background and support for our recommendation the public be empowered and educated and trained, we ought to say something about the fact that doesn't exist very well or inadequately, and actually there is a number of reports, including the IOM report, that specifically addressed this.

We heard testimony in our first session about this from Leon Eisenberg, in which he said -- you know, and there is an IOM report saying that the public should be more involved. So, something along those lines would be --

MS. POLLEN: Something rather than that.

DR. JONAS: Yes, right.

MS. POLLEN: Got it.

DR. GORDON: Wayne, I just think that some of it is kind of a little clunky, those first couple paragraphs, in the way that point is presented.

DR. JONAS: I think Gerri knows what I am talking about.

MS. POLLEN: I know exactly what he says.

DR. ORNISH: So, you will fix it, right?

MS. POLLEN: Yes, I fixed it.

DR. ORNISH: Any other comments, so we can move on?

[No response.]

DR. ORNISH: Page 12, paragraph 9. "The Commission recommends that state professional regulatory boards develop processes that will allow practitioners who have developed scientifically acceptable preliminary data" -- am I in the right place?

DR. JONAS: Eight.

DR. ORNISH: Oh, did I leave 8? Sorry, I stand corrected. Thank you.

DR. JONAS: Watch him, he will slip it under.

[Laughter.]

DR. ORNISH: "The Commission recommends that all federal agencies with research or related health care responsibilities increase CAM activities relevant to their biomedical or health services missions in a more proactive manner including the consideration of special initiatives to ensure that CAM is properly integrated into the health care system."

DR. JONAS: I think the point of this recommendation was that we wanted to say that there needs

to be proactive efforts in all the federal agencies. What we currently have is one federal agency that has a proactive effort in that area.

DR. ORNISH: Do we need to have "The Commission recommends" in each of these sentences. Can we just say -- I mean, start with, for example, "All federal agencies"? It doesn't matter, it just shortens it a little bit.

DR. JONAS: I think we could truncate at "special initiatives" if we wanted to shorten it. I would keep that "special initiatives," however.

DR. ORNISH: Except I would add again "increase CAM activities shown to be safe and effective."

DR. JONAS: This is about establishing safe and effective.

DR. GORDON: I think that is appropriate.

DR. JONAS: Not shown to be safe and effective. This is about doing research.

DR. GORDON: The point is doing research to find out.

DR. ORNISH: I guess it is a question about CAM activities as opposed to -- because this paragraph is

talking about ensuring that CAM is properly integrated into the health care system, which is not a research issue.

DR. GORDON: Right, I agree with you about that.

DR. ORNISH: But you are presuming in here that the research is going to show something positive when, in fact, it may not.

DR. GORDON: Let me suggest that last part be omitted because I think that is not appropriate to have here about the inclusion.

DR. ORNISH: Okay.

MS. POLLEN: To ensure.

DR. ORNISH: No, actually, you would end the sentence after "in a more proactive manner" -- period, and then everything else that follows is out.

DR. GORDON: That is fine.

DR. JONAS: I want to keep "special initiatives."

DR. ORNISH: I don't know what a special initiative is.

DR. GORDON: What is a special initiative?

DR. JONAS: A special initiative is an RFA where they set aside money and say we are going to fund this.

DR. GORDON: Okay. So, maybe that has got to be made clearer.

DR. JONAS: That is about the only way it actually gets done, frankly.

DR. GORDON: Including federally initiated funding.

DR. ORNISH: -- "including the consideration of special initiatives, such as RFAs or RFPs." How about that?

DR. FINS: Or "including special funding initiatives."

DR. JONAS: Yes, I think it could be a lot more than that in this, for example, developing an office at the CDC, that specifically addresses facilitation of CAM research and prevention would be an example of a special initiative. So, it is no limited to RFAs.

MS. POLLEN: I am suggesting that we take the ideas on RFAs, RFPs, and move it to the text, make sure it is in the text.

DR. ORNISH: So, the sentence would end, "including the consideration of special initiatives" -- period, and you can define what that is in the text.

DR. ORNISH: Okay? Anyone object?

DR. PIZZORNO: I am not objection, however, I think this whole section has the wrong title. It says, "Research Support," and I looked through the various topics we are looking at, and I see apples and oranges and bananas, so I think there is some different language that needs to be done here.

When I think of research support, I am thinking about things like funding where here we are talking about research scope and the kinds of research that should be considered, so some different terminology is necessary here.

DR. ORNISH: Charlotte?

SISTER KERR: This is just a clarification. Wayne, when you mentioned the CDC, I just don't know where we have done it in the report, do we have it somewhere under here in terms of funding, because I think that is something that they need money, they have got a department, but where would we do that, or have we done

it?

DR. JONAS: Well, in the text, under No. 4, Expanding -- I think this is maybe what you are asking, Charlotte, but correct me if I am wrong -- under Expanding Areas of Scientific, we actually list a number of mechanisms, as well as agencies that could have special initiatives including the CDC, but there is a number of others in there, so as long as this recommendation gets linked back to that in a specific way, then, I think it is okay, as long as it doesn't get lost.

One could say perhaps, "as described in Section 4." It is right under the same recommendation, Special Initiatives as described in Part 4, which starts on page 8, line 21, and then goes all through the top of page 9, and especially page 9 starting at line 11, in addition to NCCAM. Well, there is only a few of them listed, and actually the CDC isn't in there.

SISTER KERR: This will go back to Jim's request that we will get to 9/11, but if we didn't have 9/11, I would still really want us to be looking at CDC here.

DR. JONAS: I know that it is in here.

SISTER KERR: Really need to be getting big bucks.

DR. ORNISH: We need something on acupuncture and anthrax in here. That would do it.

DR. JONAS: I think we haven't moved off of 8 yet.

DR. ORNISH: So, what are you trying to see, if there is any reference to the CDC in here?

DR. JONAS: That is what I think Charlotte was asking.

DR. ORNISH: Why don't we just make a note that we will check on that, and come back to it, and if there is not, we can add it to the text later, but it wouldn't be a recommendation, so just to keep things moving.

DR. GORDON: Can we have the final reading on No. 8 then?

DR. ORNISH: "The Commission recommends that all federal agencies with research or related health care responsibilities increase CAM activities relevant to their biomedical or health services missions in a more proactive manner including the consideration of special

initiatives" -- period.

In the text, we will define what special initiatives mean.

DR. JONAS: I think we ought to specify this actually under No. 9, where we did talk a little bit about some of the other NIH agencies and National Science Foundation -- page 9, starting at line 11 to 16, we talk about Department of Defense, Department of Energy, National Science Foundation are examples of federal organizations that might consider contributing in these areas.

DR. ORNISH: Just add CDC there.

DR. GORDON: It also seems to me you need to define "special initiatives" in there, in the text, so that people will understand.

DR. ORNISH: We talked about that.

DR. JONAS: The question is what kind of special initiatives do we want to recommend because one of them we mentioned is RFAs, RFPs, this type of thing, but another one would be the development of offices, and I am not sure if that is what you want to say, and, if so, then, we ought to have a paragraph saying we

recommend proactive and special initiatives in federal agencies and, to me, that would then elevate that to a level of a recommendation.

DR. ORNISH: I am not sure that adding special offices at this late date is the way to go, but if it's important to you, we can include it. It is unlikely that they are going to create a special office just from reading this recommendation anyway.

DR. JONAS: Well, the NCI created one. The CDC, as a number of you know, CDC has the strategic plan around complementary and alternative medicine. I don't know, does it include an office?

DR. GORDON: I don't think there is.

DR. JONAS: Probably not, because there is not resources, but if they had resources and a mandate to do an office, they could, and it would be something that could then coordinate all those activities.

DR. GORDON: What about, Wayne, making a recommendation about special -- I mean, I think you may be right -- that we may need a separate recommendation about special offices, either that, or we have to include it here and make it explicit along with RFAs, RFPs, et

cetera.

DR. ORNISH: The easiest way to do it would just be to refer back in the text to what special initiatives include.

DR. JONAS: We could have a paragraph describing special initiatives and examples of what those are like.

DR. ORNISH: Such as a special office in the CDC.

DR. JONAS: And an example of that is the OAM and NCCOM, and Office of Dietary Supplements perhaps in NCI's office.

DR. ORNISH: That's good. Is that okay?

DR. JONAS: Okay, if we did that on page 9 at the end of that.

DR. GORDON: Is everybody following this discussion? Okay.

