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WHITE HOUSE COMMISSION
on
COMPLEMENTARY and ALTERNATIVE MEDICINE POLICY

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Draft Interim Report

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Volume I

+ + +

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P R O C E E D I N G S

[10:10 a.m.]

DR. GORDON: Good morning, everybody. I am Jim Gordon, and I am the Chair of the White House Commission on Complementary and Alternative Medicine Policy, and we are here. Before we begin I would like for us all to just sit for a moment quietly and collect ourselves, and be present with ourselves and with each other in this room.

[Moment of silence observed.]

DR. GORDON: I would like to say a few words to begin this session in these intimate surroundings and then Steve Groft, who is the Executive Director, will say a few words. Then, Peter Reinecke, who is the Legislative Director for Senator Tom Harkin, has a few things he wants to share with us, as well.

This session is different from other sessions that we have had. We have been listening over the last 10 months to a number of people, approximately 1,000 people have testified to the Commission here in Washington, D.C., and at town hall meetings around the country, and we have received about 2,000 written

submissions with recommendations, some of them extremely detailed.

We are now in a phase where we are pulling together what we have heard, the questions we have asked, the answers we have received, and we are in a place at this meeting where we are beginning to formulate our general perspective and recommendations both for the Interim Report and also in preparation for our Final Report.

The Interim Report is due July 15th and we will be taking that up tomorrow. Tomorrow afternoon, we are going to have a discussion on the draft of the Interim Report, and there will be an opportunity then for all of us to go over what we have written collectively and to make suggestions, comments, additions, ask questions, and to generally shape that Interim Report.

The work between now and then will be to go over the material that the staff has put so much energy and time and so skillfully assembled, that covers all of the issues or many of the major issues I should say that we have heard testimony about over the last 10 months.

That work will also help us think through what

the Interim Report is going to look like. So, in a sense, we are going to be focusing on the biggest picture over the next day and a half. That will, in turn, help us be clearer about what we are going to present in the Interim Report.

I wanted to say a couple of words, first, to thank the staff publicly for the extraordinary work that the staff has done in pulling together testimony really from 2,000 people, oral and written testimony, and digesting it into the form that we have it in our briefing books is really a labor of love, as well as intelligence.

I also wanted to thank each of the Commissioners for having responded to the staff. The staff interviewed all of the Commissioners since the last meeting about their thoughts about the various different issues that we are addressing in the Final Report and that we have been addressing as the Commission, and I wanted to thank all of you who responded, all the Commissioners, for extremely thoughtful and comprehensive responses to those questions that were asked.

So, I feel like we are really working together.

There is a continual dialogue going on among all of us, and the work of this next day and a half is to further and to deepen that dialogue about the broadest perspective that we are going to be taking in the Final Report and also about the Interim Report.

The structure of the meeting is going to be somewhat different this time, as well. A number of you commissioners, what we are going to be doing is addressing the four areas with which the Commission was charged with examining: research; public information; professional education; and licensing and credentialing; reimbursement, those areas we will be looking at.

Each of the commissioners, or a number of different commissioners, will be serving as facilitators for those discussions that will be going on. Then at the end of the discussion, I will be summarizing what I have heard during the discussion, what I have heard from all of you.

What I would like us to be thinking through and focusing on, since we don't have to be making specific recommendations for the Final Report in this meeting, I would like us to focus on what, are the areas that are

particularly challenging, that are particularly difficult, where we have unresolved questions, areas where we may need further discussion and/or further information, and I think that that is what is really important, for each of us to take a look at as we enter those discussions.

I would ask those people who are facilitating to help focus us. We only have about an hour for each of the discussions that we are going to be having over the next day and a half, so I think it is important for each of us to really be thoughtful, to make sure our comments are really advancing our understanding of the issues and moving us in the direction of getting the additional information or perspectives that we need.

So, the facilitators need to help and really all of us need to help as we move ahead in that direction.

Then, tomorrow afternoon, Steve and I will facilitate the discussion of the Interim Report. What we hope to do with the Interim Report is to take the information, the advice, the concerns and considerations that are given in that hour and a half to reshape the

Interim Report and get it back to everyone within the next few days, and then if there are any additional comments, we want to hear those comments as soon as possible, so that we can then submit the report to Secretary Thompson on Monday, July 16th. The report is due the 15th. The 15th is a Sunday, so we will be submitting it on Monday.

Are there any questions at this point or, Steve, do you want to clarify any of the other administrative issues, and then we can have some questions if there are any, and then Peter Reinecke will be saying a few words.

DR. GROFT: Thank you very much, Jim, and I would like to welcome everyone who has taken the time to join us today. I know several of you traveled through some very stormy weather getting here, so thank you. I hope the audience is somewhat comfortable back there. These meetings do not lend themselves to comfort for everyone, so we will try to make you as comfortable as possible, so please bear with us. Hopefully, the end result will be worth your time and efforts to attend this session, and I think it will be as you will see as we

move along.

What we hope to do with the overhead projector, we pretty much have stayed away from slides and overheads for almost the entire life of the Commission. We will be putting up the major issues that the Commission will be focusing on to help you have a little bit better understanding of where we are going and direction.

As Jim mentioned, the Interim Progress Report will be available on the Internet as soon as it is signed off at the department level as it goes to Congress and the White House. So, if it takes two days, one week, two weeks, it is coming, and as soon as we get the okay and the sign-off, it will be on the Internet and on our web site, so, please, just sort of stay in touch with that, and think you will be able to follow where are going.

It is important to remember that the report that comes out really is a progress report on the activities and accomplishments of the Commission to date, what we have heard, what we have read, just what we really are thinking about, general issues and themes, agenda, that we do need to move forward.

We would like to think that the recommendations

will be pretty close to final, but they may change based on what we hear after we go out with the Interim Progress Report. So, stay open, give us your comments. We are looking for your feedback on what is published as we are welcoming the Commission members' input into what we publish and what they agree upon.

I think when you write something at one point and you look at it two days later or a week later, it is somewhat different than what you remember, so we are asking you to give us your comments and spread it around as broadly as possible for others who you know to also give us their input into the contents of the report.

We do hope to reach some agreement on broad and general recommendations based on what we hear today and what we discuss. So, at the end of the meeting, hopefully, there will be some very, very good recommendations that will make sense and can be implemented between now and when the Final Report is issued.

I think the Final Report itself will contain some very specific recommendations and certainly more detailed discussions than what you will see in the

Interim Progress Report.

I, too, would like to thank our staff. They have made my life unbelievably easier - can I say that? We have gone through an awful lot to get to this point, and I would like to thank them publicly. It has been quite an ordeal just weeding through everything that has been submitted to the Commission, and thank you also to the Chair, who has assisted us all along, and to the Commission members who have exhibited a great deal of patience waiting for the Interim Report. We got it to them I think late Thursday night, for those who were on line, and Friday morning, for those who weren't, so it is a quick turnaround and I would like to thank everyone for their help and their patience.

DR. GORDON: Thank you, Steve.

Next is Peter Reinecke. As I said, Peter is the Legislative Director for Senator Tom Harkin, and he has been with us from before our birth. He has known us when and has helped to shape, working with Senator Harkin to shape the Commission as has been invaluable in assisting us in understanding some of the issues that we face.

MR. REINECKE: Thank you, Jim. First, just thanks for the opportunity to make a brief comment this morning and to send you Senator Harkin's regards.

You all have a big challenge out in front of you. You have all the skills and attributes and backgrounds to be successful. I think a lot of people would agree that your greatest strength is your diversity of backgrounds and opinions, and that you have a full panoply of health professions represented.

You have business people, you have people from academia. You have people with experience in state and local efforts in this field. So, you bring to the table a lot of strengths, and Congress is looking to you to give them consensus recommendations from a diverse group of people interested in health care, because I think Congress and you all share the common goal of improving and maximizing the public health.

There is a lot of interest on the Hill in your Interim Report, and people will be eagerly awaiting getting that in the next few weeks. I can say clearly that there is bipartisan interest, as well. One of my close colleagues, Beth Clay, is here. Beth is a long-

time lead health staffer for Congressman Dan Burton, Chairman of the House Government Operations Committee, and a key player in health public policy.

Senator Harkin and Congressman Burton have a different set of views on a lot of issues, but both have strongly held views and interest in the whole CAM field. I think that shows the potential of a good bipartisan coalition of support for your consensus recommendations coming forward.

Finally, I will just say in terms of the original mandate from Congress to you all, basically, is how do we maximize the benefit to the public of complementary and alternative medicine approaches, how do we maximize, continue people's freedom of choice in the United States to pick the health care that they see fit to maximize their health and well-being.

Third, how does the health care system remain consumer driven and making sure that consumers have the best of both worlds of complementary and traditional therapies, how public policy can play a role in maximizing access of the public to the best of both worlds.

Finally, I just want to thank all of you all from those of us in Congress that had something to do with establishing the Commission. Looking around the table at the attendance, obviously, it is fantastic. It looks like almost every member, if not every member, of the Commission is here. You have traveled long distances, and your personal time out of your busy schedules is appreciated by those who will be receiving your recommendations.

All I can say is keep up the good work and we very much look forward to having the results of it. Thank you.

[Applause.]

