everything else constant, is really a myth in many of these interventions. We may think that we're only intervening in one area and only measuring one thing, but often times we're doing more than that, even if we're ignorant of it.

And, finally, particularly in many -- Chinese medicine as you well know, and other systems, the interaction, even on a pharmacologic level in botanicals, the interaction, there are thousands of alkaloids that are present in a botanical. We tend to focus on one as being the active ingredient, missing the fact that not only are the others often active, but the interaction between them is different than what happens when you just isolate one thing. So those kinds of things, I think, are problems of this committee, at least I'd like to think so.

And, finally, on a completely different subject, the challenges that come from trying to get insurance companies, Medicare, mainstream organizations, to adopt these kinds of approaches. I tend to find that they either are completely rejected out of hand and only because of a lot of pressure do they finally do it, or they tend to embrace them non-critically simply because their consumers want them, without necessarily doing it in a more thoughtful way, which is why I think our committee would be helpful to them.

DR. GORDON: I want to go on to Joe and then

to Charlotte. But before doing that, Dean, how do you tie in? Is there a way that that fits, particularly in research rather than in service delivery?

DR. ORNISH: I think it's in both. Particularly, let's talk about -- the research we've already talked about. And I'm first and foremost a researcher because I really believe in the power of science to help people sort out what works, what doesn't work, for whom and under what circumstances.

And while not everything that counts can be counted, as Senator Harkin said, a lot of things can be. And while we may not be able to measure chi directly, we can -- we don't necessarily have to understand the mechanisms to understand that something is having an effect, that chi is having an effect, for example. We should be able to measure the outcome of that, even if we can't measure chi directly.

But also I think this committee can be particularly helpful from the standpoint of -- let me back up. In dealing with insurance companies or HCFA, there is a certain bureaucratic mind set where people are often reluctant to take a risk on something new. And it's understandable because if you say "no," you keep your job. If you say, yes, it's a risk; if it doesn't work, your job may be in jeopardy.

So it's this whole CYA syndrome, cover your

butt, that I come across. And if a well regarded commission like this one says, "We think this is something that's worth doing," in a way it provides permission for health services agencies like HCFA, or many private research companies, to go into the areas that provide them some degree of coverage in that area, that may enable them to take risks that they find otherwise have a harder time doing.

DR. GORDON: Thank you. Joe, and then Charlotte, and then George, and then Tom.

DR. FINS: I want to just tack onto what Dean said and suggest that we have to move beyond the purview of the science into the social sciences and a have a less reductionistic approach. I would be interested in moving the research agenda to the experience of the patients and their families more broadly construed using sociology, anthropology to understand.

Maybe you can't identify chi, per se, with a positron emission tomography test, but you might be able to look at populations of patients whose lives have been improved through an enhancement of that entity. I'd also like to look at issues of access.

I think there is a lot of anecdotal information and access is a problem. We need to really know what the scope and nature of that problem is. Who are the people seeing, what are the practitioners out there, what

are their specializations, what is their training, what is the expectation of families and patients?

And this could be disease-based, you know, patients with breast cancer, with AIDS, with sickle cell anemia. We could go through the list. And we could look from diseases, instead of botanicals, up. We can look from patients with diseases down to the various modalities and mix of modalities that they are using.

And related to this, I think people are talking about the clinical trials issue, is that I, as a medical ethicist, interested in clinical research and research issues and the ethics of the regulation, I'm not sure that the research establishment is really adequately trained, that the average institutional review board in a medical school or in a medical center is going to be receptive to these ideas.

And so I think one of the agenda items is really to find out how their training prepares them to adequately review these protocols and ensure adequate access, and at the same time adequate protections of human subjects who are being exposed to things that are a little bit off the beaten path. So I think those are my thoughts.

DR. GORDON: Thank you very much. Charlotte?

SISTER KERR: Your question was what do we need to know in order to do this number one task. And I'm

really, again, amplifying what everyone else has been saying.

But, Jim, one of my most penetrating memories of work at NIH, in an ongoing conversation over at least the last 20 years, has always been this issue of paradigms and methodologies in research. This conversation is the longest and the oldest for me and it continues, as far as I know. Which comes to your question, maybe somewhere at the same place.