DR. JONAS: I would then recommend that in this recommendation, that we say "as described in the text, Section blah-blah-blah," or whatever, so that people can see examples of what we are talking about by special initiatives, because apparently that is not clear.

DR. ORNISH: Joe.

DR. PIZZORNO: I would like to have one sentence and it could easily be in the text, and that would be part of the recommendation, but I think that as we are asking federal agencies to increase their research in this area, that they should try to do so in collaboration with CAM, public health professionals, institutions to help them think through the agenda, should not be doing it independently of that input.

So, again, it would part of the recommendation or part of the supporting language.

DR. ORNISH: Recommendation No. 9. The Commission recommends that --

DR. GORDON: I'm sorry, Joe. What happened to Joe's suggestion?

DR. JONAS: We can add that into the text.

DR. GORDON: In the text, okay.

DR. JONAS: We can put that in the text, I agree. I made a note of that.

DR. GORDON: Thank you.

DR. ORNISH: Everybody ready to move on?

Number 9. "The Commission recommends that

state professional regulatory boards develop processes that will allow practitioners who have developed scientifically acceptable preliminary data to move successfully to clinical investigation of a non-approved treatment while maintaining their ethical and professional responsibilities toward their patients and the public."

Joe.

DR. FINS: Yes, a couple problems here. First, this is a hodge-podge of things that have been said. To call something a treatment implies that it works, so I have rewritten this just briefly to something that basically wanted to give protection to the CAM practitioner to pursue research without getting sanctioned by the state medical board.

The suggestion is, "The Commission recommends that state professional regulatory bodies develop processes to allow CAM practitioners to pursue clinical research if their protocols receive IRB approval."

DR. ORNISH: I was going to suggest the same thing.

DR. GORDON: I would not say just CAM

practitioners. I would also say conventional practitioners using CAM modalities.

DR. FINS: Okay. So, CAM practitioners and conventional practitioners using CAM modalities.

DR. ORNISH: Right.

DR. JONAS: Is that substituted then for --

DR. FINS: "The Commission recommends that state professional regulatory boards develop processes to allow CAM practitioners and conventional practitioners using CAM modalities to pursue clinical research if their protocols receive IRB approval."

DR. WARREN: Doesn't that imply that you are part of an institution?

DR. FINS: There are free-standing IRBs, but IRBs have to meet certain federal standards, so this is a way of ensuring buy-in to the human subjects research protections concerns.

DR. JONAS: Go ahead.

DR. LOW DOG: I guess my question is if you got IRB approval, then, why do you need this statement? My understanding of what this -- I am not saying I agree with it -- what I am saying my understanding of this is,

is that for people that think they have got promising data, that haven't gone to get an IRB, but they think they have got some promising finding, that there is trying to be some mechanism for them to go then and present that data without fear of persecution to go get research.

What we are saying here is that, you know, you should not be impeded from doing your research if you have received IRB approval, and if you have already done that, why would you be impeded? I think that they are saying two different things.

DR. FINS: It's a quid pro quo. I want a condition of their not being impeded, that they have actually gone through an IRB, because the only way you can protect the human subject is go through an IRB, not a state medical board.

DR. LOW DOG: I think that if you read the text, that is not what this says, and I am not saying I disagree with you at all, I am just saying that that is not what this says, and that is not what I believe the intent was, and I think part of it was trying to get some practitioners in the field, who may feel that they have

come across something, to come forward to get the research done. I thought that is where this was driving.

DR. ORNISH: The text actually makes reference on line 20 to the need to follow IRB guidelines. This isn't something new. I think what Joe is trying to do is just to make it clear in the recommendation itself, and I agree with that.

DR. FINS: Tieraona, if somebody has already done the research without IRB approval, then, they have violated ethical norms.

DR. LOW DOG: Right. That is what actually is occurring right now, is that a lot of what is going on, because it has not been shown to be therapeutic or effective, much of this is a large experimentation on the population.

Much of what we do in CAM is experimenting upon the public because we don't know if it works or not. I understand what you are saying. I am saying if you take it to its logical conclusion, though, much of what we are doing is a grand experiment without people's consent or permission.

DR. ORNISH: That is what we are trying to

change here. I mean, I think it is really important that we take a balanced approach, otherwise, you can end up with things like, you know, Tuskegee, or, you know, horrible things in the name of CAM.

An IRB, if it's a good IRB, doesn't say you have to prove that something works in order to get IRB approval, because, by definition, how would you know until you do the study.

DR. FINS: Not that it has to work.

DR. ORNISH: It just has to be it is not going to hurt people.

DR. FINS: There has to be adequate informed consent, there has to be adequate safeguards. The person who is providing the intervention has to be appropriately trained, et cetera. I just want to say a CAM training program or a school can have their own IRB. It doesn't have to be in the allopathic arena. But it is the only way to ensure human subject protection.

DR. ORNISH: Joe.

DR. PIZZORNO: I need to better understand what is trying to be accomplished with No. 9, because if you are going to require they go through a standard IRB

process, this is not necessary.

If you are looking for a CAM practitioners is doing something out in the field that they think may have value, expecting them to go through an IRB process is unrealistic. They don't have the training or funding to do something of that nature.

So, what are we trying accomplish in No. 9?

DR. ORNISH: I agree with both what you and Tieraona are saying, that that is not what most CAM practitioners are doing, but that doesn't make a right. They need to do it, and to say they don't have the funding or it's too hard or they are not trained to do it is nonsense.

They need to be held to the same standard, that we all need to be held to. Just because it's CAM doesn't mean it's okay to be unethical.

DR. GORDON: Let me say what I think we are trying to accomplish here. What we have heard in the Commission is a number of people who are interested, who believe they have promising treatments, who have been afraid of prosecution from state medical boards, and who have been prosecuted by state medical boards.

We are trying to provide a mechanism by which those people who do responsible research can have a shield as they do that research. That is the purpose of this recommendation.

DR. ORNISH: Maybe we should say that more explicitly.

Gerri.

MS. POLLEN: The first step, as I understand it, when we were discussing this during meetings on research, is to be able to take data that you think is good data and that meets the requirements or the standards of good data, and somehow or other have a mechanism for submitting that data to a program like the NCI program or even NCCAM looks at preliminary data, so that the data can be evaluated.

DR. JONAS: That is not what the goal of this was.

DR. ORNISH: That is one aspect of it, but that is not the whole thing. They may or may not want to present it to NCCAM or NCI, who may or may not be interested.

MS. POLLEN: I am not saying those are the only

places. That would just be an example.

DR. FINS: The Best Case Series that Jeff White was talking about.

MS. POLLEN: Jeff White, and there were others, as well, right.

DR. LOW DOG: I am still confused. Dean, I think maybe you misinterpreted me. I agree with going to the IRB, I believe that you should have all the appropriate protocols in place.

I am hearing what Joe is also saying, though, it is not explicitly clear, and, Jim, when you say that they have got promising treatments that they don't want to be prosecuted, well, if you went and got an IRB, you wouldn't.

DR. ORNISH: That was a question actually. Are they cases we have heard from where people had IRB approval and still got prosecuted?

DR. GORDON: No. There have been cases that were presented to us where people were not able to get IRB approval for a study -- I think it was a study on qigong, I don't remember which university it was, maybe it was the University of Washington perhaps, it was one

of the major universities where they would not give IRB approval to a study, so the study couldn't go forward.

Let me just add something.

DR. JONAS: It has nothing to do with state regulatory boards.

DR. GORDON: You are asking me different issues. Let me try to explain the variety of different issues.

DR. JONAS: I am all mixed up in this one.

DR. GORDON: I have a question that is embedded in here. I don't know what the obstacles have been to getting IRB approval, and that is something I actually would like to know before we make the recommendation.

I mean, we, for example, have had IRB approval completely, not for work at Georgetown, but outside of Georgetown, just doing research on our own, so it is not impossible to get it.

But the issue that we are really dealing with is those people who believe they have promising data, I do not know -- and it's a good question -- have they tried to get IRBs or not.

If they have tried to get an IRB and they have

been unable to, or somehow been denied it, then, we need to know that, and we need to have another criteria. If they haven't tried, or if it's possible to get an IRB, and that is what relates to Don's question, then, maybe the IRB isn't an appropriate criteria.

DR. FINS: We had this discussion at the very, very beginning, in the very first meeting, I think I mentioned this, and everybody said, you know, there are not differences in the ethics.

