath the numbers don't necessarily belong under those particular categories, but given the suggestion that we had in terms of some of the categories we talked about, including things like breaking out prioritization, then putting things like 21(G), 21(L), and that type of thing underneath those, the patent issue underneath those we will do that, but let's go to the major recommendations, I think, in the interest of time.

No. 22 is the issue really about standards of evidence.

DR. GORDON: Wayne, excuse me. So, how do you want us to deal with all of these things that are broken out, what is your thought about how we would proceed, because they are all fairly specific? They are

recommendations, even though they are kind of separate.

DR. JONAS: Do you want to go through all those, do we have another hour?

DR. GORDON: I think we either have to go through them and get some very quick response, or send them back to you and go through them the next time.

DR. ORNISH: I just need a point of clarification. Wayne, are you suggesting that we consolidate these or that if anybody speak now or forever hold your peace, that they are okay?

DR. JONAS: Why don't we take these 21(A) through (D), and later you will get 21(F) through whatever, and say are there any general comments about these particular things.

DR. PIZZORNO: I think this is excellent, and there is a piece here, which I think may have been intended, but I don't think got said, and that is to research systems of healing, not just isolated modalities, because most of this therapy is part of a philosophy and integrated --

DR. ORNISH: It's under 21(C).

DR. PIZZORNO: Well, I read them all. I just

want to give the feedback to the committee that I don't think that comes across the way I think it needs to come across, systems of healing.

MS. POLLEN: Is that in 21(C) that you are looking at?

DR. ORNISH: Under 21(C), it says, "Complete biological systems and interacting biological systems including biofields and energy medicine." What is missing there?

DR. PIZZORNO: I am talking about systems of healing, that is, under a philosophical approach, there is a way of treating a patient that uses multiple therapies consistent with their philosophical approach. What you have here is different. That is looking at the body as a whole.

MS. POLLEN: Is that something that is missing?

DR. PIZZORNO: Yes, it's missing, it is not stated. For example, I will use naturopathic medicine as an example, which I know. When a patient has asthma, I have seven different interventions I use, three which I use for one patient, and different ones I use for another patient, because a way of understanding the patient that

leads to my intervention. That kind of thinking, I don't see reflected here, to do that kind of evaluation.

DR. ORNISH: There is something on individualization therapies, though, in one of these sections, I don't remember where.

DR. JONAS: It is one of our guiding principles.

DR. ORNISH: Yes, it's one of the guiding principles is individualization of therapy earlier in the report. Does it need to be repeated here also?

DR. GORDON: I think he is just adding that phrase, systems of healing I think takes care of it here.

DR. JONAS: I think that that is part of a category actually that has to do, in terms of addressing it, has to do with methods and epistemological approaches.

DR. GORDON: I have one issue that I think is omitted here under 21(A) that we had some testimony about, and this may be something we need to talk about on Saturday morning, which is how to help protect researchers, whether there is a shield that we can encourage NIH or other institutions to provide for

researchers as they under take it.

Gerri, do we have it somewhere else?

MS. POLLEN: Well, at this point it's in the background, and I think when we know a little more about what is going to be coming from the Federation of State Medical Boards, we will be able to elaborate a little more. It is a little early at this point.

DR. GORDON: I was just saying it's an issue we need to address, that's all.

MS. POLLEN: It is mentioned actually in the background.

DR. GORDON: But as a recommendation.

MS. POLLEN: We will move it in here when we know a little more.

DR. JONAS: So, you are suggesting that that be moved in as a recommendation?

DR. GORDON: Exactly what the recommendation is, I don't know yet, but I am saying we need to address it as a recommendation, and we don't have to talk about it right now. I am just saying we do need to talk about it at some point.

DR. JONAS: Just for my better understanding,

is there an area that we have been talking about where that would fit under?

DR. GORDON: In a sense, it's separate, it related to practice, the practice-based research, so it may be brought in, in that context, but there may be other ways that one approaches it that are not practice-based, because there may be laboratory research or other kinds of research.

So, I just think we need to consider it, and not now is all I am saying.

DR. FINS: I think it could be under the CAM investigator, the category, and there was language that we probably approved as a group earlier on in the pre-interim, Interim Report, where we linked up the immunity for the investigator if that investigator adhered to ethical guidelines, regulations, and submitted, and things were on protocol. If they were flying freely in free flight, they were not immunized, but if they adhered to certain regulations, they would be.

DR. ORNISH: I think that is a really important distinction, and I am glad to hear you make it, because I think there is all the difference in the world between

getting an IRB approval for an unproven approach to study it versus someone who has been doing illegally, trying to say, well, here are my data, I want you to take a look at them.

DR. GORDON: Dean, it is a complicated issue and I would like your committee to take a look at it.

DR. ORNISH: Okay. Any other comments before I move on?

DR. CHOW: I just want to state that I think those two items are really important.

DR. ORNISH: Next.

DR. JONAS: Shall we move on to the section on 22, Recommendations 22? The Commission recognizes it is essential that all biomedical research meet the highest standards of quality and recommends that standards of research quality for CAM be the same as for convention biomedical research, neither lower nor higher.

Any comments on this or some of the subcategories which actually probably don't below under 22. The first two, in my opinion, have to do with dialogue and ways of building infrastructure, for example, the NCI Score Program.