DR. GORDON: Thank you very much, Peter, and thank you, too, Beth, for your support and your loyal attendance.

What we are going to do now is we are going to move through each of the areas that we have been mandated to examine and also through the area of wellness and health promotion, and we will keep careful track of time.

I am going to turn it over for each of the sessions to the facilitator who is in charge of those

sessions, and that person will be the one who will be calling on Commissioners.

The first session is on Coordinated CAM Research. Dean Ornish will be the facilitator. In each of these sessions, the facilitator will also have a staff member working with him or her to help move the discussion ahead and deal with any issues that the staff member can provide support or information for. Gerri Pollen will be working with Dean.

Dean.

Discussion Session I: Coordination of CAM Research and Regulatory Activities

Part 1: Coordinated CAM Research

DR. ORNISH: Well, thanks, Jim, and I just want to again echo not only the appreciation to the staff who did a marvelous job in putting all of this together, but also, Jim, for your leadership in what has been a very lengthy process. When I think about the thousand people who have testified, I think you are the only one who has actually listened to every single one of them, so I want to thank you and also to thank Peter Reinecke for coming today.

I think the Interim Report is due July 16th, which is my birthday, so that is an auspicious day, as well.

I think one of the things that came out of what Peter was saying earlier, and Steve and others, is the need to try to find consensus and to find common ground, so at least for this session I would like to try to examine the specific issues that are outlined, I think that you have all seen in this most recent handout.

Does everyone has a copy of this, that says, "Coordination of CAM Research and Regulatory Activities Related to Research"?

Just to go through these one at a time, and solicit any feedback you have with the goal again of trying to find common ground here, because I think for the Interim Report, that is going to be our most effective strategy, and if there are areas of differences, we need to outline them, so that we can see if they are resolvable or not.

The first one is Evidenced-Based Research on the Safety and Efficacy of CAM Products and Practices.

DR. GORDON: Would you like to call for

discussion on each of the ones as they come up, Dean?

DR. ORNISH: Yes, I think that would be my preference, because again I don't want this just to be my opinions, but I really want to just be a facilitator to get the entire Commission's opinions on these issues.

DR. GORDON: I have something, but don't be shy. What we are going to do is each of the facilitators is going to lead the discussion on each of these issues, but, please, if there are concerns, move in and raise those concerns.

DR. ORNISH: Jim, do you want to be first then?

DR. GORDON: I would be happy to be first.

DR. ORNISH: I call on Jim. I have wanted to do that for a month.

[Laughter.]

DR. GORDON: Now it is nice because I am not Chair, I can raise my hand a little higher.

One of the issues that I have heard coming up repeatedly is, first of all, what is the nature of evidence based. I think that is one of the issues, and does evidence based vary depending on which modality or which approach we are assessing, and how do we want as a

group -- I see this as the thorniest of all of the issues that is on this page of topics, and I hope we can devote some time to it.

Rather than make specific comments, I would just like to get people's sense of what do you consider evidenced based, how important is it, is it always important.

DR. ORNISH: Well, one of the themes that we have heard I think from a variety of people ranging from the most traditional to the least, with few exceptions on both ends of the spectrum, has been the importance of evidence or scientific research in helping people sort out what works, what doesn't work, for whom and under what circumstances, and particularly in the area of CAM where so little research is there and yet so many people are using it, I think a recurring theme that we have heard over and over again is the importance of more research to try to help people make these distinctions.

So, again, it is not whether people should be using these techniques, because so many people are, but how can they choose intelligently, particularly when there are conflicting claims.

This is something that I guess I would like to ask straight up is do we have a consensus among the Commission that we need more research in the area of CAM. Before we get into the specifics of what is research, what constitutes good evidence, what is the best experimental design, but just as a general recommendation that hopefully we can start with and have some consensus around.

Is there anyone who objects to the idea that we need more research in the area of CAM? Can we start with that?

[No response.]

DR. ORNISH: Do we have agreement on that?

[No response.]

DR. ORNISH: Do we have agreement then that we need more funding for research in the areas of CAM? Are there any objections to that? Can we say we have got two areas of consensus then?

DR. FAIR: I don't think you will get any controversy about more research in the area of CAM. I think the controversy would arise is what is CAM and what areas should we be doing more research in because we

don't know where that fits in.

The other thing I would like to point out is, in reading the document before, there were several areas where the randomized, controlled trial was looked at as the gold standard. It has been said many, many times there was never an RCT for penicillin, for instance, when it first came out. It worked, and everybody jumped on it.

I think that there have been a couple articles recently in rather well-known medical journals addressing the issue do we need RCTs or good observational studies may be just as well, so I think rather than blindly going to the position that we need RCTs to look at CAM effectiveness, that we ought to leave the door open, that there may be other ways to study the effectiveness short of a randomized clinical trial.

DR. ORNISH: Tom.

MR. CHAPPELL: What worked for me on the subject of how do we go about establishing methodology for evidence based, what worked for me is the language in our draft, "to address the need for dependable information, we need to meet high standards of study

design and execution, that is, a focused question, a good study design and research team, verifiable data, and objective conclusions."

I mean that, to me is the definition of the scientific method, and I think if we adopt some language that is that specific in terms of objectives, but it is also open to particularizing the studies, then, I think we give the flexibility, on the one hand, to the difference in modalities, yet, we give some rationality of evidence-based outcomes simultaneously.

DR. ORNISH: I want to try to focus this or clarify this because part of the testimony that we have heard from various people is that, you know, without making a distinction of CAM versus non-CAM, randomized, controlled trials are not the only way that people study drugs or devices or other conventional interventions. There is a hierarchy of experimental design from anecdotal case reports to observational studies, to matched controls, to randomized controls, to small-scale, log-scale, short-term, long-term, et cetera.

So, I am not sure that we necessarily have to distinguish that there is something unique in the CAM

world, that everything has to be a randomized, controlled trial, because everything doesn't have to be a randomized, controlled trial in the allopathic world.

On the other hand, we have heard testimony from people who said that there are certain things that are unique about CAM, that don't lend themselves to research, studying energy, for example, and so I would like to just briefly ask the Commission to comment on that particular aspect of it.

Again, the overarching theme I am trying to find is where do we have consensus and where do we still have disagreement.

David.

DR. BRESLER: Well, I think it might be helpful to look at this maybe a little less so from the point of view of us academics who do medical research and a little bit more from the point of view of the public and the types of questions that they would like to see answered.

So, for example, one of the things that research has to show us, if there are any safety concerns about any of these things independent of efficacy, are there any potential risks that are associated with any of

these CAM modalities.

Another thing that the public would like to know is how do CAM modalities compare to conventional treatments, and again, without necessarily even doing randomized clinical trials, cohort studies could even answer some of these kinds of questions, and I think it might be fruitful for us, rather than applying sort of the standards that we use in allopathic research, to really focus on the questions that the public most wants answered by this Commission.

DR. ORNISH: Although if you get into areas of comparing efficacy, then, in a way you are talking about conventional research, too.

Other comments or questions? Tieraona.

DR. LOW DOG: I think I am somewhat with David there. Do we have to, in this Interim Report, say things like we think that the double-blind, randomized, controlled trial is the gold standard? I think Katchuk's [ph] recent article was kind of interesting, gold standard or golden calf.

I think Tom, when he pointed out sort of at the beginning about high standards of design and execution, I

think he sort of hit it that we need to come up with the highest standard of design that is applicable for each modality or specific thing we are trying to study, and at some point I thought we had talked about recommending bringing together some of the best minds to start to look at other ways that other designs of research could be applied to things like acupuncture or massage, and I think it is important to remember that other modalities, such as psychology, have been dealing with this for almost 50 years.

Double-blinded RCTs don't work in that discipline either, and so it is not unique to CAM, but I would still like to throw back to the group when we had talked about one of our recommendations being that there is some sort of consensus group or think tank that comes together to try to come up with some designs, I thought that was a good recommendation.

DR. GORDON: I just want to make one process point. These discussions up until tomorrow afternoon are not about the Interim Report. These discussions are really to give us the whole scope that we will be looking at as we develop the Final Report.

So, don't worry about settling the questions now or settling them for the Interim Report. This is really laying out the whole territory.

DR. ORNISH: I have to say I am really confused because I thought this was exactly about the Interim Report.

DR. GORDON: No. That is what we need to clarify.

DR. ORNISH: I mean we have got a copy of the Interim Report, and we are asked to discuss the Interim Report.

DR. GORDON: Let me try to clarify and then Steve can add, too. We had discussions about how to structure the meeting, and one of our concerns was if we did it the way we did it, that exactly the misunderstanding that would happen might happen.

The idea of this meeting, the major part of this meeting is to give us the vision based on everything we have heard over the last 10 months and everything that we have discussed as a commission, both in small groups and in the large groups, to give us the vision of where we are headed looking toward March 2002.

All of the discussions for the next day and a half are about where we are headed. The Interim Report is a moment in time, that we have created a draft of that moment in time, and that moment in time is meant to say where we are right now. That is, what do we know for sure, some of what we know for sure right now, where we do have a consensus, but without all the details filled in, and some of where we are headed.

So, if you look at the Interim Report, it gives a feeling for where we are and a feeling for where we are headed, and there are perhaps half a dozen or maybe 10 recommendations contained within that.