Now, I pointed out maybe -- if I recall correctly -- maybe the IRBs needed some education on this issue, so maybe we want to have another recommendation here that IRBs that are in the process of reviewing CAM practitioners' work and conventional practitioners doing CAM studies, should be appropriately constituted to reflect that review process.

So, that would be a parallel recommendation, but I want to just say that if an allopathic practitioner who is out there in the community is doing research, and can't get an IRB approval, they must get an IRB approval.

So, the point is if we are talking about a single standard or research, and a single standard of

ethical adherence, then, what is true for me is true for the CAM practitioner.

DR. ORNISH: So, why don't we just say something like, at the very beginning, the first sentence could read, "CAM and allopathic" -- or CAM and whatever we are calling conventional medicine -- "should be held to the same ethical standard" -- period.

Then, we go into the second part of it. "As part of that, both traditional and CAM researchers need to get IRB approval before investigating new modalities."

The third part could be, "If they get this approval, then, they should be protected from sanction in the same way that conventional medical practitioners are," in other words, it doesn't give you blanket protection, you can still get IRB approval and do something really stupid and hurt people, but it provides you the same level.

Again, it goes into the overarching thing of let's hold things to the same standard.

DR. JONAS: I would like to suggest some wording changes here. I think it would be a good idea if we did have a separate one that addressed IRB, because

that is a different thing than state regulatory boards, and actually, they have very little to do with each other.

The IRB issues are there and that we should make some recommendation encouraging appropriate education, training, representation on IRBs, and then we could leave in here the issue about IRB as being kind of the bottom line standard for everyone, but in that case, then, I would suggest we change "allow" to "encourage," make it positive rather than negative.

So, this recommendation would read -- there would be an additional one on IRBs -- but this recommendation would read: "The Commission recommends that state professional and regulatory boards develop processes that encourage practitioners who have obtained IRB approval for collecting data to move successfully into clinical investigation of non-approved treatments."

DR. FINS: But it's not treatment because it is not a treatment until it has been proven.

DR. JONAS: Okay, just CAM interventions or whatever.

DR. ORNISH: But, Wayne, if somebody has

encouraging data and IRB approval, is the same regulatory board giving them a hard time?

DR. JONAS: As I understood your recommendation, you were going to substitute "obtained IRB approval for this, who have developed scientifically acceptable preliminary data."

DR. FINS: That is not what I said.

DR. JONAS: Okay. I would like to suggest that because I think the issue here is not that you have already preliminary data, because most of these practitioners don't have preliminary data, and they want to do research in order to collect the preliminary data, that requires IRB approval in order to do that.

If it was a requirement that the regulatory boards encourage practitioners who have IRB approval to collect data, if we are to say that practitioners who have developed scientifically acceptable preliminary data, you will have that many who fit into this criteria.

The point of this recommendation was to address the testimony, as Jim said, that we heard that there were claims that the regulatory boards were preventing people from collecting preliminary data.

Now, whether that is accurate or not, I don't know, but that is what we heard.

DR. GORDON: That is their perception.

DR. JONAS: Perception.

DR. ORNISH: Wayne, you are saying that if anybody has data already, that they collected, that they didn't get through an IRB, that they should still be able to present --

DR. JONAS: No, I am suggesting we totally throw out the whole issue of preliminary data, because most all of these people are going to be attempting to collect preliminary data, and they should do that through IRB approval. Then, they can collect the data, and we should encourage the state regulatory boards to develop ways to encourage that and facilitate that process.

DR. PIZZORNO: I really like the direction you are going because I think the word "allow" is wrong. I like using the stronger word "facilitate," and in many ways we are at the pre-IRB process.

I think we need to facilitate the people, if they have an idea, to provide training and funding, so they can go through an IRB process, informally do their

own preliminary gathering of data.

I think really it's the pre-IRB process. People have an idea, they want to do something with it, let's provide them a pathway and assistance for doing it.

DR. JONAS: Maybe we could say, "The Commission recommends that state professional regulatory boards develop processes that encourage practitioners to move successfully into clinical investigation including IRB approval, collection of preliminary data," et cetera.

DR. FINS: State medical boards, those boards don't foster research.

DR. ORNISH: That is not their job.

DR. FINS: They are disciplinary bodies, so it's a different role, and as far as the education is concerned --

DR. JONAS: Do they impede research?

DR. FINS: I think what this is meant to do here is to say that if a CAM practitioner or a conventional practitioner is doing CAM research, and they have got an IRB approval, and they have punched all those tickets, and part of getting IRB approval is having taken a training course and passed an exam before you can

qualify to do an IRB-sanctioned protocol, if you have done all that, and you are collecting research, they can't say that that is an unapproved or it's unprofessional conduct because you have gone through this other regulatory -- that you have opened it up to peer review, you have ensured the adequacy of informed consent, safety, you have demonstrated your own competency to do the study, so there would not be a basis for them to sanction that person.

DR. JONAS: Right. So, eliminate then anything about state professional medical boards.

DR. LOW DOG: I am a little confused still about this recommendation. One, I support that you get IRBs before you do research. The reality is that the preliminary data, scientific data may or may not be there. People just make claims that what they are already doing treats the disease.

I mean, we keep skirting around this issue that we are not treating disease, we are promoting health and wellness, but that is not the reality of much of what is going on in CAM. Much of what is going on is people saying that what they are doing treats this disease or

treats that disease, and is effective at it, and if it has not been shown clinically to be effective, if there is no evidence that it has been effective, then, basically, you are still experimenting with people, and you never got an IRB. So, the reality is much of what is out there is not falling under this.

So, I think it is one thing to say we want to facilitate the process, but the other is to say -- I think this is not strong enough in saying actually this does not exist, and that there needs to be stronger sanctions against people that are claiming to have cures for things that they haven't done research on.

DR. ORNISH: I like that.

DR. GORDON: That is a somewhat different issue. I think that either we have to come to a decision right now -- we have 13 more items, we have 25 minutes, and we need to either refer this back to the group, which is my sense, that there is a lot going on, on many different sides. There are now two recommendations that are possible. I think we don't have much information about what is actually happening with IRBs at the present time.

DR. JONAS: I think that that would be fine to put it back and have us work on this again, realizing there may be two recommendations, but I would like some feedback from you in order to help do that about state medical boards, should that be part of these recommendations at all, or should we eliminate any statements about the state medical boards being involved in this process or any recommendations directed towards them.

MR. CHAPPELL: I am just not seeing why the state medical boards needs to be part of this, because the issue is much broader, so I need an explanation of why they need to be part of it.

DR. FINS: I think we heard from people like Nicholas Gonzalez and others, and other people as well, that they were fearful of even trying to do research because they would be sanctioned for unprofessional conduct.

DR. ORNISH: Even if they had an IRB, you mean?

DR. FINS: No, the idea of linking it to the IRB was an idea that I came up with to somehow shield -- in other words, it was a quid pro quo, if you did this,

you would get protection on the other end, because we just wanted to have them buy into some of the safeguards, so as not only to safeguard themselves, but --

MR. CHAPPELL: Could I make a suggestion that this be limited to regulatory boards, because if I am doing preliminary research, it is not the state that I am concerned about?

DR. JONAS: Do we need a statement then about regulatory boards? Take out professional, take out state?

MR. CHAPPELL: I am saying you drop "state," and just say "professional regulatory boards" or "appropriate regulatory boards," because the state is not the one that is governing my work.

DR. ORNISH: Again, the regulatory boards don't encourage research, they regulate, discipline. That is not their job. It is the wrong organization to do it.

MR. CHAPPELL: That is not true. I just have to say that is not true.

DR. GORDON: Regulatory boards have been discouraging research.

DR. ORNISH: They can discourage it, but they

don't encourage it. You can ask them not to discourage it, but you can't ask a regulatory board to facilitate research. That is not what they do.

MR. CHAPPELL: No matter what I do, I am regulated by the FDA, period, whether I am working on new ground, unknown ground, or known ground.

DR. ORNISH: The FDA may say you can't make a claim on a certain toothpaste, but they are not going to facilitate doing research on what is the best toothpaste to use.

DR. GORDON: I want to ask you guys, what you need to go back and cogitate on this. Do you still need anything, because we need to move on.

DR. JONAS: All I need is whether state regulatory boards should be part of any of these recommendations at all.

DR. PIZZORNO: This is a fascinating discussion because there is this gray area here that seems to be significant in CAM. On the one hand, you have the Textbook of Medicine, or Textbook of Natural Medicine where it says this is how you do it.