DR. ORNISH: One of the things that Wayne and I talked about earlier was there is a group of people who testified, who said that it is not really CAM or not CAM, either it is scientifically proven or it is not, and as journal editors we will publish good science whether it is CAM or not CAM, and I think with The New England Journal, I think we asked, well, how many CAM articles have you ever published, and they said "zero."

So, I am not sure whether that is worth getting into here or not as an example, or whether it is just a subtext that we are working from.

DR. BRESLER: I think this is a really critical point, and unfortunately, I think it is very unlikely that anybody is going to rise to the occasion and sponsor these kinds of interdisciplinary meetings unless we put a little bit more teeth in it.

It is the kind of thing that I would like to encourage matching funds from the government to match the private sector or to match foundations or to match other people to give them some incentives, because this is critically important, and they won't do it otherwise. I would like a little more teeth in this one.

DR. FINS: I just want to, for the record, have this paper circulated from Controlled Clinical Trials. The title is "Do Certain Countries Produce Only Positive Results: A Systematic Review of Controlled Trials."

They found, they looked at acupuncture, and they found that the countries where acupuncture was traditionally practiced invariably said it was effective, whereas, other countries didn't.

So, this, I think, may help us unearth this notion of a double standard and how there is a perception of bias, both favorable and unfavorable, in the literature. It may help you guys in the background section.

DR. ORNISH: Yes. Maybe we could cite The New England Journal as an example of how the philosophy and the practice don't always come together, and then this paper as an example on the other end of the spectrum, so that we can have a more balanced approach.

DR. JONAS: A book came out two days ago that I edited on clinical research methods in complementary and alternative medicine, and I will see if I can bring a copy that addresses these issues and gives specific

examples actually documented in the literature including that study. Maybe that could be useful to draw from to put In there.

DR. ORNISH: That would be great.

DR. GORDON: What about the three recommendations that are here, 22(A), 22(B) -- I mean I think we are agreed on 22 fundamentally.

DR. ORNISH: Let's go through them real quickly. 22(A), any comments or problems with that? I know, for example, the National Cancer Institute, I was on their first review committee on looking at CAM through the National Cancer Institute. It might be nice to mention them as an example of an organization who is already moving in that direction, that we want to encourage others to do.

Tieraona.

DR. LOW DOG: Just for clarification, could we put an example on 22(C), request recommendations from the NSF on how to study in a credible manner high risk? Are you talking about like chelation?

DR. ORNISH: I was just actually trying to go through these. 22(A), any comments or questions? 22(B),

any comments or questions?

DR. BRESLER: Just stronger than "encourage."

DR. ORNISH: Mandate?

DR. LOW DOG: No.

DR. ORNISH: Incentivize.

DR. JONAS: Stimulate.

DR. GROFT: There already are possibilities for workshops, and I know '96 or '97, where we had the large conference, or '95, I am not even sure, on acupuncture, research methodology surrounding acupuncture, so it is possible to do it. It is just a matter of someone taking the initiative, and I think NCCAM is doing that in some instances, but there is certainly the opportunity.

DR. ORNISH: What is we change "encourage" to "incentivize"?

MS. POLLEN: It could also be put on that are supported collaboratively by the public sector and the private sector together. That is another way of doing it.

DR. ORNISH: So, Tieraona, 22(C).

DR. LOW DOG: I had to read it a couple times to understand what it meant, and I am still not sure what

it means, but I am thinking it is like chelation. Is that what it is intending to mean? I just think we need an example, because if I read it, I wasn't quite clear. I don't disagree with it, I just think we need to explain it better.

DR. JONAS: There is a background paper on this actually, and the specific reason this particular recommendation is targeted towards the National Science Foundation is because the recommendation is to look at the scientific issues of things that are generally taboo in conventional medicine, but are standard basic assumptions in every-day use in unconventional medicine, and this is a category, for example, where energy medicine fits in.

These areas are avoided by science generally, but they are very popular from the public perspective, and so how can we begin to bridge this gap, how can we begin to develop a process that encourages scientists to begin to explore these areas, and we can give some examples and change the language if you want to.

Something like chelation, which is really a socially controversial area, that is something that I

would see falling more in the category of 21(L), I believe the recommendation is, which is asking for a similar process by the Institute of Medicine, and there are particular examples that we could put into that.

DR. LOW DOG: But, Wayne, why do we have "high risk" when we are talking about energy?

DR. JONAS: Because this is how it is perceived in the scientific community.

DR. LOW DOG: Risky?

DR. JONAS: Yes, absolutely, these are seen as areas that could not be examined by science or at least if they were examined by science, they would be very risky for one's career or for even discovering anything relevant. A lot of people feel like they are a waste of time, especially the scientific community, they don't think that anything is going to come of them.

DR. ORNISH: What if we just say "perceived as high risk by many convention researchers," or something like that as opposed to saying that they are high risk, they are perceived as high risk. Would that do it, Tieraona, for you?

DR. LOW DOG: I just think risk isn't the right

word, "high risk."

DR. ORNISH: Unconventional? What word would you use? "Controversial."

DR. GORDON: Again, we have a huge number of recommendations to cover. If we are feeling uncomfortable, let's send it back to the committee and let them work on it, and come back to us, having heard some of the concerns in a better way.

DR. ORNISH: We will make recommendations that aren't so controversial.

DR. JONAS: I think we need to find out, though, what the issue is, Jim, in order to be able to figure out how to address this in the committee. Otherwise, it will come back to the committee, and we won't even --

DR. LOW DOG: But I am on your committee.