What we are asking everybody to do now is to step back and look at the long term, look at everything that we have learned and where we are going as a whole commission as of March 2002, and if these discussions then modify the Interim Report, which we will talk about at the end, so be it, then, we will use that information, but don't be thinking in these discussions of coming up with recommendations for the Interim Report, think more of what is the territory that we are going to be looking at in the Final Report.

That is the basic idea. So, it is much broader than the Interim Report, and that is why we want to surface, not only issues in which we have consensus, but also issues where there is not consensus in these discussions, and, in fact, in some ways the issues where there is not consensus are even more important than the ones where there is consensus in these discussions, because those are the areas that we want to be exploring over the next months.

DR. ORNISH: Let me just say in response to what Jim said, that I think that is very helpful. What I would like to propose for your consideration is that, at least with the time I am doing, is to try to highlight where we do have consensus and where we don't. I think that can be very useful, but also to see if we can find ways of -- I think Tieraona's language was really great.

You know we could argue about whether everything should be a randomized, controlled trial or not, whether you can measure certain things like energy or not, and get really bogged down in that, but when you come up with a sentence like we want to come up with research using the highest standard of design appropriate

for the modality study, which is what you were just saying, I think we could all agree on that.

It conveys the intent without getting bogged down in the details that might create controversy where we could have consensus, and allows everyone who reads it to project onto there what that means to them.

I think that is really brilliant, I mean what you said, so would that be a good way of going about this? Tieraona, you wanted to say something.

DR. LOW DOG: No, I am done.

DR. ORNISH: Are you sure?

DR. LOW DOG: Yes.

DR. ORNISH: Wayne.

DR. JONAS: Now, I am very confused because I read the materials we got ahead of time including two versions apparently of the Interim Report, which maybe I am just confused about; one, the draft Interim Report here and then things that were in the briefing book which were different than that, although complementary.

Now, I have this thing for discussion parts and I have no idea where this fits in, and I think we need more discussion about what we are going to focus on here

in this meeting. I will give you my bias. My bias is not to be broad and general. I think we have been doing that for the last year.

We have some language here that is very useful, it is concrete, there is terms in there. There is things that are going to move this forward in terms of eventually putting them in the report, and I would like to see us discuss that.

DR. ORNISH: Thank you.

Tom.

MR. CHAPPELL: I think we can do both. I think we can use the draft as a point of departure, it's a work in progress, and we can keep where we are headed in mind by building on the document. So, I feel, I mean for myself, it just seems logical that we comment on where we find the draft at the present time and build upon it for clarity or creativity, because we are still looking for solutions. So, that is how I interpret what we need to do.

DR. GROFT: I think what we want to do here is give you the opportunity to look at all of the recommendations that the Commission has received at this

point and then at the conclusion of the day and a half session, then, to get some agreement on the Interim Report.

DR. ORNISH: I don't see these goals as mutually exclusive by any means. We can talk about these goals as they relate to the Interim Report, but at the same time, try to find language that we can use to build consensus or, if not, then, we can outline things we need to have for further discussion. So, that is how I would like to use this time.

Michele.

MS. CHANG: Just to clarify in response to what Wayne said, the two drafts of the Interim Report that you have are actually identical. One is formatted differently, so that you can use it more easily in the discussions tomorrow.

I would guess that you would want to try to use the one that is in your briefing book that we have gave you this morning, because it is numbered by lines, you can refer to line 14, you know, whatever, it will be easier for everyone to follow since you have the same draft. Regretfully, we didn't give that to you early

enough for you to have only the one copy, but that is really the only difference between the two drafts.

The second thing is that every discussion session has a set of worksheets that are identical to this overhead that we are providing for the public. They are just for you to follow along, the major discussion topics that we are hoping that you will cover during the hour that you have per topic, and that is what those are for.

DR. ORNISH: I would like to move along just so we can actually focus on these issues.

Yes, Joe.

DR. FINS: I want to just say that I don't think the two objectives are mutually exclusive, and I think those should have kind of an eye towards the end of the two-day process of the Interim Report.

Getting back to your charge, Dean, about research, if you would like to do that, I think we should say in addition to the statement about the methodology which Tieraona said so well, but I think we want to talk about the need for basic science research and translating from the bedside back to the bench and understanding the

biological foundations of something that might be very promising.

The other is in the health services research, that is, integration of these modalities into a traditional system and studying the sociology and methodology by which successful programs have integrative care plans, because I think that is a different kind of research, so I wouldn't want that to get lost in the shuffle.

DR. ORNISH: No, I agree with both of those, and that is something that we have been talking about also that Gerri actually gave me a whole handout on health services research and talking about the Institute of Medicine, the Agency for Health Research and Quality, and other governmental agencies that are involved in that, because those are key allies that we can work with.

Just to follow up on your point, Wayne, are comfortable as the former head of what is now the National Center for CAM, what Tieraona said about research with the highest standard of design appropriate for the modality study, is that specific enough for you, or would you want more specificity than that?

DR. JONAS: No, I think the wording is misleading because it uses a hierarchical language, that there is a higher and lower standard of design, and we have had a lot of discussions over the past year about the importance of matching the goals of research with the particular type of information that you are going to get, and it isn't in a hierarchy, it is really in a strategy, and that for different uses, there are different types of research and research designs, and within those you need to have high quality research.

So, I think it is a bit misleading because people interpret that, when you say highest, lowest, as a hierarchical approach, when what we need is a strategic approach, and I would suggest the language needs to be modified appropriately.

DR. ORNISH: So, what would you suggest, Wayne?

DR. JONAS: Well, should we go to the language? That is why I wanted to focus on the language in the Interim Report.

DR. ORNISH: Well, if you look at the language in the Interim Report, on page 5, lines 7 through 10 --

DR. JONAS: I would like to do that.

DR. ORNISH: It is a lot easier if we can use the ones that are numbered, just because everybody can refer to it quickly, and then you can just cross-reference it.

DR. JONAS: Except now I will have to find where the numbers correspond to the one that I wrote in, but anyway, here is some language.

DR. ORNISH: It is also page 3 towards the bottom of the original. That is easier.

DR. JONAS: Well, the page number of the original I wrote over.

DR. ORNISH: The original is page 3 towards the bottom.

DR. JONAS: Exactly, where it says, "To be methodologically sound, studies need to be focused, good design," et cetera. There were two items that were listed in there, which were both fine. I suggest another phrase, "that research should be designed to provide the types of information most useful for those seeking and delivering CAM services, such as the public and practitioners," not in lieu of, in addition to, in other words, perhaps a third item.

You listed 1, 2, 3. It was noted that in seeking evidence about CAM modalities: one, research methodologies should be appropriate, et cetera; two, creativity in research flexibility. I would have to think about that wording if that same format was going to be addressed.

DR. ORNISH: It may be worth commenting as an example for the kinds of discussions we are going to have in the next two days, of the level of detail that we want to get into, at least as far as an Interim Report would be concerned.

DR. JONAS: Right, I agree. You asked for wording, and I was hesitant to provide that.

DR. ORNISH: No, no, I am glad you did, because I think it illustrates an important point, and that is, I don't know the answer, I am not saying one way or the other, but I think that clearly, the more specific we get into, the more we are going to offend one group or another. In other words, the people, the Marcia Angells, for example, who testified that there is either good science or not, it is CAM or not CAM, to the degree that we start talking about flexibility of research design, we

are going to be pushing their buttons.

On the other hand, if we make a more general statement saying that we want the highest quality research without necessarily implying a hierarchy of values or of designs, is that specific enough for an Interim Report? That is the question.

DR. GORDON: Let me just make a comment. I think that is certainly specific enough. The Interim Report is not meant to be exquisitely specific in all of these. I think the larger issue, though, as we think through recommendations for the Final Report, it may become more important because we may want to make specific recommendations about funding priorities.

Again, I see this as less important for the Interim Report and more important to shape our thinking for the Final Report, as long as we are not off track for the Interim Report.

DR. ORNISH: Well, then, maybe what we can do is try to do a parallel track here, where we come up with language that we could perhaps build consensus around for the Interim Report that is more vague, but still conveys an important idea, and then keep in mind the kinds of

issues that Wayne and others are raising that we need to be more specific about in the Final Report.

Is that a general approach that we can all agree on? I want to call on people that haven't been called on.

DR. GORDON: Great. That would be really helpful.

DR. ORNISH: Jim, are you okay with that?

DR. GORDON: I am fine. That is excellent. In fact, that is exactly what we are looking for from this discussion.

DR. JONAS: I agree with that, and along those lines I would agree with what David said, and others said, is that we need to make sure that what is communicated in this document is that research is to provide tools for a variety of constituencies and audiences, and those tools must be appropriate to the type of information that those audiences need.

Within those research tools, they have to be obviously high quality tools. You can't have your hammer that breaks. So, it is really about coordination, and that is really what the title of the thing is,

coordinating research, so it is about research strategies, identifying the audiences, and the type of information they need, and then making sure that the prioritization process for research then is going to deliver that type of information.

DR. ORNISH: Thank you. That is very helpful.