Over here you have got this data, which means I

am ready to go for an IRB. In between, there is this gray area that practitioners see by doing something different, they might do a little bit different in one patient, do it a little different in another patient. They start seeing some experiences building up to the point they get to doing an IRB.

Well, those people are seeing things somewhat differently, in particular, we are seeing them do it in CAM, then get nailed by the state disciplinary boards.

So, how do we deal with this gray area in between? I think that is what we are talking about, between standards of practice, Textbook of Medicine, and we are ready for an IRB proposal.

DR. FINS: I think that's a very good point, and it's like when does clinical innovation, when does therapeutic innovation become experimentation, and I think most people would say when you generate a hypothesis, and if you are going to publish it as data.

So, if you are still in the practice of your therapeutic intervention, and you decide, well maybe, you know, two pills are better than one pill, and you are just sort of fiddling around with an established dose or

something, at a certain point you say, well, let me study it formally, when you start wanting to study it formally.

But in the CAM arena, what we might have to say is we have to actually move that line back, and that all practices that are involved in any kind of risk to a human subject, should be construed as should be on protocol.

We do that with chemotherapy. There are things that are historically efficacious, so we don't do a protocol on Didge [ph] anymore, you know, because there is 10 years of history, and maybe we should.

DR. ORNISH: Part of the problem is some of the people who testified said oh, we don't even see how CAM could ever hurt anybody, so there is this presumption that everything is safe, so therefore, it is okay to try anything without having to have a protocol.

DR. FINS: I think this is getting overly complicated.

DR. JONAS: Let's finish with Effie and then we will move back and redo these ourselves, and we will bring them back.

Effie.

DR. CHOW: I think it is complicated, but I think the key issue here is that if the regulatory boards don't understand about research, and is not sympathetic to research, and doesn't support the individual who is practicing and experimenting, to do research and protect them when they come out to do research on a particular methodology, that does add to the problem.

I think that somehow the regulatory boards need to be stated in here, because we are talking about the future, not just immediate.

I just have one general concept, is that a lot of our discussion is now edited by what is happening and what isn't happening, and I would like to bring our vision back that we are envisioning for the future, not just what is possible right now.

I don't know whether I am clear or not, but a lot of discussion is saying what is happening and what isn't, and then we are adjusting our recommendations to what we see as possible right now.

I would like to just expand our vision a bit more.

DR. JONAS: Thank you, Effie.

DR. ORNISH: Let's move on. So, just to be clear, we are going to just go back to our committee and address all of these issues, the issues including are people experimenting on the general public now without IRB approval as part of the norm, the issues about applying the same ethical standards to both conventional and CAM approaches, that both need IRB approval, both need the same protection from sanctions if they have IRB approvals, those issues.

DR. GORDON: And third is are there obstacles to obtaining creating an IRB for some of the CAM research, because that is the crucial factor.

DR. ORNISH: Obstacles unique to CAM.

DR. GORDON: Understood.

DR. FAIR: I don't know the answer to this, maybe somebody does. When you are doing multi-institutional trials, many pharmaceutical firms will have a CRO, a research organization, clinical research organization, and I know in some of those, some institutions, if you get approval by the CRO, which may apply to 10 institutions, you don't need to an IRB.

Does anyone have any more information on that?

DR. GROFT: There is an IRB approval, it's just that it's a common IRB that it goes through one -- it may go through one, but many of the universities will require that it go through theirs also.

DR. FINS: It depends on if there are consortia agreements.

DR. GORDON: We have 13 more recommendations in this section, so can we move ahead. Anyone who would like to participate in this discussion can be in touch with Gerri, right, to get on the participation? So, please do that.

DR. ORNISH: Number 10. "The Commission recommends that the agencies, as appropriate, develop programs to evaluate practice-based data for potential research support, communicate the availability of such initiatives in a proactive manner to CAM and to conventionally-trained practitioners who believe that they have promising data on non-approved treatments and provide training and data collection, protocol development, and ethical guidelines on human subject protection."

Comments?

DR. GORDON: Seems like a good idea.

DR. JONAS: I think I would phrase this much differently. I think that the most effective effort in this area would not necessarily be to develop training programs for practitioners who are too busy actually to collect practice-based data in any case, but to target resources, since this is in Resources section, for research institutions to do that, so that then they could use practice-based research networks and other types of mechanisms that are in place to look at CAM practices in practices.

So, I think the recommendation is slightly off the group that it should be targeted towards. It should be for research institutions that could collect practice-based research data blah-blah-blah.

DR. ORNISH: We won't even talk about whether that practice-based data was generated under an IRB or not.

DR. JONAS: Well, IRB, I mean, if you target it towards those who professionally do research, and that is part of their business, then, they have IRBs as part of the process.

DR. ORNISH: Okay.

Can we live with that? Any comments, questions, concerns?

[No response.]

DR. ORNISH: All right.

Number 11. "The Commission recommends continuing adequate public funding for research on promising and/or frequently used CAM products that would be unlikely to receive a patent, and therefore not likely to attract private research dollars."

My own bias here, of course, would be to say research on -- I mean, it would have to be more than promising really, but I am open to any suggestions.

MR. CHAPPELL: This is where you want the safety and efficacy qualification.

DR. LOW DOG: This may be where you are trying to establish safety for some of these, because of the way DSHEA is written. You don't have to prove safety before they are entered into the marketplace, and so what you may want to do research on is to determine its safety if taken in pregnancy, et cetera.

DR. ORNISH: Yes, I like this the way it is.

DR. JONAS: I actually again think we are missing the boat here in terms of our role as someone that can target things towards federal policy. I think it is highly unlikely, nor is it even probably advisable to suggest that the government be funding safety and efficacy research on non-patentable products, because that is infinite, it's huge, we will never be able to do that. Just look at all the herbs.

DR. GORDON: But that is not in the recommendation, Wayne, we are not talking about safety and efficacy research specifically.

DR. ORNISH: Well, in a way we are, though, I think. That is exactly where we need it.

DR. JONAS: What we are currently doing now, and this is a explicit policy of NCCAM, is that they fund research on publicly used supplements, for example, and herbs, because there is no private money going into it, because you can't get a patent that is going to guarantee your intellectual property on that.

I am suggesting we are missing the boat by suggesting that, because that is a drop in the bucket as to what needs to happen in these areas, and instead, what

we should be doing is addressing the intellectual property and patent laws to facilitate the private sector moving into these areas, and not simply saying the government should be providing more money to do that.

DR. GORDON: Wayne, doesn't that come under the next recommendation?

DR. JONAS: I didn't see patents address in that.

DR. GORDON: The question here -- and I want to try to simplify things because again, we have 10 or 11 recommendations in 10 or 11 minutes --

DR. ORNISH: I know what you are going to say, so let's just --

DR. GORDON: What I would like to do is to go ahead with this recommendation and then amend No. 12 to reflect your concerns.

DR. ORNISH: Can we live with No. 11 as it is written?

DR. PIZZORNO: Why the word "continuing" --

DR. ORNISH: We can say "continuing" or you can say "increasing," because, as Wayne said, there is research that is being done through NCCAM on this very

issue.

DR. GORDON: But it's not adequate.

DR. ORNISH: Why don't we just say "increasing public funding," or just say, "recommend providing adequate public funding," how about that? All right, so "providing adequate public funding."

Number 12. "The Commission recommends that the federal government provide incentives to stimulate private sector investment and research on CAM products and NDA development, and on developing analytical methods for producing better quality CAM products."

If you want, Wayne, we could say, "private sector investment" -- da, da, da -- "such as changes in patent laws" without specifying what those are.

Would you be comfortable with that?

DR. GROFT: Changes in patent law are very difficult, Dean, I don't see that happening.

DR. ORNISH: How about if we leave it the way it is? Wayne, are you comfortable with that the way it is?

DR. JONAS: No, I think that we should say something about patents.

MR. CHAPPELL: I would like to hear, Wayne, what you have in mind, because --

DR. JONAS: I don't know.

MR. CHAPPELL: Then, let me just say that we are dealing with public health when there are 15 herbs being used commonly in this country right now. This is a matter of public risk. I see no point to privatizing the opportunity side of that use.

In fact, I think it is the government's responsibility to weigh in where small companies do not have the dollars to demonstrate safety of these very complicated interactions, and it is precisely the government that should bear the burden of establishing safety of these most commonly used, because it is a matter of already public risk.

DR. ORNISH: So, Tom, what I hear, an unintended consequence I hear you saying is that the large multinational corporations could end up with patents on these products because smaller companies couldn't afford to do those kinds of things.