DR. JONAS: Well, then, don't say anything.

[Laughter.]

DR. LOW DOG: But when I read this, I hadn't heard where we had talked about like high risk, and so all I can tell you is if we lined up 100 people, 90 people wouldn't know what that meant. They wouldn't know

that you were talking about energy stuff.

DR. ORNISH: Are you comfortable with "unconventional," would that work? Or "controversial," I mean?

DR. LOW DOG: Yes, emerging controversial.

DR. ORNISH: Great. Let's move on.

Recommendation 23. Any concerns or comments about that? Do you want to explain anything about it?

DR. JONAS: Any comments on this? This is the recommendation that basically says that we should have public input into this process including advisory committees, review boards, research teams.

DR. ORNISH: I was only going to add that it might be useful to draw the parallel with other accepted organizations -- accept is probably the wrong word -- conventional organizations that have advocacy groups, and we heard from some of them in their testimony, the breast cancer community, AIDS advocacy groups, the prostate cancer advocacy groups, et cetera.

DR. JONAS: Right. And there also are examples within the federal government where they are doing this. NCI has a whole program on training the public to be on

these boards to properly represent their groups and their constituencies.

DR. ORNISH: Joe.

DR. FINS: Again, this has come up before, but institutional review boards do not set policy, they regulate research, so they are not, that second sentence, and public membership is mandated on IRBs, but IRBs do not set priorities, they regulate the research endeavor, so it is a little misleading. Under 23.

DR. GORDON: That issue also applies to the next several recommendations, too, and maybe this is providing a little more context, that is, already some of these things are either being recommended by other groups or, in the instance of 21(E), (F), and (G), NCCAM is already doing some work in these areas, and I think it is a matter of providing some of that context, and some of the questions about it will go if we do that.

DR. ORNISH: So, basically, just saying that these are already in process, and we are just encouraging more of that.

DR. JONAS: That applies to many of these areas actually.

DR. ORNISH: Would it be helpful, then, to distinguish where we are saying that we like this and we would like to see more of it versus something that is not being done, that we would like to see beginning?

DR. GORDON: That is my thought, and I think that is what Joe is saying, as well, if I am correct about that, that we need to be saying we are in agreement with other organizations that are already advancing these.

DR. ORNISH: It certainly makes it stronger to point out and educate the reader of the document that a lot of this is already going on by these conventional agencies, which gets us out of the us versus them mentality, but say there is already collaboration that is beginning, and we would like to see more of it.

DR. JONAS: Yes, I think that would be good to do throughout here actually.

MS. CHANG: Just a time check. You have about 25 minutes left.

DR. ORNISH: Plenty of time.

DR. JONAS: We are doing fine.

DR. ORNISH: Anything else on 23 before we move

on, Joe?

DR. FINS: We talk about this and maybe it comes here, but I think everybody agrees since we have talked about this before, we talked about having the same sort of set of standards to evaluate the scientific method da-da-da-da, but I think we also want to say that research that is conducted in the CAM arena should follow the same ethical guidelines as conventional, and it is the expectation that there will be IRB review, et cetera, and that should be in here in the research chapter somewhere.

DR. ORNISH: I agree. Anything else before we move on?

Issue 3. Research, training, and infrastructure. Shall we just go straight to the recommendations in the interest of time since we know you have all read this? 21(E), (F), and (G). Any comments?

DR. PIZZORNO: 21(G), on the first line after "to enable," and insert in there "both CAM and conventional medicine investigators," just to recognize that we are enabling both types of investigators, research investigators.

DR. ORNISH: Okay. Good. Other comments on 21(E), (F), or (G)?

DR. FINS: Dean, I think we should, maybe, say that we should incentivize the relationship, joint submissions from CAM and non-CAM institutions. It is here, but somehow you will get a higher priority score if you go in jointly than if you go in separately.

DR. ORNISH: Something along the lines of how they incentivize studies of women or minorities -- I can't remember what the other ones are -- that all things being equal, you get extra credit if you include subjects or approaches like this.

DR. FINS: That fosters the synergism that you are stating out here in No. 3.

DR. ORNISH: Isn't that going to be in direct contradiction to the overarching theme of it should be held to the same standard, no higher, no lower? It almost makes it more like giving it an advantage.

DR. FINS: No, it is the same scientific standard, but you are saying that we believe that there will be better science if investigators from both sides of that street come in together, it will be a better

product.

DR. GORDON: Again, this is another area where NCCAM, I think has done quite well in terms of encouraging this to happen, and we don't need to reinvent what they are doing. We need to indicate that they are doing it, we encourage them to do it, and move it ahead, and they are doing just what you are saying, Joe. They are saying if you are going to start one of these centers, you had better have CAM folks on the board along with conventional folks.

DR. ORNISH: Good.

MS. POLLEN: I need a clarification from Joe Pizzorno. You had a comment on 24 that I am not sure I got.

DR. PIZZORNO: 21(G)?

MS. POLLEN: Was it 21(G)?

DR. ORNISH: It was 21(G) he was referring to.

MS. POLLEN: Okay.

DR. PIZZORNO: After "enable," insert "both CAM and conventional medicine."

MS. POLLEN: Thank you.

DR. ORNISH: Other comments on these three

recommendations?