DR. JONAS: I think, just as a subset of that, and this is what I think David referred to, is that the public needs to be an integral part of that prioritization process.

We need to develop processes whereby the public can have educated and influential input into the prioritization process, and that should be an effort in this area, and that is what coordination is about.

It is not so much about saying you should do this type of research or that type of research. It is really about the process that leads to the public's input and other audience's input into the development of research and then ultimately the funding.

DR. ORNISH: Thanks, Wayne.

Charlotte.

SISTER KERR: I had wanted also to speak to the

need for specificity in terms of research. I point to one of my colleague commissioner's statements, page 13 in the original book, and I was wondering if, in our thinking, that we could speak in a way that teaches when we speak about research even in our report.

This is just sort of a sketch statement. For example, if we said something like research, everybody wants a rigorous product. This is taken from a colleague.

2. Evidence based usually refers to double-blind studies.

3. What about outcomes research in health education, the sociological, epidemiological, anthropological, psychological research advances.

4. We strongly recommend looking into innovative research methodologies.

5. It takes into account the advancements we have made in science that is not the same old double-blind method.

My point there is I think both the content there is specific and good, and also, it is a way in which you teach as you make your recommendation.

Thank you.

DR. ORNISH: Thank you.

Joe.

DR. PIZZORNO: This is a request to Wayne. At the CAM industry summit meeting in May in Arizona, that Wayne, Jim, George, and I were at, Wayne presented a diagram of CAM research and broke it down according to the appropriate types of research to be done and who the target audiences were, and how then ranked its quality.

Wayne, I thought it was brilliant. I think a copy should be made available to all the Commission members and also to the staff, because I think you laid out a blueprint for how we can recommend appropriate research for the questions being asked. I think that is a key element is what is the appropriate research.

DR. ORNISH: Thank you. Wayne, can you do that?

DR. JONAS: Yes.

DR. ORNISH: Great. Other comments? Joe.

DR. FINS: I don't think necessarily what people want is the way that we gauge the level of scientific rigor. I haven't read what you have written

on this, but I think it is not necessarily a democratic endeavor to decide whether something works or not.

If an advocate wants to believe in something, it doesn't really matter what the science says. So, I think we have to have the hierarchy. You know, things are more clearly defined as you go up that hierarchical tree. But having said that, and wanting to cast this in a positive way, I think we should say that when possible, the highest standard of design appropriate for the modality being studied should be employed, however, the Commission recognizes that there is an evolving need to design new methodologic strategies to understand these complex and difficult questions, and resources should be funneled in that direction to make this kind of compromise methodology that is more synergistic than indicting of the scientific method.

DR. ORNISH: Right. My suggestion for the Interim Report is that we don't get into that issue at all, that we simply say we want the highest quality of research, leave it deliberately vague, and not get into do we need to come up with new experimental design methodologies.

DR. FINS: There is a fundamental question on the table here, that we are sort of talking around, and that is what kind of valence do we put on science, do we believe in science or do we discount science, and it is a fundamental kind of question, so I think we need to be very careful.

DR. ORNISH: But, Joe, I think we addressed that issue at the very beginning when I said do we all have consensus about the importance of science and helping people sort through these, and I think we all agreed on that.

DR. FINS: Yes, but certain kinds of research cease to be science.

DR. LOW DOG: Right, because your statement actually was research, did we all agree on research.

DR. ORNISH: Scientifically based research. Is there any agreement on the general concept of the value of scientifically based research and applying that to CAM?

DR. GORDON: To help clarify this, I am not sure what the difference is between your position and what Dean is saying. I think this needs to be

articulated a bit more.

DR. ORNISH: I understand what he is saying. He is saying that there actually is a hierarchy in research, that randomized, controlled trials are better than anecdotal case reports, and we need to state that, and I am saying whether or not I agree with you is irrelevant, that for the interim report, I think we shouldn't get into that issue at all.

I think if you say randomized, controlled trials are better, you are going to offend people like Wayne. If you say that randomized, controlled trials aren't as good, you are going to offend people like Marcia Angell.

MR. CHAPPELL: I think the materials we have been given on page 5, sentences 7 through 14, provide the framework for any further clarification or specificity that may be needed, but I don't know of anybody that has come before us in the hearing process that would find this language anything less than a rational approach, a scientific and a rational approach to providing some kind of evidence.

Evidence can be established no matter what

modality we are involved with, and this gives us a framework, which is why I think it is so valuable to us, and every modality can take this into their specific world just so long as they are meeting these criteria. That is why I think this is so valuable, and I haven't heard anything yet that really improves on this.

I think this is the language we need to ask do we have consensus on this as we think about the peer-reviewed journals that have been before us, all the groups that have been before us. It seems to me that this provides the direction.

These are the objectives and parameters that need to be met if we are going to allow CAM to move into all the elements of freedom and equality that we seek. I would like to see consensus asked for on these sentences.

DR. ORNISH: Okay. Bill.

DR. FAIR: Well, maybe taking the surgical approach to this, if we don't have good research right now, there are two reasons. Either we don't have the right people doing the research or we are not doing it correctly.

I think one of the things that we really need

is to consider bringing in basic scientists and others who are not interested in CAM right now to study the problems, and the way that is done is by providing the money. I can think of my own field of prostate cancer. Ten years ago, there were no basic scientists really, except a handful, interested in prostate cancer. They didn't know a prostate from a mushroom.

But at the last meeting of the American Urologic Association, 16,000 people, there were as many basic scientists as there were urologists, and they have brought urologic research, particularly in prostate cancer, to the forefront. I mean we have PSA to follow, which is an advantage, but many of the innovative approaches to tumor vaccines are coming out of urologic research.

What made this possible is the SPORE mechanism, Specialized Programs of Research Excellence, which specifically went out to institutions to encourage them, bringing people into the area of prostate cancer research that never were involved before. These were statisticians and basic scientists of all ilks.

The second thing I would like to see in there,

that unlike traditional biomedicine where we can pick out one point at a time, and it has been written in here several times, I think we have to hold fast to the idea that we evaluate a system rather than a specific program.

I talked to friends at the New York Botanical Garden with whom we did some work, and they are the experts in herbs, but they call themselves ethnobotanists because they recognize that taking that herb out of the cultural milieu in which is it is being used may have a totally different effect.

I have had thousands of people call me and say, what are those herbs you were taking, and I said, well, listen, you know, I resigned my job, I started doing yoga, I started meditating, I started this, started that, and maybe the herbs had some effect, but I am not willing to say what one thing was.

So, when we study these things, and I know people like Roland and Tieraona would agree with this, we need to study them within the context of the system in which they are delivered, and not just take one thing out and look at it.

DR. ORNISH: Thank you.

Well, that is a good segue into the second topic, which is the federal government's commitment to, and support for, CAM research, biomedical health services, et cetera, through federal agencies with research and research-related responsibilities and their missions.

Just to bring up one point related to that, a number of people who testified said, okay, we have got the National Center for Complementary Alternative Medicine, but that is a small fraction of the overall NIH budget, how much of this should be part of the NIH overall mission as opposed to being something segregated off into the NCCAM. Certainly the idea of increasing funding for CAM research, I think is something that we may be able to build consensus around.

Do any people have any thoughts on this particular topic?

We could start with the language that is in the draft of the Interim Report that we received. Do we have consensus around that, or are there areas that we don't?

DR. GORDON: Dean, I wanted to raise a somewhat larger issue. I think that we need to think through, as

time goes on, where the bulk of funding ought to go from our perspective.

DR. ORNISH: Ought to go and be from, as well.

DR. GORDON: Exactly. So, issues like funding approaches to whole systems or complex interventions, if we have some consensus on that, then, we can begin to develop some thoughts about that for the Final Report, health services research.

I think that the tasks that we may want to, without saying exactly who is going to do that, because that is not so much our function, our function is to look at the overall picture, what directions do we, as a commission, feel that research should be taking, is it different from the present direction that research is taking.

DR. ORNISH: Can we all agree on a statement something along the lines that we recommend that there be more funding in CAM research and from the basic science levels, as Bill Fair said, to health services research, to clinical outcomes, to systems outcomes? Do we have any disagreement on that?

Then, the question next would be where does

that money come from, how much, and to whom, but at least in terms of what, is that something that there is any difference on? David.

DR. BRESLER: I do have some thoughts about it because research is often considered a luxury when budgets are tight, and I would like somehow the Commission to put some sense of urgency behind our request for research.

People are using these modalities anyway, and I think somebody has to take the responsibility to say what is safe and what is not safe, and what is more efficacious than conventional treatments that we have because people are already engaged in these practices, and I think there is a sense of urgency in getting this research out there. It is not just a luxury that when we have the funds, let's do it, but it needs to be done now.

DR. ORNISH: Thank you.

Other comments?

DR. GORDON: I just wanted to make a comment about what David said. I think that is exactly the kind of comment that is enormously useful to us in helping us to shape where we are going with the final report

especially, so I just want to thank you and just point that out to everybody, that where you have those kinds of perspectives, please say them, don't be shy in case you were thinking of being shy about it.