MR. CHAPPELL: That is one of the implications.

DR. ORNISH: Okay.

DR. LOW DOG: The other side of that, though, is that because of the way that the laws currently are written under DSHEA, it is not just the 15 herbs. I take Wayne's point seriously, that it becomes this endless, I mean, endless, so every new compound that comes out, not just the 20 tops herbs, but every new compound, we are going to have to do research on, and it puts the onus on the government while the companies make the money, so they can put whatever they want out there, and the FDA has to prove it is unsafe.

Now what we are saying is the government has to then do all the research to show -- it's a public health issue, I agree, I think we need more research on it, but I think there needs to be some tweaking of the language here a bit, because I am not sure all the responsibility should fall under the government to do all the research.

DR. ORNISH: What you are really saying is you should look under DSHEA and say that DSHEA should be modified, so that the burden of proof is on the person who is selling the supplement to show it is safe as opposed to the government to show it is no safe.

DR. GORDON: I would like to return to the

recommendation, what do we want to do with this recommendation? Do we need extensive discussion?

MR. CHAPPELL: No, I think other than changing the word "providing," we are there. I think we ought to keep -- I did not want to amend it to include some adjustment to the patent laws, as Wayne was suggesting. I think it is fine the way it is.

There might be incentives that could be made available, the smaller companies, very legitimate --

DR. ORNISH: Just in the interests of time, can we leave it the way it is, or did you want to change it?

MR. CHAPPELL: Yes.

DR. JONAS: I just want to just make a statement, that we are missing. There is an entire section that is completely absent from incentivizing research in the private sector, and that is, what do we do about intellectual property, the problems with intellectual property other than say dump more government money into it.

We currently say to be established as safe and effective, you have to meet certain criteria, and those criteria are set up for drug law, for drug production,

and the current laws, intellectual property laws, allow a huge investment in that.

So, if we are going to hold herbs to the same standard, then, we should something to try to encourage the private sector to do that, or say that they are different and we shouldn't be treated as --

DR. GORDON: Is this an area where we need another recommendation?

MR. CHAPPELL: This is a gap recommendation.

DR. JONAS: And it not be just patent, and I am not saying we know the answers, but I am saying intellectual property issues around these areas need to be address in some way.

MR. CHAPPELL: I am fine with that.

DR. ORNISH: Let me just get some closure on this because we have to move on. Everything that you are saying, Wayne, is a subset of what is here. If you think it needs to be more explicit than what is here, then, we need to go back to our subcommittee and talk about it, but everything you have said is really contained within this, it just doesn't explain it explicitly.

DR. PIZZORNO: I have one solution to

recommend. Back in October, 14 months ago, there was a representative here from a drug company who discussed the methodology they have for protecting the research they were doing on an herbal product.

I don't recall, I didn't fully understand how they were doing it. It might be worthwhile to go back to that October notes and see what the methodology was, because maybe we can facilitate that.

DR. ORNISH: Okay. Why don't we just table this for now, and we will send it back to our committee.

DR. GORDON: Excuse me. You want to table the recommendation or approve this recommendation and make another --

DR. ORNISH: My suggestion is that we approve the recommendation and that we make more explicit in the text the ideas that Wayne is talking about, because they are subsumed within this, unless you prefer to do it a different way.

DR. JONAS: Well, I think we could accept this recommendation as long as it is part of our charge is to develop a recommendation that addresses intellectual property rights and how we can use that to incentivize

private sector investment.

DR. GORDON: Let's move on then. Good.

DR. FINS: There is a law called the Bayh-Dahl Act, which is meant to bring basic science innovation to the marketplace. One of the problems is, is that it is predicated on patents and it is predicated on disclosure of patent methods and dissemination, so I think whatever gets said here has to refer back to Bayh-Dahl.

Also, things could be patented, I mean, to answer Joe's question --

DR. GORDON: Joe, I am going to ask you if you would help them with this. Okay?

DR. ORNISH: Okay. Moving on, No. 13. "The Commission recommends that the federal and private sectors provide support for workshops to discuss research needs for regulatory review and approval of CAM products and devices, as well as for other purposes."

Comments or questions?

[No response.]

DR. ORNISH: Sold.

DR. WARREN: This statement here pretty well correlates with No. 4, that you had earlier in this

section, and you are dealing with supporting conferences or workshops.

DR. ORNISH: You are right, it does, so maybe it's redundant. Why don't we just delete it.

DR. GORDON: It is regarded as redundant?

DR. ORNISH: This is a conference on regulatory review. I think we can delete this myself, but I don't feel strongly about it.

DR. GORDON: So, we can either delete or compress.

DR. ORNISH: Maybe we could cover that in the text.

DR. GORDON: Okay.

DR. ORNISH: Any objections?

[No response.]

DR. ORNISH: Number 14. "The Commission recommends federal and nonprofit support for research on practices that build on lifestyle and self-care, and support for new, innovative and sometimes controversial CAM research in emerging areas of scientific study that might expand our understanding of health and disease, and encourage support for basic research on core question

described in many CAM systems, such as bioenergy."

DR. GORDON: This speaks to my gap recommendation, because I think there are at least two separate thoughts in No. 14. My gap recommendation that relates to it is, "The Commission recommends that a high priority be given to research on complex, multimodality CAM and integrative therapeutic interventions and to research on the individualization of therapeutic interventions."

That seems to me to go with the first half of No. 14, and then there is the second thought, which was separate, I think before on the sort of emerging areas in No. 14.

DR. JONAS: I agree that they are separate ideas. I actually think what you just read is even separate than self-care, and self-care is important enough that we ought to have it --

DR. ORNISH: I agree with Wayne that those can be two separate things, but I kind of like the way they are, just separate them, that's all.

DR. GORDON: You like them together?

DR. ORNISH: No. I mean, we can separate them,

but there is two different things, because I mean, they are separate things. I mean, personally, I like the first part up to the semicolon. When you start talking about support for new, innovative and sometimes controversial, I think that is just a big land mine you want to stay away from, because I mean, either it has got some innovation or it has not, and whether it's controversial, that can be something that's equally whether it's allopathic or not.

DR. JONAS: That is very important. That's where the money is. Well, that's where the excitement is. I mean, that is what the paradigm issue is all about. The ones that are controversial often ignore data, and people argue simply over beliefs.

DR. ORNISH: Well, I am not any stranger to controversy, but I don't think we have to make it explicit in here that just because is something controversial, that it should have a higher priority.

DR. JONAS: Yours isn't nearly controversial enough.

DR. FINS: Simply by saying it is not going to make it happen. It is really establishing a structure

that can review it. This is like a throwaway recommendation.

DR. ORNISH: It is.

DR. GORDON: Which is, Joe?

DR. FINS: The second part of 14.

DR. ORNISH: The second part of it especially.

DR. GORDON: The second part or the first part?

DR. FINS: The second part. If you have an entity that has a funding opportunity, and they are in a process to review new proposals, that is productive, but to say we should fund as an idea, you know, bioenergy, decontextualized from an NCCAM or some substantive thing, it is not going to play.

DR. ORNISH: It raises questions about our bias, that's all. That is what I mean, because it raises those questions.

DR. GORDON: Is there a later recommendation on frontier science here, or that is it?

MS. POLLEN: The text at the bottom of page 8 and 9, the first half of the first paragraph on 9, the text, I think gets to this issue.

DR. GORDON: But not the recommendation. Joe,

I would argue the other way. I think it is important to emphasize. We may have made it too specific here, but I think it is important to emphasize frontier science and some of those core questions.

This is one of the areas that, you know, we can really make a difference by making that kind of statement. We are saying research on it, we are not saying you should believe in it. We are saying this is an important area to study, and this is an area also that is implicit, if not explicit, in virtually every traditional system of healing.

So, I think it is important for us to approach it. I am not sure the wording here is actually really strong enough or comprehensive enough, Wayne, to really say what we are talking about.

DR. JONAS: Right, I agree. I think the issue is frontier sciences and the emphasis, that we encourage that or we would like to see more -- not encourage frontier medicine, but we encourage research in the area of frontier sciences, and focusing it just on bioenergy is probably too narrow, and that needs to be expanded.

I do think that should be -- we essentially

have within this one, this could be split up if we include what you mentioned, what you read, three potential recommendations.

DR. GORDON: What do you want to do with that, how do you want to handle it?