DR. JONAS: I think linking to where this is already going on, because a lot of this is already going on, is important, however, I think what our recommendations should target really is the need to have this done in a broader number of agencies. There is one lead agency, and they have money to do it. So things get stimulated in that particular area. But we would like to see that coming from other agencies, within and without, outside the NIH.

DR. GORDON: In my opinion, it is a very good way to word it, because it indicates this is happening and we want to encourage it elsewhere, and we can do that throughout.

DR. JONAS: I agree. Most of this comes under stimulating more research, I think. My suggestion is that when we put those subcategories in there, we actually name agencies as potential areas where this could occur, that already to this, it is part of their job. Some of these are in here like this, but we will hopefully make it clear, like NCRR and other groups.

We need a glossary. Is a glossary in

preparation?

DR. ORNISH: You mean with all the acronyms?

DR. JONAS: Abbreviations, terms.

DR. GROFT: That will all be taken care of in the final report, glossary and acronyms. We will have it all together in the final report.

DR. ORNISH: Effie, you had a comment?

DR. CHOW: I know things are happening and in every category we have been talking about that. We said that things are already happening in the system, and it is already happening in this department and everything.

Do we have an idea of really how much needs to be done in terms of research, because if people who are going to pick up this document and say, well, everything is happening already, and the comments here is that a lot has been happening.

Do we really mean that a lot has been happening, or is it some has been happening? I think we need to differentiate, and not just say we encourage more. Perhaps we need to think how much more we need and in what categories of research, et cetera, because if you talk about $100 million, $250 million for FDA to turn out

one pill, 15 years to get one pill out into the public -- I know it has been changing -- but, how does research in CAM compare with that, instead of $30,000 for a year's research, or just $1 million for research on trying to establish the validity of a system of practice.

DR. ORNISH: I think you raise an important point about distinguishing the fact that while some things are ongoing and we encourage them, they are still at a fraction of a percentage of the overall NIH budget, let's say, and that on the one hand, we are glad these things are occurring, it makes our recommendations seem even more generalizable and acceptable, but we also need to point out, as you have indicated, that the magnitude of funding in many of these areas, or the magnitude of support is still only a fraction of what it could be or what it should be.

DR. CHOW: The other figure that we use is increased by 600 percent or 800 percent, I have been hearing this, and I mean funders will say, oh, wow, then, you don't need any money if they don't know what the level is, et cetera.

DR. ORNISH: I agree with you.

DR. CHOW: I think we have to be real careful about expounding that so much is going on.

DR. ORNISH: Thank you.

Tieraona.

DR. LOW DOG: Would it be helpful, then, I mean because there was this nice chart at the back, which was enlightening for me, CAM spending, and then you had the NIH, which I found interesting for 2001, 89 million for NCCAM, but 192 spent, so actually, more than 100 million in the other institutes put together.

Maybe putting that with what the total budget for the NIH was for that year and what percentage of that went to CAM research, and while we applaud how much that is, what is it in percentage to the total budget of the NIH.

DR. PIZZORNO: I think it's about 1 percent.

DR. LOW DOG: But including that in here.

DR. ORNISH: I think putting on that chart, because if somebody is reading that, it might look at first glance like NCCAM is spending more money total than NHLBI as opposed to just that fraction of NHLBI that is going for CAM, and I think it would be useful to say what

the denominator is of total spending in each of these organizations.

MS. POLLEN: In each of the institutes.

DR. JONAS: Including NCCAM.

DR. ORNISH: Well, with NCCAM, I presume it would be 100 percent.

DR. JONAS: Oh, is that right?

DR. ORNISH: Not when you were there.

[Laughter.]

DR. JONAS: We don't want to get into too much budget clipping because it is a political game, you want a big or a small number. But certainly, I think what I have been hearing is, the message is, we need more in this area. Proportionately, it is fairly small, so we need to stimulate it in some way. We need to incentivize it in some way.

So, in other words, just to leave things, as usual, to the committee is not adequate enough. Is that correct?

DR. ORNISH: Yes.

DR. FINS: In a way perhaps of tracking this is every institute knows a percentage of applications that

scored high enough to be funded, but weren't funded because of resource issues, and maybe we could look at that and track it, and if the number of applications of projects, proposals that are well scored increases and the percentage goes down as the field goes larger, then, we might have a good indication that funding needs to be increased.

DR. JONAS: That actually is already out and NCCAM is less than the average in NIH.

DR. GORDON: Wayne and Dean, we really have a lot to go through. I think some of these specifics, assuming we are generally agreed, that it is better to communicate directly with the facilitators or with Gerri and get the information back to them, because otherwise, we will never get through these.

DR. ORNISH: Let's move on. Next.

DR. JONAS: 21(H) is addressing specifically the private sector issues.

DR. ORNISH: Why don't we just say, in the interests of time, we have got 21(H), (I), (J), (K), and (L). Any comments or questions? Why don't we just go through them real quickly.

21(H), any comments? Since I am getting very strong direction to move things along, I am going to move things along.

MR. CHAPPELL: I'm sorry, but this is important to me.

DR. ORNISH: I am not trying to do short shrift, I just want to see if there are comments or not. If you have any comments on 21(H), I would welcome them.

MR. CHAPPELL: I would like to have the recommendation explained in a little more detail for me. I don't know what you mean by "CAM patents." I have read the partnerships and the opportunity, you have the footnote. I would just like to know what you are intending by these recommendations.