Now my number one question, and I suppose from Steve at NIH, would be where are we now in the conversation of methodologies and paradigms? So, basically, an update, because this same conversation goes on and on and on. It is essentially a study of the part, in the reductionistic theory, not the whole.

So I think that's the first thing I would like to know and not so much that we've got three studies on osteoarthritis, you know, whatever, which is important, but I'd like to know that.

For myself, I just want to make a comment about something that's been said early on, is the study of chi. My own persuasion is that until we -- of course this is the Nobel Prize for the person who is up for it -- as we all know in this room, the chi, concept of chi, is the fundamental starting point, in my opinion, of the theory and

the application of Chinese medicine. And, I believe it is the fundamental starting point for most of the energetic medicine which is the medicine of the future, or in the present, and acupuncture just being part of that.

What I want to say is that if we have conceptual frameworks that embody some of what I'm saying, which are ones of relationship, if we have ones that believe what the physicists are saying, and as far as I know they are still saying, their philosophers, that were probability patterns of interconnectedness, then not only is our research going to be, it will be the place out of which we flow into research.

But it then it has to inform our practice, it has to then inform the health care system, if you want to call it that. It has to inform education. For me, this still remains one of the most important points we need to converse on.

DR. GORDON: Thank you very much, Charlotte, for calling us to those issues. I have a question for you and maybe for everyone, which is, do we want, in addition to Steve Straus presenting where NCCAM is, do we want other presentations, the state of the art of looking at a new paradigm of understanding chi, of understanding --

MR. CHAPPELL: Yes.

DR. GORDON: Yes. Okay.

DR. FAIR: What is the problem with the botanicals, looking at them singly?

SISTER KERR: The botanicals, I hadn't really put that together. To me, this conversation is gifting us again to call us back to have a look at the whole. In this conversation it seems even more apparent than the individual, even though I think it's the same.

DR. GORDON: Let me go to George, Tom, Effie, and George DeVries. That's who I have on the docket right now.

DR. BERNIER: Thank you. I'd like to go back to the original question that was asked. And that is, is it to be the scope of this group to decide what can be studied and what can't be studied? Are we to put down a prescription for what can be studied?

I've been personally very impressed with studies that I have read in the medical literature that have been comparing activity or outcomes with people who have been treated with one form of medication versus another. And they have found in that literature that it is possible to come to a conclusion.

But if we as a group say that it is not going to be possible for a whole area not to studied, I think that's very important for us to be up front about. I think that's probably the single most important issue that we are

dealing with under research.

DR. GORDON: Is there an issue that you -- I don't know that we have any particular -- is there some that you have seen that can or cannot be studied?

DR. BERNIER: I guess it was in Senator Harkin's talk to us today. I think he was saying that it's NIH's job, not ours.

DR. GORDON: No, I don't see that. It's not our job to focus on critiqueing their research agenda. It's our job to consider -- there is a lot more research than is being done currently at NIH. It's our job to think about some of the research issues in the broadest possible way. And that's there in the Executive Order.

I think what he doesn't want us doing is passing judgement on research grants that have been given by NCCAM to particular entities, or focusing at that micro level. I think that our charge is very different. I think the dialogue between us and NCCAM, and us and the Defense Department, and us and many other entities who sponsor research, I think will help to clarify some of the questions about what should be studied and who should be studying them. And also, what's left over, you know, what other issues are not being addressed.

DR. BERNIER: I think the implication has been that there are some that cannot be addressed. Several

people from this group seem to feel that way.

DR. GORDON: I don't know that I've -- do you know which ones, because maybe we should talk about that? I haven't heard that.

DR. BERNIER: I thought that's what the bottom line to Dean's discussion was.

SISTER KERR: Dean's not here. George, you said this, you thought, was the fundamental issue. And I didn't understand what you thought was the fundamental research question.

DR. BERNIER: I'm sorry. What I was trying to say, and I don't think I made it so clear, was that if there are areas that are going to be considered to be out of bounds for research, for comparative clinical trials, for instance, that it's really important that that be identified up front.

DR. GORDON: I think my interpretation, and let me see if there is agreement, my interpretation is that there may be different methodologies that are needed to address different kinds of problems. And that the same methodology will not fit with some of these issues that we're raising. And I think there is a question of appropriateness of methodologies to some of the studies that we feel should be done, rather than that there is anything out of bounds. Is that the sense of everybody?