DR. ORNISH: Why don't we just say Recommendation 14 would be until the semicolon, Recommendation 15 could be, "The Commission recommends support for new and innovative" -- I would leave out "sometimes controversial" -- "The Commission recommends support for new and innovative CAM research and emerging frontier areas of scientific study that might expand our understanding of health and disease, and encourage support for basic research on core questions in these areas."

DR. GORDON: I think we have to give some examples because otherwise people won't know what we are talking about.

DR. ORNISH: It's in the text, so we are just referring back to the text. There are lots of examples in the text.

DR. GORDON: Okay. Do you want me to read my

recommendation now, since it goes with these, or do you want to wait until the end?

DR. ORNISH: Go ahead.

DR. GORDON: The recommendation that I made again is, "The Commission recommends that a high priority be given to research on complex, multimodality CAM and integrative therapeutic interventions, and to research on the individualization of therapeutic interventions."

DR. ORNISH: I don't know what that means, but it sounds good.

DR. GORDON: Do you want me to explain? It means like the Ornish program, for whom it works and for whom, those few for whom it doesn't work.

DR. JONAS: Except for the complex side.

DR. ORNISH: I am just a simple guy.

DR. PIZZORNO: I really like Jim's recommendation because this is what we are actually doing. We are using complex multiple therapies that we individualize to particular patients, and nobody studies what we actually do. Let's state what we actually do.

DR. GORDON: Gerri, I can hand you this.

DR. ORNISH: As chair, you get the prerogative.

I might as well agree with you.

DR. FINS: It's just very high on jargon, the way it reads. One man's jargon is another man's idiom, you know.

DR. GORDON: I will accept any de-jargonifying.

DR. JONAS: Examples would help, and we can put some of those in.

DR. ORNISH: When you combine five-syllable words with seven-line sentences, it is dangerous.

DR. GORDON: If we have consensus, can we move on to No. 15, the actual No. 15 in the text?

DR. ORNISH: Which will be No. 16 now.

DR. GORDON: It will be No. 17.

DR. JONAS: "The Commission recommends that NCCAM conduct a review assisted by the National Science Foundation, the Institute of Medicine, the World Health Organization, or other federal and non-federal bodies on methods to study, in a credible manner, emerging areas of scientific investigation associated with CAM."

DR. PIZZORNO: Isn't this the same as No. 4?

DR. GORDON: Is it the same as No. 4 or the same as the second part of 14? To me, this seems like

the frontier science recommendation, just worded slightly differently, or do you mean something else?

DR. JONAS: It depends what you mean by "emerging."

DR. ORNISH: My short recommendation here is just accept it as it is, because it is going to provide a lot of credibility for mainstream readers who read that. The fact that we have just mentioned these organizations will make them feel better. So, I think it is worth putting it in there.

[Laughter.]

DR. ORNISH: You think I am joking, but I am not.

DR. JONAS: Well, in that case, we should just fill the whole thing full of that. What confused me on this was the term "emerging." I mean, if we need frontier medicine in these areas, then, do away with the above, merge it with the below, but define what "emerging" means.

DR. ORNISH: We will accept the recommendation to do away with the above and merge with the below.

DR. JONAS: I mean, is that what this is

focused on? It is also focused more on methodology, right? Is it on methods of frontier areas?

DR. ORNISH: What they are trying to say here is that there are new, emerging areas of scientific investigation like energy medicine, and they may require the very thing that you are talking about, which is new methodologies, and as a way of trying to ground this, so it doesn't sound so airy fairy to say let's have some conventional organizations help us develop these new methodologies to avoid the criticism that I hear all the time, that people say oh, CAM wants to develop its own methodologies that are inferior, because they can't stand up to the scrutiny of -- you know, there is good science and bad science, and it doesn't matter what you are studying.

DR. JONAS: Thank you, Dean, I understand it. No, I do, I am serious. That was very clear. I actually recommended this, but now that you have explained it to me, I understand it. I agree.

DR. FAIR: I like the term "emerging" because it also applies to new applications.

DR. JONAS: Excuse me?

DR. FAIR: I like the term "emerging" because it also applies to new applications of old drugs. Joe mentioned we are not studying things like digitalis, but there are a number of studies now on Coumadin, warfarin, it has been around for years, and now it turns out it has some anti-metastatic properties, so it is being used in patients with cancer to try to stop the tumor from metastasizing, and no one would have thought of that in the 25 years it has been used.

DR. GORDON: We have six minutes and six recommendations.

Are we okay with this? Yes? Okay.

DR. ORNISH: All opposed say no or forever hold your peace.

Number 16, please.

DR. JONAS: Number 16. "The Commission recommends providing increased public and private resources to strengthen the CAM research infrastructure at strategically located conventional, medical, and CAM sites, to expand the corps of researchers knowledgeable about CAM who have received rigorous research training in basic clinical and health services research."

I think we could probably reword that and still get the essence of it.

DR. ORNISH: Is everybody okay with it? Anybody opposed?

[No response.]

DR. ORNISH: Great, No. 17.

DR. JONAS: "The Commission recommends strong support for enhanced research training by all federal agencies with research and training program and responsibilities that encompass CAM-related questions."

DR. GORDON: So, these two we may be able to condense, as well, as we move ahead.

DR. ORNISH: It is hard to argue with those.

Number 18.

DR. JONAS: "The Commission recommends utilizing existing resources, such as NCCAM-supported centers and the National Center for Research Resources, general clinical research centers to increase opportunities to conduct clinical research and training on CAM and examine the integration of CAM into the clinical setting."

DR. ORNISH: Okay? Okay.

Number 19.

DR. JONAS: "The Commission recommends continued strong support for career development awards that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards to provide the time required to mentor new CAM investigators."

DR. ORNISH: The only thing I would add is something to even just highlight what may seem redundant, which is so that they can be strong scientific researchers, something like that.

DR. JONAS: There is support, it is debatable how strong it is.

DR. ORNISH: Let's just delete the word "continued."

DR. JONAS: Maybe not strong, just continued support. It is ongoing.

DR. ORNISH: All right.

DR. JONAS: Bill.

DR. FAIR: What happened to the SPORE?

MS. POLLEN: It's in there. It is in the text. It's on page 10, first paragraph. On Methodology and

Design, the Commission notes. It starts obviously the page before, but if you get down to the specialized awards, it isn't the only one, exploratory grants and center core grants, they all encourage interdisciplinary research approaches, including SPORE.

DR. ORNISH: Number 20 is too long to read, but does anybody have any recommendations on it?

DR. WARREN: I have a question as to what you really meant there. I want an explanation of 20.

DR. ORNISH: Of which one, 19 or 20?

DR. WARREN: Twenty. That is the one we are on, isn't it?

DR. ORNISH: Then, you are going to make me read it.

DR. WARREN: I thought you said it was too long to read.

DR. ORNISH: That's the problem.

DR. WARREN: Go for it.

DR. ORNISH: Well, they are basically saying that somebody should create an evidence-based database, so that people can access and get to see what is the level of evidence for any particular CAM modality,

preferably be available on the Internet.

DR. GORDON: I feel we have to recommend strongly that it be public funding. I don't think we should wait for somebody to do it. We can say this should be publicly funded.

DR. ORNISH: If you put public and private, that doesn't take anything away from it.

DR. GORDON: I understand, but we are in no position to do anything with private. We are in a position to recommend either legislation or administrative change.

I think this is one of those areas where we can make a fairly pointed recommendation. If we talk about private resources, it becomes more diffuse.

DR. ORNISH: We could do that although we have talked about private things throughout this whole document.

DR. GORDON: I'm sorry?

DR. ORNISH: We have talked about private support throughout this whole document.

DR. GORDON: I understand.

DR. LOW DOG: You have got already people doing

this. You have got Cochrane, and you have got AHRQ, I mean, so you already have people doing systematic reviews and some doing actually a lot.

I think that you want to do public and private, because there is already a lot of this being done.

DR. GORDON: I am saying there should be public funds made available to do this is what I am suggesting.

DR. LOW DOG: Doesn't it say public and private resources?

DR. ORNISH: It does.

DR. GORDON: I think the tendency is to say we will let -- what we have heard from people in the private sector is it is happening, it is happening somewhat slowly and very incompletely, and what they are saying is we don't have the money to do it.

DR. JONAS: It is also not authoritative if it's generally done by private --

DR. GORDON: Unless there is significant government effort to do this, it is not going to happen. That is my concern.

MR. CHAPPELL: The consumers will tell you their primary concerns are that they need an education on

what these modalities are for, and then they need to know they are safe.