DR. FAIR: Well, again, I would just like to point out that giving more money to the same old crowd is not the way to go. I think we have to have something in there that would indicate that we would reach out to people that are not involved in CAM research right now, particularly the basic scientists, who can really help forward the field, because often it is just like in conventional medicine, the basic scientists have all these wonderful techniques that can solve the problems, but they don't know the problems, and the clinicians are struggling with it at the bedside, and they don't know the basic techniques which could help them.

So, we really do need this bridge, and whether it is a SPORE mechanism or something else, and if I were a congressman and I was looking at something that said give more money to the guys who have been struggling with this for 20 years and haven't made any progress, I would not be very enthused about it.

DR. ORNISH: Bill, just to interrupt you, we have already agreed with you. We agreed that we should say there should be more money for basic science research. Is there something more than that?

DR. FAIR: No. I guess I didn't recognize you agreed with me.

[Laughter.]

MS. CHANG: Dean, we have 10 minutes for this.

DR. ORNISH: I know, that is why I am being a little bit abrupt here, so forgive me for cutting you off. We still have four more areas to go into.

Joe, can we skip this and can we go on now?

DR. FINS: I want to embellish something that Bill Fair said, that I think is important to just put on the table, is that we are talking should all the money go to NCCAM or should it go to their brother and sister institutes in the NIH, for the basic science and the other institutes.

I think that there should be some sort of cost-sharing mechanism or revenue sharing, because I think that NCCAM can do certain things well, like the promotion of expertise and training grants, and that sort of thing,

but I think that if something does come up that is related to heart disease, the National Heart, Lung, and Blood Institute might be a better place for it, and we should recognize that.

DR. ORNISH: But are you saying -- this is where it gets controversial -- that the NHLBI, for example, should use their existing funding and allocate some of it to CAM research, or there should be additional funding for NHLBI for CAM research?

DR. FINS: That brings up the other question, is that if we increase funding for this entity, it is at the cost of something else, if we are talking about a global budget, unless we increase the expenditures.

So, I think that that is a legitimate and important question as we are in balanced budget territory.

DR. ORNISH: Well, it is particularly true if you are talking -- you are talking about the global overall U.S. budget -- but if you take the budget of a particular NIH institution, and you say we want you to reallocate some of that money versus giving them new money, that makes all the difference in the world in

terms of how receptive they would be.

DR. FINS: I personally think it should be new money, because it is an additional added and value-added function, but I think there should be some mechanism to have the NCCAM and the partner institutes working together in a more synergistic way, especially if we want to access the basic scientists that Bill is talking about.

DR. GROFT: Just real briefly, I think you have to remember that there is a great deal of cost sharing going on already within the NCCAM and the institutes of NIH and other government agencies. Wayne has some experience with this, I think, in setting up some of the studies, but I think it is occurring even more, but it is a good message to put forward.

DR. ORNISH: Michele, we got started about 15 minutes late plus we spent a lot of this time just talking about the format of how to talk about these things. I am wondering if we could have a few minutes extra to at least continue the full hour of what we started.

MS. CHANG: I think we have built in a little

bit of a buffer, about 10 minutes, but that was just a break stretch before we start the regulatory discussion, so at your discretion, five is what I am hearing.

DR. ORNISH: Effie, you haven't said anything.

DR. CHOW: I wonder whether it has to be either/or, you know, with the NIH, because I think there is a combination and also public monies, private monies, you know, from the businesses, and so forth, so it is both private and public, and where the source comes from, I don't think we even need to be that specific.

I want to go back to a very generic field, is that we have never really defined what evidence based means. We keep using evidence based, all the testimonies, et cetera, and I am the one that keeps hammering, but we don't have it written down as to what evidence based is.

I cornered Wayne at the meeting one time, and he said it ranges anywhere from an example by a person, as long as it is identified that the person says it is my observation.

DR. ORNISH: In the interest of time, we have already discussed this. What we would like to do is

rather than getting into the definition of what is evidence, what is the hierarchy, is it a randomized control, is it an anecdotal case report, is it something in the middle, to just simply leave it deliberately vague to be defined more clearly in the Final Report.

Am I saying this clearly enough?

DR. GORDON: I think that is true, but I think the issue that is there is there needs to be more of a discussion about this and more information provided the Commissioners, and I would anticipate having that kind of discussion in depth in the October meeting. It is clearly one of the areas that is still there.

DR. ORNISH: Exactly, because it is such a wide-ranging discussion, there are so many aspects to it, there is no way we are going to make much progress about it now other than to say I would like to table it for later, because it is so important, Effie. It is not to diminish it, but, as I say, it is because it is so important we need to discuss it at a time when we have adequate time to do that.

DR. CHOW: Okay.

DR. ORNISH: I really do want to move on to the

other issues.

DR. LOW DOG: Could you just make a note, though, that I think that is one area that we are going to have a hard time with consensus on. I think the staff has to really allow some time for this.

DR. ORNISH: I completely agree with you, and that is part of the reason I don't really want to get into it now.

DR. GORDON: What I am going to do incidentally is when we are finished with each of the discussions, I am going to give a summary of some of the hard issues that are still out there, as well as some of the ones where we have agreement, and if my assessment is incorrect, I will accept correction.

DR. ORNISH: Thank you.

Wayne, before we move on, do you have something brief?

DR. JONAS: Yes, just related to what we had been talking about before, is I think we should make this a very positive spin, and it is in here, continued support for the NIH, NCCAM, HQR, et cetera, and I think we should build on that and say look at this example,

look at what has happened at the NIH by simply starting a little, old office in there, you know, several years ago, so it is clear that similar types of activities and support coordination efforts are needed in other federal agencies. If we want to list them, we can, but perhaps not even list them.

DR. ORNISH: We have 10 minutes left. We haven't even gotten to the last four things. Tom, can this wait, or is it something that is really urgent?

MR. CHAPPELL: It hasn't been said.

DR. ORNISH: Okay.

MR. CHAPPELL: CAM is value-added. I think unless we always think about value-added, we are going to continue to play in the either/or world.

If we are trying to bring a new realm of health and wellness to the consumers, we need to be able to think that this is going to take extra money - always value-added, always requiring more funds than we are talking about. It is not an either/or.

So, I just want to introduce the notion, it is my point of view that we need to be thinking about bringing additional funds and resources to the research

or any of these processes we are talking about.

DR. ORNISH: Thank you.

Can we move on to the next, which is the dialogue and interaction between the conventional medical research community and the CAM research community.

Does anybody have any thoughts or ideas about that? Joe.

DR. PIZZORNO: I would like to make a couple word changes. Rather than "dialogue and interaction," I prefer a strong term "collaboration."

DR. ORNISH: How do you see that as being different?

DR. PIZZORNO: I would like to see us strongly recommend that conventional and CAM institutions do research together rather than just talk to each other, and I think it is critical because CAM institutions understand this medicine, conventional institutions understand how to do research, we need them both working together, not just talking to each other.

DR. ORNISH: Thank you.

Other comments on this topic?

MS. SCOTT: I just wanted to also bring in the

consumer in this. I think one of the issues for us in the advocacy community, certainly around women's health, has been that research is done in a vacuum and done in these white towers and without the input of consumers, and nowhere in the seven points here do I really see an emphasis on the involvement of the consumers.

Conventional research has been absent that voice, and about 10 years ago, in the women's movement certainly, there was a push to make sure that advocates and consumers were involved in decisions around research, what gets research, the development of the questions, the protocol, and I see CAM, you know, with the broader vision of the inclusion of the person it is aimed at, at the highest level.

I think any document that we come up with has to show, both in words and spirit, the involvement of consumers in research, and not just as the people who are being researched.

DR. ORNISH: Thank you.

Other comments before we go on to the next one?

DR. WARREN: Yes, I have got a question. The role of CAM research community, what is the CAM research

community if it is not the practitioners utilizing CAM?

DR. ORNISH: Well, I think it is left deliberately vague, because as I read it, that could be anyone from the basic scientists working in CAM to the clinicians, as you referred to, to the health services research. It could be anyone who is involved with CAM research at any level.

Moving on to the next one. Again, forgive me, I will apologize in advance if I seem rude or abrupt, but I am just trying to get everything in here in the limited amount of time we have.

DR. GORDON: You are doing your job. That's great.

DR. ORNISH: Thank you. Someone has got to do it.

The role of academic health centers in CAM institutions. Any comments? Joe.

DR. PIZZORNO: One of my dreams for a couple of decades is to recognize that conventional medicine has advanced substantially because of academic health centers in conventional medicine. We need academic health centers in CAM, as well.

DR. ORNISH: As separate institutions or bringing CAM into academic medical institutions?

DR. PIZZORNO: Clearly, as separate institutions and including in conventional, as well.

DR. ORNISH: Okay. Any other comments on that before we move on to the next issue? Effie.

DR. CHOW: Oftentimes or most times, the centers that are funded are placed into academic health centers, and people that are hired to head those programs know nothing about CAM.

They may know research, but they know nothing about CAM, and I think there should be something that says they should know about CAM, have experience with CAM, because they call the CAM community and they are paid $100,000, you know, a year, and they get volunteer information from the CAM community. It is a little bit unfair. This is not just one case, it has been many cases that it has happened this way.

DR. ORNISH: Thank you.

Bill.