MS. CHOW: Also new methodologies.

DR. GORDON: Yes, exactly.

MR. CHAPPELL: Related to the question of methodologies is the underlying assumption that there is a difference between illness and wellness. And in this Country we have historically thought of medicine as something for illness. Yet the popular movement, the self-care movement really thinks of wellness as the goal.

And if we don't define the domain of medicine, complementary and alternative medicines and practices, we will continue to be dragged into this debate of whether it is reductionistic or holistic, and so forth. It has to be tied to a new vision, a new definition of what it is we're trying to solve.

And consumers are looking, the reason there is a popular movement is because they want to prevent, they want to take more responsibility for their health and they are going to become as preventative in their practices as possible.

So I believe we need to wrestle with this question of wellness versus illness, or whether we're going to talk about wellness as the overall goal that includes illness. And that's my first point.

And, secondly, if we're going to increase knowledge, that knowledge has to exist at the FDA. There is

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such a demand for pharmacognosies right now, or anyone involved in natural medicines, that they are moving to private industry, they are moving out of the research places, out of the universities, and out of the FDA.

We don't have sufficient talent at the present time to assess these debates about DSHEA claims or over-the-counter drugs as they relate to -- because the talent in this specialty field has gone from the FDA. We have to expect that as well.

DR. GORDON: Thank you very much. So just to restate it, you are talking about possibilities of addressing research issues with regard to wellness and the wellness-illness continuum?

MR. CHAPPELL: I was saying that all the methodologies that we're debating here really are tied to the bigger question of wellness not illness.

DR. GORDON: Okay, thank you. And we're going to Effie, George Devries, and then Charlotte again.

MS. CHOW: You stole part of my idea. But I'd like to reinforce that because I think we maybe need to redefine "complementary and alternative medicine" and see this as a part of only the health care system, and that it really is a life system.

We're talking about promoting health. Like the Olympic athletes, you know, are using herbs and Qi Gong,

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We're talking about promoting health. Like the Olympic athletes, you know, are using herbs and Qi Gong,

and acupuncture, and all that. So we need to study the super healthy to get the human being at a higher level. And then, of course, a practice of having people come in for tune ups, you know, like cars coming for tune ups.

And I think I'd really like to throw that out in order to say research, are we really talking about complementary and alternative medicine? We're drawn into a medical model. Are we really still talking about a medical model? And so I would just like to throw that out. Maybe it's something that we need to deal with, I don't know.

I see it as a life system. When we deal with the people in working with them, we don't deal with their pain, we deal with the relationship, right? We deal with how politics is affecting them, too, and how economics is affecting them; this isn't medicine. So, again, it goes back to social issues as well.

DR. GORDON: Thank you, Effie. George Devries?

MR. DEVRIES: This is a question almost, for the Commission, more than a statement, which is we've talked about, shall we say, taking some latitude with how we're looking at the different subjects related to complementary and alternative health care. And part of that is, as a Commission are we willing to look at some of the experience that other health care systems have had outside of our

Country, taking more of an international approach than just an American approach? Because I think certainly there are other countries who have perhaps more information, more experience, better backgrounds.

And, in particular, with research, there has been some promising research in Europe related to herbal supplements. We've actually looked at some research coming out of Asia related to traditional Chinese medicine. And while we may not rely on these as conclusive, they may provide this Commission with some direction, some ideas and approaches that are interesting.

DR. GORDON: Let me say, on both issues that have been raised, the answer is, yes, we can expand. And I think it's really up to us to judge the limits of the expansion. We don't want to get so broad that we lose everything. But on the other hand, issues of wellness and illness certainly, I believe, tie into our mandate on complementary and alternative medicine. And, as well, issues related to how other cultures, human systems and in this context, the kinds of research that are going on in other cultures.

And I just want to remind you all that we welcome and really need specific suggestions. If there are particular research councils in particular countries, or particular individuals who have grappled with some of these

questions, we need to hear, we want those names. We don't have to have them now. So please feel free, as you make your suggestions, to remember to send in follow-up information about people who you think are doing the most exciting work, because that's how we're going to form the panels.