I would say right now safety is the even greater of the two questions, and since that is the prevailing number one concern among probably the 20 percent of the population that are using these, I would agree with Jim that it does bear a burden, you know, we ought to put the burden of support of research on the government, because it's a matter of great public safety.

DR. WARREN: Can we leave off the second sentence in that recommendation? That is just an explanatory sentence anyway.

DR. JONAS: Put it in the text.

DR. ORNISH: That's a good idea.

DR. GORDON: I didn't understand that.

DR. ORNISH: Take the second sentence and put it in the text.

DR. GORDON: Okay.

DR. ORNISH: So we delete the word "private"?

MR. CHAPPELL: I am not sure you need to delete the word "private," you need to make the case for the public first, and no need to delete the private. I don't

think you need to delete the private, do you, Jim?

DR. GORDON: I just think that the federal government, either itself or through contracting with private entities, however you want to say it, do this. All I am saying is we need to focus on federal money being used to do this, not necessarily the government is doing it itself, but contracting out.

DR. ORNISH: So, in summary, you want to take the words "and private" out, and leave the first sentence the way it is?

DR. GORDON: Yes.

DR. ORNISH: I don't have any strong objection to that.

DR. PIZZORNO: Can we wipe out the second sentence just for brevity?

DR. ORNISH: We are going to put it in the text. You weren't listening.

[Laughter.]

DR. ORNISH: Twenty-one. Any comments or questions? You hurt our feelings so badly, you are going to have to read it yourself.

In a way, 21 is really a subset of 20, isn't

it?

DR. GORDON: Right, exactly.

DR. ORNISH: I think we could just put that in the text.

DR. JONAS: Actually, they are all a subset of 22.

DR. ORNISH: Yes. Let's combine --

DR. GORDON: Combine 21, 22, and 23?

DR. ORNISH: There is no 23.

DR. GORDON: Oh, 20, 21, and 22, sorry.

DR. JONAS: Charlotte, there is a book sitting on the corner of the desk there, would you hold it up, please? This is what I think we should try to get done. I think if there is one thing that we get done out of this entire section here, if the federal government -- and I agree the federal government should be doing this because actually the federal government is supporting that one in England -- were to produce an ongoing publication like this one is, it is periodically updated, it is current state-of-the-art evidence for safety and efficacy from the clinical research in CAM, this would go a long way towards facilitating the whole process of CAM

use, regulation, research, et cetera.

They do include CAM someplace, the criteria are there, the methods to do it are there.

DR. GORDON: Wayne, can you and Dean come back to us with something that summarizes those three, with Gerri, those three?

DR. JONAS: We can. I mean, these aren't all completely redundant, for example, because what AHRQ is doing is much more expanded than that book or even than what Cochrane does, so they are different, and they cost a lot more.

DR. GORDON: Understood.

DR. JONAS: So, they are not all exactly redundant, but they are all subsections basically of ongoing summaries.

DR. GORDON: Why don't we leave them and then let you all, if you feel they can be condensed and reordered, please do them. Is that okay with everyone? Basically, we are leaving these, and we are allowing some condensation and reordering with the clear notion that these three recommendations, as they are, are the ones we want.

DR. ORNISH: Thank you. I couldn't have said it better myself.

DR. TIAN: The Commission recommends who should do the summary report?

DR. ORNISH: You mean?

DR. TIAN: Number 22.

DR. JONAS: Number 22? The federal government.

DR. ORNISH: The federal government is what they are advocating.

DR. TIAN: Can we put the federal government --

DR. ORNISH: We are going to consolidate.

DR. GORDON: The federal government fund the summary report.

DR. JONAS: Right.

DR. ORNISH: Thank you all. This has been a real pleasure.

DR. GORDON: Thank you, guys. You did great.

[Applause.]

Session Summary

DR. GORDON: I am sure everybody remembers everything that transpired in the last two hours, so I hardly need to go over it.

For the most part, the recommendations were accepted as amended. There is a Recommendation No. 9 regarding IRBs, protection for clinicians who want to do research, and professional regulatory boards was referred back to the committee to work on, so anyone who wants to work on that with them, please do so.

Also, the discussion of intellectual property is one that the committee is going to take up again.

Recommendation No. 23 is very much related to Recommendation No. 4, and is either going to be folded in or deleted. Gap Recommendation Nos. 14 and 15 were split, and the gap recommendation was relating to complex interventions and individualization was also put in there.

The last series of recommendations, it is clear that there needs to be federal funding for some of these efforts to bring together research and make that research available to the public.

Thank you again. Let's break until 3:20. Well, to be fair, 3:23, and then we will come back and are going to be moving into Wellness.

[Recess.]

Session IV: CAM in Wellness and Prevention

DR. ORNISH: You all know how much I hate being late, so let's get started.

[Laughter.]

DR. ORNISH: Why don't we take the same format that we did with our last one, which is we will go through the recommendations, and if anyone has any questions or comments about the recommendations or the text that elaborates on them, speak now or forever hold your peace.

The first recommendation is on page 4 in Tab 8. "The Commission recommends" -- you will notice these recommendations are shorter, that is the first thing -- "The Commission recommends that DHHS review the 10 leading health indicators and, where appropriate, develop strategies to encourage the use of safe and effective CAM principles and practices in these areas."

Comments, questions? Bill.

DR. FAIR: Two comments. First, I couldn't believe that hypertension wasn't among the 10 leading health indicators. The second thing was, as I mentioned, I was very disappointed not to see --

DR. ORNISH: I think hypertension was No. 11.

DR. FAIR: You mean it is better than environment quality? I don't know.

At any rate, I was very disappointed not to see as our No. 1 recommendation, actually the lifestyle modifications as part of an educational program from grades K through 12.

Certainly, we talked about lifestyle modifications in the elderly and the dying, which is a very short-term problem, and I think there is little better we could do for children than to start teaching them as soon as they got to school the lifestyle changes that would be beneficial for them.

They are not getting it from their peers, they are not getting it from their families, attested to by these figures.

MS. AXELROD: Bill, can I just interrupt you just for a point of clarification? One of the things that we changed in this go-around was we switched what was previously No. 1 and No. 2, so you will find the recommendations that address children under the second issue.

We put this one first because it is kind of even broader than that. It is really, you know, the recommendation that applied to the whole country, to all populations. So I think some of your concerns may be addressed in the second one.

DR. FAIR: I have read all of them, I can't find it.

DR. GORDON: There is no specific recommendation on schoolchildren.

MS. AXELROD: There is a reason for that and perhaps when we get to No. 2, we can elaborate on that because we had quite a bit of discussion on that.

DR. FAIR: You mean Recommendation No. 2?

MS. AXELROD: I mean, Issue No. 2.

DR. FAIR: Are you going to wait for that? I mean, you do say "where appropriate, CAM practices." I guess I would ask the question, where is it not appropriate?

DR. LOW DOG: When you look at Healthy People 2010, reducing vehicular deaths, that is not a lot to do with CAM. So, I think "where appropriate," is appropriate when you are referring to the top leading

health indicators, and also where you are talking about the preventive strategies for different things that are listed in 2010. I think "where appropriate" is okay.

DR. GORDON: Can we stay focused on one recommendation at a time?

DR. LOW DOG: That is where we are. We are on Recommendation 1.

DR. GORDON: You're are on Recommendation --

DR. ORNISH: No. 1.

DR. GORDON: I'm sorry. I thought you were on Recommendation 3.

DR. LOW DOG: No. I am right where I am supposed to be.

I am glad that we added the specifics, Corinne, in the text, but my comment still remains what it was, that I think we want to be careful not to co-opt a lot of the preventive strategies that have been done through the CDC community prevention, the prevention guidelines.

There has been an awful lot of work that really has not come out of complementary and alternative medicine practice. We have a lot to offer, but a lot of this has not come through the work that we have done.

DR. ORNISH: But, Tieraona, don't you think that by saying "where appropriate," this is an augmentation to that?

DR. LOW DOG: I am talking about the text, the supporting text for that. It is the tone, the general tone still, and I think it is better than it was, I think it is not there yet.

DR. ORNISH: So, would you like it to make more reference to Healthy People 2010, and so on?

DR. LOW DOG: I just think that we have had a tendency to neglect the down sides of CAM and to then co-opt everything that is good, even in conventional medicine, and then use it under the rubric of CAM.

DR. GORDON: Where in the text, Tieraona?

DR. LOW DOG: It's all throughout.

DR. GORDON: But is it there under Issue 1?