DR. FAIR: I would just like us to obviously include the academic health centers, but not make it to

the point that that is the only place where good research can be done. Your own institutions is a perfect example, and at our center, we have a consumer advisory board that directs us in what kind of things we should do, and so forth.

So, good research can be done outside of academic health centers, and even the CCAP Cancer Program is an example of that, that you can get a collection of physicians in private practice and come up with some meaningful data.

So, I wouldn't want it to slant it that it had to be academic health centers because you know the problems of that sort.

DR. ORNISH: Right. Presumably, this will be inclusive and not exclusive.

DR. JONAS: Dean, I think one way to do that actually is to emphasize building a research infrastructure rather than focusing on one particular group that would be doing that and saying we need to build a research infrastructure, and then you could list a number of groups that might be involved in that.

DR. ORNISH: Good.

DR. CHOW: And that assistance can go to the CAM institutions for research.

DR. ORNISH: Got it. Okay. Moving on here again, forgive me for being so directed.

Coverage of CAM Research Results in Medical Journals. We heard a number of people saying that there already is CAM coverage in medical journals, and yet when pressed, you would say how many, like from The New England Journal, CAM researches have you published, and they would say zero. So, the question is how to resolve that discrepancy.

George.

DR. BERNIER: I just wanted to suggest that we make it scientific in medical journals, because you might be able to attract a body of investigators that would be different.

DR. ORNISH: Thank you. Other comments on that?

DR. LOW DOG: Dean, one thing I thought was interesting was when asking the medical journals about their peer reviewers for CAM, they said that they were self-described, which was kind of interesting to me, so

people just sort of describe themselves as liking massage or knowing about it, and we don't do that. They ask if you are going to be a reviewer, what your board specialty is, I mean so you don't just sort of say I like cardiology.

DR. ORNISH: So, would it be enough to just say that we want well-credentialed and qualified reviewers?

DR. LOW DOG: Yes, I think that that came out of there.

DR. ORNISH: I think that is something we can all agree on. Again, it is specific enough, but being vague enough that we don't have to get into controversy. I don't think anybody would take a position that we want unqualified reviewers.

DR. GORDON: Let me just add one thing. I think that the distinction that Tieraona is making, and that we are making here, is a very important one with that concrete example. Again, this is another place where a concrete example of the difference between current practice and what we would advise is very important and can be very useful.

DR. ORNISH: I agree.

Let me just finish here. We have got two more to go, and we have got a couple minutes. One is the Private and Philanthropic Sector Involvement in CAM Research. People have already said that in one way or another that it would be nice to bring in the private and philanthropic sector. I think we can all agree that there should be increased support for CAM research from the private and philanthropic sector. That is kind of a no-brainer.

DR. JONAS: Dean, does that include business, private?

DR. ORNISH: Private sector would include business, individuals, private foundations, I think anybody that has money who wants to --

DR. JONAS: So, the key issue is incentivize, and Tom could probably address that.

DR. ORNISH: Tom.

MR. CHAPPELL: Only that the private sector will want the data to be private, number one, and everything we have talked about so far presumes the publication of the data, so they will have a different issue.

The second would be whether or not there is any exclusivity of the information.

DR. ORNISH: I think those are important points, but probably more detailed than we need to get into here.

MR. CHAPPELL: Okay.

DR. ORNISH: I know there are a number of private people, individuals, corporations that fund research that don't demand exclusivity. Those are important issues, but again I would save them for the October discussion at this point.

DR. GORDON: One other thing I want to say about those issues is I think it is important that the agenda be set by as wide a body as possible. One of the problems sometimes of public-private partnerships is that the established agenda is always the one that is propagated, so that the government may say, well, we would like you to do a little more work in this area, and I think having private and philanthropic groups involved can open up the field a great deal, and we can address this in more detail later. I just want to make that as a principle, that this is not about saying you have to do

it my way, this is about all of us getting together and figuring out what is the best thing to be looking at.

DR. ORNISH: The last issue, I think we will defer to Tieraona's discussion.

Joe, did you want to add anything?

DR. FINS: I am not exactly sure what that discussion will be, but on No. 7, just briefly, I think that whoever engages in research should adhere to standards for the protection of human subjects research whether they are within academia or outside of academia, there should be IRB protections, et cetera.

DR. ORNISH: I think that is something we can all agree on. I don't think anyone is going to take a position against that.

Session Summary

DR. ORNISH: So in summary, then, I think we have several areas that, as I hear you all, we have consensus on, but if I misheard you, or if I am misunderstanding you, please jump in.

One is, I think we all agree that there should be more research to fund CAM, that it should cover the entire spectrum of research, basic science, health

services, clinical research, that there is a sense of urgency for funding, that it should be as widely inclusive as possible, not just more money to the same old crowd, as Bill would say, that it should also include consumers' involvement, as well as other advocacy groups; that the money should go not just to NCCAM, but also to the NIH, that new money is more likely to be welcomed, and not to be viewed as controversial or as threatening; that it should be the highest standard of design, whatever language we come up with, it doesn't necessarily apply a hierarchy.

I guess the language that is in here, that we have already gone over, I think we are all pretty comfortable with that paragraph that begins, "To address the need for dependable information, it was generally agreed that research that meets high standards of study design and execution is required," and the rest of that paragraph. That is page 5, beginning line 7 on the one that is line numbered, and page 3 at the bottom of the original version.

There is some question about whether there should be separate CAM academic medical centers or

including CAM in existing medical centers, but I think we could all agree that CAM should be supported as widely as possible, in as many different venues as possible, which would include academic medical centers, but not necessarily limited to that, that we want to build a research infrastructure.

That there should be well-credentialed reviewers for journals, which would include scientific, as well as medical journals, and that any research should adhere to basic human studies, IRB protections.

There is a controversy having to do with what constitutes evidence based, is there a hierarchy of experimental design or is that not necessarily true; which areas of CAM should be funded, and who should do the funding and to what amount, and are there areas unique to CAM that require special designs like energy medicine, for example.

Have I missed anything, and do we have any differences about where we agree and where we disagree, or my assessment of where we agree or disagree?

DR. BRESLER: I would just add some language saying that research is urgently needed since consumers

are using these modalities anyway.

DR. ORNISH: Good. I agree. Anything else?

[No response.]

DR. GORDON: Dean, I would say you have done a terrific job of summarizing, so I don't have to summarize anything else, and I really appreciate it.

DR. ORNISH: Thanks. I have more respect for Jim, what you have to do now.

DR. GORDON: Thank you. It was a great job. We have pulled it together. We are going to take a five-minute break and then we will begin on the next topic.

DR. GROFT: Let me make just one comment to the audience. The report may not necessarily be available on July 16th. The report will be submitted to the Office of the Secretary of the Department of Health and Human Services by the 16th, as requested last year at the first meeting of the Commission. So, when it is released to the public, we are not sure.

If you have any questions, please come and see me at the break or during the two days of meetings. Thank you.

[Recess.]

Discussion Session I: Coordination of CAM Research and Regulatory Activities

Part 2: Regulatory Activities-Research

DR. LOW DOG: All right, if we can get started again. We are actually starting at No. 7 down here, The Role of Government Regulatory Agencies, Federal and State, Regarding CAM Research.

Here, if you can refer in your briefing book under the first section on page 4, so we are sort of all in the same place, under the first tab, Coordination of Research and Regulatory Activities, and then on page 4, you will find under No. 6, where we talk about state medical boards here.

We would just like some comments and feedback. Tab I, page 4.

You may have noticed there is also a notation. We want to expand this beyond just state medical boards, because state medical boards are what are regulating physicians. We would like to include all licensing bodies basically for acupuncture, chiropractic, other licensing boards, as well, not limit that just to physicians.

Do we have any thoughts or comments on this topic here, on how we can improve the role of the government regulatory agencies in research, in CAM research?

[No response.]

DR. LOW DOG: Part of what we heard here also was about some of the fear that some CAM practitioners had about really stating what they were doing, what kinds of treatments they were using, et cetera, for fear that somehow they would be punished or sanctioned by the state medical boards. I think this is where some of this comes in, is when we have got nonconventional or nonstandard sort of treatments, what are the limitations that keep people from applying for research.

We heard good examples of this with the NCI and their best-case series, but then we had CAM practitioners that talked about how they have been afraid to come forward to apply for research because they are afraid that they somehow would be sanctioned for that.

So, this is sort of the areas that we are talking about, how do we begin to resolve or address those issues and do we have recommendations around this.

DR. GORDON: Tieraona, do you want to talk about some of the problems that the people raised when they testified, some of the community-based CAM researchers raised, so that people can respond to that? They may not remember.

DR. LOW DOG: Well, I think that the ones where Nick Gonzalez came, and there were several other practitioners that were there with him on that panel. They talked about an open hostility towards what they did, and they felt that because of that hostility, and also the lack of information, they just didn't know how to go about accessing where do you go if you think you have got a treatment that might work for something, where do you begin to go.

When you are practicing medicine or treating disease, and you may be beyond your scope of practice, I think there are some real fears that somehow they would be persecuted or prosecuted.

So, we are sort of giving them this dilemma. We are saying you need to prove what you do, but we are going to make it very difficult for you to come forward because we may take legal action or sanction you in some

way if you come forward and say this is what you are doing.