DR. ORNISH: Part of the problem in CAM is that a lot of research on drugs is sponsored by the pharmaceutical companies that make them, a lot of research on stents or other devices ditto.

Part of the problem with CAM modalities is that there isn't a patentable device or drug that allows for investment in doing the kind of research, much of what gets funded in conventional medicine by drug and device

manufacturers, and the fact that you can't patent many CAM approaches limits the amount of private sector funding that is available to do research.

I think that is all that we are talking about here, and trying to find ways to incentivize manufacturers to do that.

MR. CHAPPELL: If there is known bioactive properties to an herb, then, under the current laws, manufacturers are encouraged to apply for an NDA, so I am not sure the assumptions are actually correct in this.

There is protection. Once you have established the activity, bioactive component, then, the FDA wants you to apply for an NDA and get protection that way. We are not talking about millions of dollars of research, but probably a few hundred thousand.

So, I just want to be sure that we understand what the ground rules are currently.

DR. ORNISH: But, for example, if you are looking at a low fat diet and reversing heart disease, there is no bioactive component to patent, and yet the studies need to be funded.

So, how would you like us to clarify this?

DR. JONAS: The recommendation actually is to either solicit or conduct a study to examine these issues. It is not necessarily about what issues should be done. I am wondering how you would do that. I mean is there an agency, for example, or is there a group that could be the lead in terms of looking at these issues, how to stimulate private sector investment in research in complementary medicine products and practices?

MR. CHAPPELL: I think perhaps one way to proceed is to differentiate between the products and the practices or the modalities because I think there are differences in the way they are handled.

DR. JONAS: So, you would see two different --

MR. CHAPPELL: Well, I am hearing there are.

DR. ORNISH: Actually, the recommendation, as Wayne is saying, is to study this more with this intention. Is that something that you would be comfortable with?

MR. CHAPPELL: Yes.

DR. BRESLER: A comment. It seems to me, I mean I had raised this earlier in our hearings, too, but we have had not had input from the investment community

about what kinds of incentives or ideas they would have that would bring them in.

I think one of the most obvious things is low interest loans which are missing from your language. If you look at things like the Stafford loan program and other examples in government, when the government wants to incentivize something, it makes money available to people very inexpensively.

Just in the language here, tax incentives mean nothing to a company that is not making a profit, okay, and early in the game we have a lot of fledgling industries that are not going to benefit from tax incentives, they are having a hard time getting their hands on capital.

DR. ORNISH: What if we just add tax incentives, loan interest loans, et cetera?

DR. BRESLER: I think we need to solicit the investment community's input to this, too.

DR. ORNISH: I agree, and that is why we are talking about doing a study as opposed to making recommendations right now.

DR. JONAS: This actually has already started

and NCCAM had their industry conference, for example, which they brought in industry and had a dialogue about how to stimulate collaborative research in these areas.

DR. ORNISH: So, we need to make reference to that then.

DR. JONAS: Yes.

DR. ORNISH: Tieraona.

DR. LOW DOG: Yes, and could we change from projects to standardize the composition of CAM products, could we say projects to investigate ways to improve the quality or analysis of CAM products, because you are not going to standardize most of them.

MS. POLLEN: Proof of quality?

DR. LOW DOG: And the analytical methods and quality of CAM products.

DR. ORNISH: Weren't you arguing earlier about the importance of standardizing under DSHEA?

DR. LOW DOG: No, you will never hear me talking about, arguing really for standardization, because it is impossible for most botanicals. We are not at that place yet. However, quality control is not the same thing as standardization where you have identified

some bioactive marker, and GMP should address identity and quality, but I think that is misleading that we are going to find standardization for all of this.

DR. ORNISH: Other comments?

DR. FINS: On 21(J), I think we should also mention in there the Bayh-Dole Act.

DR. ORNISH: B-a-y-h.

DR. JONAS: Any comments on solicit a study of FDA methods? 21(I).

DR. GORDON: This is a more general comment. We are recommending a lot of studies here and a couple in other places in this research, sort of studies of how to proceed. I think that we have to decide how many studies -- I mean it sort of gets to be a little cumbersome.

There may be some of these areas where we can make specific recommendations based on testimony that we have heard so far, and I would not recommend a lot of studies. I think it just delays things and doesn't really take on our responsibility.

I think we have some pretty good ideas under some of these, and my inclination is to ask you all to reconsider most of these studies, and not tell us to have

studies, but tell us what to do.

I mean you have been meeting, and where do we go next?

DR. ORNISH: Let me just ask you, Jim, which ones -- let's go through them.

DR. GORDON: I think that we have heard some mechanisms, which we have already discussed in here, for incentivizing for development of products. We have heard that from some of the big manufacturers and from some of the small health food places.

I think we have a sense of how to proceed with studying difficult areas or challenging areas whether they are science that is sort of frontier, what we call frontier science.

Wayne, you did a piece of this. We had studies like you were the director of the OAM.

I think we should just come out and say it right now, and not bump it off to NSF or IOM. We know this stuff. I think that we need to surface that -- this is my feeling -- we need to surface that, have it back at the next meeting, and see where we are. If we agree, great, and if we don't, then, we can let it go and call

for a study.

DR. ORNISH: Do you want to go through each of these recommendations that requests a study, and decide now whether you think it is ready for prime time or not?