DR. LOW DOG: It's under the introduction including. We still talk about that preventing heart disease, cancer, stroke, others, yet, there has only been limited success in reducing the occurrence of these conditions.

DR. GORDON: Where are you reading from?

DR. LOW DOG: Page 1.

DR. ORNISH: Look at page 3, line 75, because the intention there is to acknowledge Healthy People 2010 and to say, in line 87, how CAM principles and practices are consistent with two of their overarching goals, and then it goes on to talk about that.

The intention of these was to not co-opt it, but to augment it, to say that CAM can add something to the important work that they have already done. Now, if that didn't come through, we need to change it, but that was the intention.

DR. GORDON: I would also like to offer another general perspective here. My own work in working in schools is that in spite of everything, certainly in the D.C. schools, in spite of everything that the Healthy People 2000, 2010, the Surgeon General has said, none of these things are happening or virtually none are happening in the schools here where I live.

From my point of view, one of the opportunities we have is precisely because we are coming at it from another place with a fresh kind of energy and a fresh crew of people who are available, that we may be able to

have an influence in a kind of synergistic way.

The Surgeon General has been saying many, many things, the President's Council on Physical Fitness, Healthy People, but it is just not happening most places.

So, I think we can contribute and we can help to move things ahead without saying that we are the only people who are talking about it.

DR. ORNISH: Okay? Can we move on or you seem like you are still not satisfied?

DR. LOW DOG: I sent you comments, and I am glad that we beefed it up with some of the examples, I mean, I came up with a lot of the examples, because I do think CAM has a role to play here.

It is just that there is still this feeling, one, that CAM can prevent illness, and I think you have to be specific, what are you talking about. When we talk about CAM nutrition, that is also one for me. It is like, well, is that the Atkins Diet, or is it the Right for your Blood Type, I mean, what is CAM nutrition? I don't even know what that is.

MS. AXELROD: It might be helpful if we just add an introduction, you know, to introduce the whole

concept of some balance in this subject.

DR. ORNISH: Why don't we just use what we were talking about before -- Bill, could you turn your mike off -- is to talk about in the case of nutrition or CAM modalities that are proven to be safe and effective. We don't have to get into identifying which ones are and which ones aren't, but certainly that is the overarching theme.

I have had a problem all along with the whole idea of this chapter, you know, that, to me, what is wise wellness part of CAM, you know, some of these things are to me not really CAM anyway, and yet here we are with this section, so now having made the decision that we are going to talk about wellness, self-care, and prevention, I think it does a reasonably good job of that, but we can always make it better.

DR. FAIR: Now, can I put my light on, Dean?

DR. ORNISH: I'm sorry, Bill. Yes, now you can turn your light on.

DR. FAIR: I think we are being a bunch of wimps if we don't come out and make that comment that we need to have education. In schools, fire drills are

mandatory. Even some schools had to put condoms on are mandatory. This is just so reduced here.

I know you said you were going to add something, but I 8-fold increase in incidence of diabetes in 30-year-old among minorities, is an absolutely staggering statistic, and it just means that we are not doing anything --

DR. ORNISH: Bill, look at Recommendations 3 and 4. I think part of the confusion is that they flipped those two, and so they are under that. Now, we will get to those in a moment, and we may want to expand them in the ways that you are talking about it, but that is where those ended up.

DR. FAIR: "Where appropriate," I mean, to me means where the school board is not getting money from McDonald's to put McDonald's in the cafeteria.

DR. ORNISH: What I am just suggesting is, can we stay with Recommendation No. 1, and then defer your comments until we get to Recommendation 3, which is really where they are.

DR. FAIR: I think it will be one, that is what I am saying. I think we ought to come right out and take

a strong stand on it.

DR. ORNISH: It is not a question of priority, it is just a question of what is in that section, that's all.

DR. GORDON: Although let me say that if there are strong feeling about priorities, it is fine to put those out there now, and we will sort of take them into account as we look at prioritizing.

I am not trying to interrupt with your order, Dean.

DR. ORNISH: I am just saying, just so we can get through, let's do No. 1, then No. 2, and then we will do No. 3. If we decide that No. 3 should be put up at the very beginning, we can do that, but let's just, for the sake of discussion, let's try to focus on one issue at a time.

With Recommendation 1, Tom?

MR. CHAPPELL: I think we are missing an opportunity by not being more explicit about CAM principles and practices in No. 1. We have been very explicit about the 10 health indicators, and we are being very general about the usefulness of CAM.

So, I actually think this should be built up quite a bit to be more specific if we can. I mean, I know we can.

DR. ORNISH: Here again, in the text, we do give specific examples, and we want the recommendations to be broad, they are under the overarching theme, the things that are safe and effective, and we do give some specific examples.

MR. CHAPPELL: I have seen those in the text. Is that as far as we want to go?

DR. ORNISH: They are just examples, they are not the only places that CAM has been found to be useful, but again, in the interests of space, we are just trying to give a general principle here.

MR. CHAPPELL: I guess I don't, and this is one case where I don't think reducing it is helpful. I think it ought to be built up with more --

DR. ORNISH: What would you like to include in here, specifically? What is missing here?

MR. CHAPPELL: Well, specifically, I would like to see those items mentioned in the text brought into the recommendation, and I would like to see CAM practices

that are relevant beyond what is mentioned in the text enumerated.

DR. ORNISH: With the first part, we have made a decision not to put the specific things in there because once you start giving specific examples, then, by exclusion, you are eliminating many, many more. We already made the decision even before this section, to put the principle as the recommendation, and give the specific examples in the text.

So, I am not really interested in deviating from that unless there is a really compelling reason to do so.

MR. CHAPPELL: If you read the recommendation, do you get a full sense of what is being said, Dean?

DR. ORNISH: Well, I don't think you get a full sense in any recommendation, otherwise, we wouldn't have text, but the principle that --

MR. CHAPPELL: I don't agree with that, Dean, not everyone is going to read the text, they are going to read the recommendations, and especially when we reorient this to the kind of rationalization that has been suggested by Steve earlier, this is going to be showing

just as a separate bullet point, and I think it needs to be built up with specifics and action steps.

DR. ORNISH: Why this and not the other examples?

MR. CHAPPELL: I can't answer that, I am focused on the topic at hand right now.

DR. GORDON: Tom, there are two questions. One is what would you like to say, and then if this recommendation doesn't lend itself to that kind of strength, we may want, as Bill is suggesting, to move it back down in the order.

I am hearing from both of you that you want stronger and more specific recommendations, but we need to hear what they are.

MR. CHAPPELL: I guess I need to ask for help from the committee who has done the work. We could lift out the specific references to massage therapy, meditation, Tai Chi, of nutrition. I am just trying to direct us to have more influence, to be more helpful when we come up with a recommendation than this does.

I think we use CAM practices and principles often, and I think this is one case, because you have

enumerated the 10 leading health indicators.

DR. ORNISH: The 10 leading health indicators are in text, they are in the footnote. In the last two hours we spent the whole time going through and shortening recommendations by eliminating the specific examples and referring people back to the text, so it is just puzzling to me why this has suddenly become such an important issue.

MR. CHAPPELL: Because I think this is so dilute. I think this is going to be glossed over as it is presently written. I am just trying to be helpful, gentlemen, I am not trying to be difficult.

DR. ORNISH: Nobody has a greater interest in lifestyle and health than I do, it is very dear to my heart.

MR. CHAPPELL: Okay. Then, let's put some punch into it, let's say what we want to say.

DR. ORNISH: I think it does say what I want it to say.

MR. CHAPPELL: But it's euphemistically described as effective CAM principles and practices.

DR. ORNISH: It talks about safe and effective

CAM principles and practices. We have spent earlier in this thing --

MR. CHAPPELL: Then, let's be specific about what they are as they relate to the 10 health indicators.

DR. ORNISH: We could broaden the text.

DR. GORDON: You mean give examples?

MR. CHAPPELL: Yes.

DR. ORNISH: We can give examples in the text and broaden that, and I am certainly very familiar with that literature.

MR. CHAPPELL: I am sure you are.

DR. ORNISH: But I don't think it belongs in the recommendations.

DR. GORDON: I would say, Tom, that the 10 -- and this relates to Bill's point -- I don't think the 10 health indicators are the best place to get more specific. If I were getting more specific, I would talk in terms of wellness programs, whether in the school or for the elderly, or in the federal government, this is so diffuse because as Tieraona is saying, what does it have to do with car accidents, it just gets to be too complex.

I think that we should get -- what I am hearing