So, it is sort of this dilemma that these practitioners described themselves in. So, if we are talking about medical boards or we are talking about licensing agencies, and we are talking about governments, and we are talking about then the reality of these people out there that are treating cancer, treating HIV, treating conditions, and they think they may have something, how do we begin to address that, and are there recommendations that we can make about this very real problem.

DR. GORDON: Let me just expand a little bit on that. One of the issues is people who are doing clinical work often do not have the expertise to do the research. They don't have the funds to do the research, and there is the fear of this kind of prosecution or persecution.

So, I think all three of those have to be addressed, and one of the issues that we have discussed over the last 10 years really is what Berkeley Bedell has called, and does call, field studies, field research, going out and helping people in the field do this work,

which requires experts and requires money.

Then, the other issue which I think I may have mentioned, that I have talked about more recently with NCI, with Drs. Jeff White and Bob Woody [ph], among others, is how do we provide and do we want to recommend providing some kind of shield for people who are doing legitimate research with an IRB as they do the research on these conditions.

Those are a little more specifics about some of these issues, and we can clearly, as a commission, we can make recommendations in these areas, and I think it is an important one that we ought to hear people's opinions about.

DR. LOW DOG: Effie.

DR. CHOW: I know this is about research, but education goes into this, and so, therefore, the state doesn't necessarily know what we do federally, like the Commission being existant. Perhaps there needs to be an educational aspect to the government regulatory bodies about the activities that is more accepted now, because many of them are still kind of their head in the sand.

This is what goes back to the definition of

"evidence based," what it means, because it scares the community. They think it is that white tower out there and very complex, and it is.

So I guess I am recommending education at all levels in order to move through this.

DR. LOW DOG: Joe.

DR. FINS: One of the things, going back to the Nuremberg Code, was that anyone who did research would have to have the same level of competence to provide the clinical care, so what this suggests is we need to have partnerships because to do this kind of research, collegially and responsibly, a CAM provider would have to partner with perhaps a doctor who cared for the disease under consideration to make sure the person got the best available, you know, traditional care, and this was complementary and additive.

So, I think we should foster mechanisms for that, and I think if we bring them in and they have IRB approval, an IRB would probably not approve it if the investigator wasn't credentialed.

So, it gets back to Effie's point about education and licensure, so I think it is a kind of a

Gordian Knot, and it gets more and more complicated. But I think the thing is here that it has to be done collaboratively, and I think we have to foster the collaboration word again. Otherwise, it can't be done appropriately.

DR. GORDON: Maybe one of the things we can do is, for example, to point to the model that Nick Gonzalez and NCI and NCCAM have been doing, which was we really presented as a model of a way to work together, where there is support for the research, there is work with a major mainstream institution, and at the same time, somebody is doing a very innovative and controversial therapy. So, I would suggest that as one model.

I think that we also have to address the earlier stage, though. I speak from the experience of our cancer conference over all these years, of finding people who are doing work that they believe is extremely helpful, that their patients believe is extremely helpful.

They don't have the resources even to put together the best-case series that is the first level of evidence that NCI and NCCAM are asking them for, and I

feel like I would like to once again say that there should be support to help people develop their research models, and that the CAPCAM panel that NCI and NCCAM have created is a beginning of this in the field of cancer.

Such a panel does not exist in any other field. So, it is an interesting model. I believe it is a good model. It has not yet gone as far as I would hope it would do in terms of reaching out and providing support, but they are trying to reach out and bring people in for a best-case series, but something like that needs to be available. Cancer is not the only illness or condition we are dealing with.

DR. LOW DOG: Can you put that in some sort of a simple, two-sentence kind of suggestion or recommendation, Jim, about best-case series research, because it is applicable to arthritis, it is applicable to diabetes, it is applicable to all the other institutes within the NIH and other academic centers and research centers, as well?

DR. GORDON: I will. Just at this moment, what I would say is that we, as a commission, feel that it is important for research institutes, including NCCAM and

the NIH institutes, and others, as well, to provide support for people who are beginning the process of doing research on promising CAM approaches, something like that.

DR. LOW DOG: Any other comments on this? Veronica.

DR. GUTIERREZ: I am thinking of a medical doctor in Washington State that has given up his medical license because of some approaches that he is using, and more recently I have heard he is thinking about going to Minnesota because of the law that is in place there.

I am wondering, and there is probably an organization in place already, a place we could have people who are serious about having their approaches researched. They could file somehow with their interest, their desire, their intent to pursue the research because it will take a long time to get all 50 state boards and professions on line with this, but perhaps we could have them file someplace, which would give them an umbrella of protection. It would make them legitimate in what they are doing, and let the public and all levels of government know that they are serious about their intent.

I think this would weed out a lot of people who are doing things less legitimate.

DR. WARREN: Which means by coming clean, they have protection against board actions.

DR. LOW DOG: Right, and I think part of our mission here is to support practitioners, but it is also to protect the public. Certainly, if you have somehow registered, then, you would also be expected to maintain certain ethical standards and informed consent.

DR. WARREN: Basically, do no harm.

DR. LOW DOG: Right.

George.

DR. BERNIER: We have understood that there are some CAM practitioners who are not licensed since that doesn't come in their discipline. Would the same kind of guidance be offered for those individuals, the same kind of protection we have talked about them having licensure. We have also talked about the fact that not all practitioners are licensed. How would doing research fit into that situation?

DR. LOW DOG: How would you see that?

DR. BERNIER: I would think that it probably

would end up without going through any regulatory body, and I am not advocating that.

DR. GORDON: I would see that if that occasion arose, for example, Feldenkrais practitioners in many instances have said they are not particularly interested, they may not be interested in licensure, but if they have a legitimate study that they would like to do, I would see it going the same route potentially through this. You would need the same protection of human subjects, they would need the same kind of consultation with people who knew about research or they might, and they would certainly need the same level of support that anyone else might to develop a study.

So, I don't think the licensure or non-licensure necessarily would make the difference. The standards could be just as rigorous if they didn't have licensure if they were going to be protected under this kind of research clause.

DR. LOW DOG: Does anyone know the answer on sort of the extent of the Nuremberg Code, because that actually is in violation of that?

DR. GORDON: What is in violation of it?

DR. LOW DOG: Of having a practitioner that is not deemed clinically competent to be able to manage that disease. That is part of the Nuremberg Code. So, I think one would have to take into consideration --

DR. GORDON: But that doesn't have to do with licensure or non-licensure. The issue is not licensure.

DR. LOW DOG: Well, you have to be able to define competency, though, and so you will have to have some sort of mechanism for determining competency in somebody who is not licensed, where there is no body even if it is their own body that would develop that.

DR. FINS: Maybe what we could posit is a certification for NCCAM-related research, so that it is a special certification process if they want to engage in this even if they are not licensed, but it would be rigorous in order to protect the subjects involved and to ensure that there is adequate referral at the follow-up, but some sort of certification process.

DR. WARREN: You are not talking about a restrictive type of certification, though.

DR. FINS: No, just if they want to participate in the best-case scenario kind of scenario.

DR. WARREN: I see licensure as almost a censorship.

DR. LOW DOG: I don't think we are getting licensure here. I think that there is a distinction that is being made between research here and practice. You can practice, going out and practicing. If you are participating in research, though, because of some of the horrors in our history of research, there have been codes that have been set in place to protect human subjects, and part of that is you have to be competent, clinically competent to be able to care for that person.

In individuals who are not licensed, that competency will be difficult to ascertain. So, I think Joe's recommendation there is simply that through NCCAM or through NIH, the NCI, other places, there could be some sort of instrument set in place that would allow them to participate in research, so you are not censoring them, so this is different from practicing and participating in research and research on subjects.

Are there any final thoughts on that before we move on, because we have got the juicy stuff still coming?

[No response.]

DR. LOW DOG: If you will turn over to page 8 in the same area you are at, the FDA Insert No. 2, the Draft Issues and Recommendations. That will sort of help guide you with some of the language that has already been attempted to answer some of these next questions.

The first one obviously has to come down to the whole DSHEA, which everybody has raised issues around Dietary Supplements Health Education Act across the board. This was the staff's attempt to try to address some of these issues, and I would like some comments and feedback where we have got adverse event reporting, if we can start there. Page 8 in your briefing book, the FDA Insert No. 2.

I think this is a big area about DSHEA, and I was sensitive to Tom's point about botanicals not sort of overtaking the whole commission here, because there has been so much focus, but I think we need to address it and see where we come and where we have consensus on this.

George.

MR. DeVRIES: In terms of AER, it seems like the same rules should apply for conventional, as well as

CAM practitioners. There shouldn't be a higher standard or a lower standard for CAM would be my suggestion.

DR. FINS: The OIG report that some of us had, I guess, says that the standard for these agents is lower than over-the-counter drugs, and they have a whole series of recommendations that seem very prudent and well reasoned. That might be something, you know, you are not getting into the details, but it might be a way of embellishing what was intended in DSHEA in the OIG report from the Department of Health and Human Services. They are very concrete recommendations.

DR. GORDON: Maybe one thing we need to do is make sure that at least a summary of that report is available for everybody.

DR. LOW DOG: We have gotten it, the OIG report.

DR. GORDON: So that we can all take a look at that between now and the October meeting to have a sense of what is recommended.