DR. GORDON: My opinion is I would like you all to reconsider this as a group and tell us what we know right now, and not go in for a lot of study. There may be some specifics you haven't worked out, but I would like some general guidance about what to do and where to go next.

DR. ORNISH: Well, just as a process issue, Michele, we have until 3:30, right, which gives us another 40 minutes or so?

DR. GORDON: I am only going to need about 15 at the end to summarize, so I am okay with giving up that, but I don't think we can resolve these issues here in half an hour or 40 minutes. My feeling is I think this takes your committee meeting and really thinking hard through some of these issues.

DR. ORNISH: We can do that except we only have a few recommendations left, so we are going to have some time unless these last recommendations take a lot more

time than I think they will.

DR. GORDON: We have got about 15 left.

DR. JONAS: No, we don't.

DR. GORDON: Yes, we do.

DR. ORNISH: The last pages, 12 and 13 and 14 are just a restatement of the ones we have already done.

DR. GORDON: I'm sorry, you are right. We have about four or five left.

DR. JONAS: We are just actually just about at the end.

DR. ORNISH: Why don't we go through those and if we have time, we can circle back to this, and if not, we will do it in the committee.

Before we leave 21(H), (I), (J), (K), (L) -- I feel like I am teaching my son the alphabet here -- any comments or questions? Effie.

DR. CHOW: A point of clarification here. The challenges are written in this section more as recommendations than challenges. I don't know, it seems to be.

DR. ORNISH: I'm sorry, I don't understand.

DR. CHOW: The challenges before the draft

recommendation, I have written in this section more like recommendations than challenges.

DR. JONAS: Effie, you caught us. You figured out how we got rid of most of the recommendations.

[Laughter.]

DR. JONAS: We made them challenges.

The wording, in terms of a recommendation and an issue, it describes the issue, I think is important.

DR. CHOW: But the other spoke to kind of what the challenge is, but here it is like just stimulating, it speaks more like it is a recommendation, stimulating them. Anyway, I just throw that out.

The others are (H), (I), and (L), it says solicit a study, request a study. Do we want to lock us in, it is only one study? This says "a study."

DR. ORNISH: Before we get into that issue, why don't we circle back to see if we are going to just make recommendations rather than a study anyway.

DR. JONAS: Let me just clarify. We may be getting confused here about studies. I mean, there are studies which are research studies, which is one type of thing, and then there are suggestions that a particular

agency group that evaluates areas and makes recommendations to the government about how to go about doing things.

The IOM is one, the NSF is others, there is a variety of groups. NIH does it in certain areas, et cetera. That is basically saying this is a complicated area, it is important, it needs to be addressed, and so as an overall government commission body, you are making a recommendation that this agency do this particular study, this particular evaluation.

Those can be put into different categories like we have talked about possibly organizing them, but some of them may be very important. The prioritization ones are going to be extremely important because those tell you, now you have some money; where are you going to put it; you can put it in the important stuff; or at least, how are you going to go about deciding that.

So, those are studies, those are specific studies that are solicited from particular agencies, and I think should be as specific as possible.

DR. CHOW: I understand about the nature of the study, but we said "a study." Are you going to lock

yourself into a study or studies as necessary?

DR. JONAS: Well, my personal bias is that you actually say "a study," and you put it into a agency, and then that agency can convenes a committee like this, and says, gee, we can't address products and practices in the same thing, we need to have two groups or we need to have a series of studies, et cetera, but that is not our determination as to whether we want one or want another.

DR. ORNISH: Why don't we just table that for a moment because some of these, as Jim said, some of these things that we are requesting studies, if we have time, we may circle back and just make recommendations, in which case it is a moot issue.

Tom.

MR. CHAPPELL: I think 21(H), forgetting the study part, I mean what we need is incentive for private sector research investment, so that the discovery has some kind of protection for marketability by the discoverer, whether that is an NDA, which gives you five years of marketing exclusivity while you are continuing the research, is it a patent, but clearly, this is needed.

So, what kind of incentive can you provide other than marketing protection either through a patent or an NDA? You can provide reimbursement or some sharing of the cost public/private to the manufacturer, because in CAM, you are dealing often with smaller companies, and they don't have the funds to do this.

I don't know whether you can differentiate between small and large company here, but I think the proper incentives are market exclusivity for a period of time and reimbursement to some extent of the research cost itself.

DR. ORNISH: Do you want to get into the -- there are really two levels here -- one is to say let's do a study, the other is to say let's incentivize the manufacturers, and the third is to actually get into specifics of what that would be.

Are you arguing for the latter or the third approach here?

MR. CHAPPELL: No, I am just trying to help you all get to more specific recommendations, and I am saying you are clearly on the right track when you address let's provide protection for the market, or let's provide

reimbursement for the market or the research company.

I do think you are going to have to get a tax policy consultant, an intellectual properties consultant for you to get any more specific than that, and I am not sure you want to.

DR. ORNISH: Just in the interest of clarity, how would you like us to change 21(H)? We will take out the part about solicit a study.

MR. CHAPPELL: Other than to say "to provide," instead of "solicit a study," to provide private sector research investment in blah-blah-blah.

DR. ORNISH: Incentives, right, to provide incentives in those.

MR. CHAPPELL: Yes.

DR. ORNISH: And then leave the rest the way it is?

MR. CHAPPELL: Yes.

DR. ORNISH: I am trying to just be as specific as I can here. Got it. I agree with you. Are you comfortable with that?

MR. CHAPPELL: I think so. It's tough.

DR. ORNISH: I know it is.

DR. FINS: I really think that this 21(H), what Tom was just talking about, and 21(I), and to a lesser extent (J) and (K) are sort of in the wrong place. They are really not research questions, they are regulatory questions, and it is the good news/bad news part of what Tieraona was talking about before.

If we modify DSHEA, if we put more of an onus, Tom, on the private sector to provide services in compliance with new regulations, then, there has to be some perhaps compensatory mechanism to allow that to happen.

The reason we are sort of saying create a study to do this or that is because we still haven't reached a conclusion about how we are going to regulate supplements and whether they go to OTC or they go to real drugs, so it is part of that overall package.

I think we should perhaps shelve that, no pun intended, and put it all together because it really is the other half of the regulatory piece that Tieraona was talking about.

DR. ORNISH: Part of it is, I mean part of it isn't. The 21(I) clearly could go in the regulatory with

those things which are designed to incentivize research.

DR. FINS: But that is a subset of the same problem. You know, 21(J) can stand there by itself as a generic statement, but that might also be part of the remedy related to the regulatory piece that we were talking about.

DR. ORNISH: There is no reason that it can't be in both places.

DR. JONAS: I think you are right, Joe, I think we need to actually rearrange these categories in all areas to get them a little bit further together, and then we may be able to eliminate and consolidate a number of those.

DR. FINS: But it relates to that regulatory piece. The other thing I just want to say real quickly is I think that it would be immensely helpful. I agree here completely with Jim, that 21(L) is such an important issue.

You will see tomorrow, I think, when we talk about the Access and Delivery piece, that we have begun to try to suggest a way of thinking about access and delivery, and also, to a lesser extent, the Educational

section, that a little bit of a topology about, not necessarily make a recommendation that X percent of the NIH budget should go to CAM, but, how would you begin to dissect the argument for a fixed percentage, a needs-based kind of mechanism, an efficacy-based mechanism, and just begin to think about that so that the next entity that takes that question on will have the benefit of our deliberative process.

We probably can do more right now to make a recommendation, not a fixed recommendation, but just an argument that would be helpful for the next iteration.

DR. GORDON: I am going to agree with Joe and myself again. I think that applies to 21(L) and to 22(C), that there are no people probably on the planet than many of us sitting here who have thought longer and harder about these issues or are likely to for many years, and I think we just ought to give it our best shot.

DR. ORNISH: I think there is some value above and beyond whether we are qualified to make recommendations, I think there is value in having the National Science Foundation and the Institute of Medicine

involved in the process, both in terms of building bridges and in terms of actually ultimately getting more funding in these areas.

DR. JONAS: I guess I am confused, Jim, by what you mean by "give it our best shot."

DR. GORDON: I think we should make our recommendations.

DR. JONAS: In terms of what the priorities are?

DR. GORDON: In terms of what the priorities are or what the criteria for deciding the priorities area.

DR. FINS: Even laying out the argument. I mean it is like what is the argument in favor of fixed number, what is the argument in the context of global budget, what is the argument for more money.

DR. GORDON: Right.

DR. FINS: And just lay out the argument, say, while we have not reached a conclusion that that is how we end up, we think these are issues that the IOM or NSF should consider, but at least we have taken what we know already, and we have put it down on paper, and it is

planting the seed for the next phase of this.

DR. GORDON: Wayne, I remember very clearly when we were working with OAM, you had a very clear scheme and we discussed it at length for prioritization. It seemed perfectly good to me then, it may have to be revised somewhat, but that should be presented.

DR. JONAS: So, you would like that type of thing.

DR. GORDON: Yes, and as far as the sort of frontier science questions, again, several of us in this room have thought a lot about that. I agree with Dean, it is great to have the NSF and the IOM with us, but I think on these issues it is going to take a long time to get -- there has to be a study funded, they have to get involved.

I am happy for that to happen, but we don't need to wait for it. On some of the larger issues, we are very closely allied with them already, and we have indicated those issues.

DR. ORNISH: I think that makes a lot of sense. From the process standpoint, we will take this back to our subcommittee by conference call and see how far we

get with it and come back and report to you.

DR. BRESLER: Dean, you also might want to solicit input from the various Commissioners as to what they think are the critical issues around this, too.

DR. ORNISH: Consider this an open invitation to anyone, and if you have any thoughts in these areas, please e-mail them to us, and we will discuss them at our committee meeting. If any of you have really strong feelings about it and want to participate in the conference call, we would welcome that, too.

MS. POLLEN: May I say something here? It would be better, I think, if you would just e-mail them to me, and then I would just make sure that everybody got them, nothing would fall through the cracks that way.

DR. ORNISH: Great. Is it okay with you if they want to participate in the call verbally?

MS. POLLEN: That's fine.

DR. ORNISH: Great. Moving along, where are we now?

DR. GORDON: 24 on page 11.

DR. FINS: I think it is sort of self-evident and it just doesn't make sense to me. I mean I don't

think it adds anything.

DR. ORNISH: I would agree.

DR. FINS: I would delete it.

DR. ORNISH: How do you feel? Done. 25, any comments on either 25 or its subcategories? These are the last three we have.

DR. FINS: I think 25(A) is critically important, and it is about the utilization piece that has really, as I said earlier, has really gotten buried, so I think AHRQ has a huge role to play here.