DR. LOW DOG: Dean.

DR. ORNISH: I just want to point out that Senators Harkin and Hatch were the authors of DSHEA, and

so anything we say about it, we should say with that in mind.

DR. LOW DOG: I think we should keep that in mind, but we should also just keep in mind what we really need to do on the Commission, as well, and what is in the best interests of the public.

Adverse event reporting, OIG was interesting, because you need to get some industry buy-in here, and the report was quite interesting because a number of the industry and industry-advocating bodies had some real issues with it, because they see this as being more under food adverse reporting than pharmaceutical drugs because of the language of DSHEA, as well, so I think that it was an interesting report.

DR. ORNISH: I just want to clarify that I am not saying that we should abandon the interests of the public in favor of politics. I am simply saying that for the Interim Report, we might want to avoid taking positions that are more controversial than they need to be or more specific than they need to be, that's all.

DR. GORDON: I think for the Interim Report, what is in the Interim Report, and I think the focus that

everybody needs to turn to first in their minds, is looking at what the provisions are of DSHEA and what is not being implemented. I think that covers such a huge territory at this point including the adverse events reporting. There are plenty of sort of language in DSHEA that is pushing for much better reporting of adverse events, it is just not happening, just as there is language in DSHEA about good manufacturing practices, which have still not been implemented.

I think that we are in the area where we really have not worked with DSHEA to see what it can do at this point, and part of what we can I think is to lend our weight to implementing DSHEA as it was meant to be implemented.

DR. LOW DOG: I think that that is a real important point. If we recognize or believe that there is beneficial effects from dietary supplements, that some dietary supplements and botanicals can be beneficial, and we are trying to maximize the benefit to the public, part of maximizing that benefit will also be assuring the public that there is a route for reporting adverse effects and that manufacturers can be notified when there

is a potential problem quickly.

I think some of the European models would be interesting to look at, how they go about reporting adverse effects. We would have never determined the problems with St. John's wort in this country as rapidly as they were able to find, isolate, and discover the problem in Europe only because of the way they report these problems, and notifying manufacturers rapidly of the problem.

In this country, if there are 1,000 manufacturers making a botanical product A, and nobody knows who they are, there is no way to really get the information out to the manufacturer. We can put a very positive spin on this including making sure that DSHEA is implemented and the funds are implemented, but I think that adverse events, there has been a lot in the media lately, and I think the consumers are concerned about this, so we really do want to address it.

DR. ORNISH: Just to follow up on the point I was trying to make, it is my understanding that with DSHEA, at least from talking to Peter Reinecke, is that the legislation is that it needs to be truthful, non-

misleading, and substantiated, and yet, the FDA has never asked the company to substantiate its claim.

The question -- and this is really not a point, it is really a question -- is it simply a question of implementing DSHEA or revising DSHEA? Is the language there, but it is not being implemented, or is it not really there at all?

DR. LOW DOG: Joe.

DR. FINS: The OIG report does not make any comment as far as I can tell about amending DSHEA. It just has other recommendations, which would be in concordance with the goals of DSHEA. It is an implementation issue.

So, I don't think we necessarily have to make it more complicated. I mean this I think would be a very important first step in identifying adverse events, which they say are less than 1 percent, actually come to regulatory attention.

I think you are going to put it in a positive light, which I think is important if we are talking about consumer choice, we also want to talk about consumer protection. This is in that spirit that I think it is

being recommended.

DR. LOW DOG: Do we all have consensus that we would like to recommend funding, so that FDA could fully do its job to be able to implement DSHEA? Is there anybody that really doesn't agree with that?

[No response.]

DR. LOW DOG: Any other comments? Bill.

DR. FAIR: Maybe you or Joe could answer this. I am curious, the business about less than 1 percent, the FDA receives reports on less than 1 percent of all adverse events.

Now, in my experience, we are all familiar with the Pomerantz study showing there is 106,000 deaths per year from adverse effects to standard medication, and I think adverse effects on clinical trials are very assiduously reported, but I can tell you my experience is that a lot of adverse effects goes on in the routine hospital that are never, ever reported, so I don't know what this 1 percent, how that relates to the total, you know, the denominator of adverse effects going on in the hospital in a voluntary report. I suspect it is very low also.

DR. LOW DOG: I think we would agree that adverse event reporting is low across the board, period, by all, and that we don't want to single out CAM as somehow being this dangerous dietary supplements or this dangerous thing.

DR. FAIR: Exactly, that is my point.

DR. LOW DOG: I don't think we want to do that, yet, I think it is irresponsible to say that we are going to go down the same path that is bad in conventional medicine, just as in conventional medicine, that dietary supplements, there should be an adverse event report for serious adverse events, so that we can detect trends or patterns where they might arise, or certain groups, that a certain dietary supplement, a particular group where that may be dangerous for a particular health condition.

So, I think that those are important. I don't think this Commission, I think we have to make some sort of statement about it without overburdening, without making a big thing about this, I think we do need to address it.

DR. FAIR: Okay. That is my point.

MR. CHAPPELL: To reinforce your point and your

question about the efficacy of DSHEA, DSHEA gives manufacturers a range of language that it can use for claims. It gives a boundary as to what it cannot say, and then it requires substantiations of what it is they are saying.

So, if FDA were to implement DSHEA, they would be able to contact manufacturers and find out whether or not those files, their files contain the necessary substantiations. So, it is a rational piece of legislation and it is a model for implementation that is done elsewhere and it is something that can be implemented.

DR. LOW DOG: So, again, what I am hearing from you is that the funding and that should be in place, so that DSHEA could be fully implemented and that perhaps it is premature or not accurate to say it doesn't work because it has never been fully implemented, so nobody really knows if when it is fully implemented, if there is holes.

MR. CHAPPELL: I am just wondering whether we should be asking for funding or not. I think we should just ask that it be implemented, because who is to say

whether you give them the funds, that it still will be implemented. I mean the point is our claim should be that FDA implement DSHEA. I am not sure we should ask for additional funding, but just implement DSHEA.

DR. LOW DOG: Yes, I think that FDA was pretty clear when they were here, that they were given this big burden and were given no additional funds, and from speaking to people at FDA, perhaps we could just say whatever is necessary basically, and that maybe the funds should be earmarked, Tom, for this particular --

MR. CHAPPELL: I don't know enough about implementation strategy at this point to comment on that, but I will go with your wisdom on that.

DR. LOW DOG: Joe.

DR. PIZZORNO: Two comments. First, although we have talked about this a lot in our discussions, I don't see this showing up in the actual recommendations, that is, the need to have CAM professionals involved in advisory boards for the FDA and these other regulatory agencies. I think we just need to be real explicit in our statement that that happens.

The second is in talking to leaders in the

natural products industry, they are in full support of FDA fully implementing DSHEA, however, they are concerned about simply giving a blank amount of more money to FDA. They would recommend that that money be clearly identified with specifics tasks the FDA must accomplish.

So, I think the regulation we need is there, let's make sure it is going to implement it.

DR. FINS: I think, you know, what we could perhaps suggest is that full implementation of DSHEA, consideration of the OIG report, and some sort of reporting back to Congress or an oversight committee at a designated period of time to revisit the legislation with additional data.

DR. LOW DOG: One of the issues that has also come up has been about research and dietary supplements and proprietary protection, and we have heard from pharmaceutical companies, as well as industry members, that this has been a real barrier in their opinion to furthering research or paying for research because if they pay and go through a new drug application, and go through all the rigors that come along with that, and then get to make a drug claim on the product, you can

still go to the health food store and buy any one of those types of similar products off the shelf, and they have no way of recouping their investment.

Now, that has been raised by a number of people, and I just wanted to know any thoughts about that.

MR. CHAPPELL: First of all, the route of the NDA allows you to complete that process with a very clear claim, and that claim is disease prevention based. It is a tighter, bigger promise than you are allowed to make with DSHEA. So, it is worth the pursuit to be able to make a tighter claim.

Secondly, there are lots of ways that you can formulate a product to put it into the range of an invention. Those opportunities presently exist. If I want to mix three different kinds of echinacea, no, I am not going to be able to make a patent, build a patent around that, but if I have different ways of processing echinacea, I have an opportunity for a process patent.

So, I feel that natural substances, as they are, are natural substances. They are there for the public, and whatever we do as manufacturers to provide

those substances for their benefit, that is public domain. If there is something I do to a formula that is an invention, then, it ought to be allowed for an invention, but those opportunities exist today.

I see no need for changes in patent laws, and I do see a benefit as a provider to consumer benefits to go the extra mile to make the promise that you can't make in DSHEA, to say this product will do the specific thing you are looking for, and that is worth getting an NDA for.

It is long and expensive, but you make those judgments in a business, so I have to say it would be nice if there were a middle ground here, where you didn't have to spend five years or $5 million, and I am open to that possibility, so there is a great gap between DSHEA and an NDA, and we ought to look to how you can fill, and that is addressed in some of these other recommendations here, but at present, I don't see that the intellectual properties laws need to be changed.

DR. GORDON: Wayne.

DR. JONAS: I just want to reiterate that. I think that we will get into a Pandora's box if we try to say change NDA, change patent law, that type of thing,