It is not just treatments for use by private and public entities, but as well as systems of care and infrastructure and managed care and delivery systems, and those kinds of things. We are going to bring that up again in the access and delivery piece where we talk about demonstration projects, but I think it is a kind of public health research that needs to happen.

DR. GORDON: 25 seems very clear. I don't know if 25 gets lost among 25(A), 25(B), and 25(C) because we are not recommending a method for those systematic reviews to be done, and perhaps we should, because we get specific in the A, B, and C's, and I think maybe we

should either -- it seems to me the most important thing is that those reviews get done, they get translated into language, so that everybody can understand them, that it happen on an ongoing basis.

I am not saying anything different from what you have. I am just trying to think of how to focus a little bit more.

DR. JONAS: Would you like it more specific?

DR. FINS: I think AHRQ has its own method, I mean it's health services research.

DR. GORDON: But it is not just AHRQ. See, that is the thing, AHRQ has done certain systematic reviews, but are we saying that we want all systematic reviews to be done through AHRQ or not? I don't think so. Do we want to encourage NCCAM?

I am just saying that we have a level of specificity in certain areas, but we leave it very vague in the sort of largest area, which is sponsoring the systematic reviews. It doesn't feel quite right to me. I feel like we should be a little more -- either a little more attention to detail with systematic reviews or it should be all part of one recommendation of which the

creation of systematic reviews, and then the translation of those systematic reviews into forms that anybody can understand be done.

That seems to me to be the essence, and then where it is done are the particulars that come afterwards. Does that make sense to people?

DR. JONAS: In other words, not specify where it is done, but recommend that it should be done?

DR. GORDON: Again, it is just a matter of prematurely breaking things up here. We have to make it clear what we want to have happen, and then we can list underneath that a variety of different mechanisms through which it could happen or maybe we have specific as we want it to happen.

MS. POLLEN: May I ask a question? 25(C), does that begin to get to -- in other words, if that were developed a little more?

DR. GORDON: It is not so much that. I am simply saying that it is clear we want systematic -- the overarching points are we want systematic reviews, we want them to be developed perhaps in a variety of different places, and we want all the systematic reviews

regardless of where they are developed to be made available in lay person's language easily, probably through the Central Office, but we haven't said that yet here, but somehow easily available.

DR. ORNISH: So, you would like to collapse all this into one?

DR. GORDON: Yes, exactly.

MS. POLLEN: That is what i was getting at, take that and develop it. Okay.

DR. ORNISH: That's fine.

DR. BRESLER: But to play devil's advocate for a moment, again, it brings up the issue, if we were to get very specific and ask NCCAM or AHRQ to do it, then, they can be mandated to do it, and then it becomes their problem to figure out specifically how to do it.

I am concerned when we throw this stuff in the air and say, well, it would kind of, sort of be a good idea if we kind of had some reviews, of all the priorities that everybody else has, it is going to fall through the cracks. If this is important to us, again, I think we should put some teeth in it and make a specific recommendation.

DR. FINS: I don't think AHRQ is especially well positioned to do health services kind of research that is really needed for the rollout of delivery and infrastructure kinds of issues, so I would like to have them specifically mentioned, but at the same time, I don't want this to be an exclusive mandate for two entities like NCCAM and AHRQ.

So, why don't we just say, such as NCCAM and AHRQ, and other --

MS. POLLEN: Examples.

DR. FINS: As examples, right, but not exclusively.

DR. ORNISH: IOM, Cochrane Collection.

DR. JONAS: But would you agree that the goal is to have a central updated source of the current evidence, clinical evidence on the safety and efficacy of complementary and alternative medicine maintained, produced and maintained?

DR. FINS: But it really goes back to what we talked about in the information section. I think we did a better job sort of flushing out what that would be earlier this morning in David's session than here.

The research folks are not the people generally who translate it into a package that is understandable by the public or media. That is an informatics kind of group or the Library of Science.

DR. JONAS: So, we should pull out things like guidelines, for example, out of this, and this should be really what is the current state of evidence on safety and efficacy, and that is a research role, if you will, or function.

Then, a lot of these other groups then would pull off of that in order to look at the implications, guidelines, et cetera, yes.

DR. GORDON: We have a minute and a half left and then try to make some kind of summary of where we are.

DR. ORNISH: Effie.

DR. CHOW: Systematic reviews of literature, research literature, I hope to go into non-English speaking, as well, and can be translated into English.

DR. JONAS: Should we say the world literature?

DR. CHOW: World literature, yes.

DR. JONAS: Available literature?

DR. CHOW: Well, when you say "world literature," does that mean non-English?

MS. POLLEN: Why don't we just say English and other languages?

DR. CHOW: Well, for example, Chinese medicine, there is a lot, and then in acupuncture, there is a lot of Chinese, but not in English.

DR. BRESLER: How about scientific literature?

DR. CHOW: Scientific, but different language, though.

DR. JONAS: Yes, emphasizing not just making it exclusive to English is what you are saying.

DR. CHOW: Right.

MS. POLLEN: How about English and other --

DR. FINS: Again, I think that is really in the information section, and we discussed it this morning, it is not here, and Medline does translate stuff.

DR. JONAS: So maybe a subtext thing saying that it shouldn't be exclusive to English language or limited to English language, I should say.

DR. GORDON: I am going to need the 15 minutes to present what I believe I have heard and get