Let me go the Charlotte and then back to you, Effie.

SISTER KERR: After Tom spoke, I wanted to push the "pause" button. And I feel a real need to pause because when you spoke about the popular movement, I don't know if you said it this way, but what I heard was the popular movement really is creating a new vision. I was then able to go back to what I really feel.

When I look even at our four mandates, I feel like I'm supposed to think about how to teach people in Western medicine about how to find an acupuncturist, or a chiropractor, or what echinacea is. And I don't I hear philosophy and healing, I don't hear anything about ecology. I am primarily a public health person, whatever else all I've done in my life. I don't hear the talk of nutrition. Even today we had something new on the horizon in terms of cancer research. So some of what Effie and Tom are saying, we'll probably have to drop down into that again.

I feel really happy about this conversatio

because I really have been around a while and I'm not sure -- I feel like I've been a part of this 20 years on that track or with it, I'm still not sure we're on the right track. It may be the conversation of wellness and medicine again, but what we've done has been really important and wonderful.

And I almost feel like a moment to pause and breathe again and say, "If I had to give directions to this wonderful Country, to other people committed to healing, what do we want to say to them and to myself?" And I think it's a little bit different than I started to feel here.

DR. GORDON: We have Effie next and then Dean.

MS. CHOW: Go ahead, Dean.

DR. ORNISH: It may be easier with the microphone here. I really appreciate your saying that, because, you know, the longer I'm in this field, the more I realize that sometimes the most healing things are the ones that are the most difficult to measure.

And what I love about the battles with various agencies that we've had over the years, and insurance companies, is that the breadth of people who come together. In this room, in this Commission being formed is a perfect example of that even. When HCFA finally approved our demonstration project, the people who fought the hardest

for it were people like President Clinton, but also Dan Burton, who ordinarily had nothing to do with each other, and everything in between.

The Senate hearings on alternative medicine a couple of months ago, we have Arlen Spector and Tom Harkin, who are on different sides of the aisles. I don't know of any arena that brings together a wider range of people who have a common goal here. And that itself is healing.

You know, the idea of finding common ground and creating community, of getting past the polarization that not only separates us and often brings the Government to a standstill, but I personally believe is a root of illness and suffering, That what's happening around this issue of complementary and alternative medicine is a model of the very conditions that I think we need healing. And I would love to somehow bring that perspective into whatever report that we bring as well.

DR. GORDON: That is certainly my hope that this perspective will inform every aspect of the report. I think there is, again, and we don't need to think too far down the line except just to share our perspectives, that there absolutely needs to be this balance between the sense of connection and the sense of some of those things that count that can't be counted.

And at the same time there need to be

specific recommendations for legislation. And I think if we can maintain, all of us, that balance, as a committee we'll be doing an enormous service. Effie?

MS. CHOW: That's what my former comment was, that CAM, complementary and alternative medicine, is really about life and the promotion of connectedness in people and nature. And nutrition is very important.

But back to the research issue. We've been talking about examining the herbs for what components herbs have, and what it works or not, and how it should be done. I think in education as well, we have to do research into methodologies of how education can be given, developed.

It perhaps doesn't take, also, the usual protocols of education, the rules and regulations of education, it has to be more creative and it has to involve more demonstration types of things. So I would think research into methodologies of education.

And then also systems integration. China was given as a good example of how Chinese medicine is integrated with Western medicine. It is totally not ideal, but we need to do research on the integrative aspect, the systems approach. So I just wanted to move into the broader picture.

DR. GORDON: Thank you. Tom, before you speak, Steve wants to introduce someone who is in a

Mr. Groff

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significant measure responsible for all of us being here.

MR. GROFT: One of the nice things about a new position, it gives you the opportunity to work with different people. And one of the individuals here at the Department and who is instrumental in getting all of you here, has been Steven Ottenstein, who is a White House liaison from the Department of Health and Human Services to the White House.

And it has been so gratifying to be called down here and get someone who not only answers the problem but gives you feedback rather quickly. And he just did want to mention the clearance about another Commission member.

MR. OTTENSTEIN: Yes. Ms. Low Dog, who is the 15th member to the Commission has just cleared. So, in addition to the other two, that was the intent to announce, we'll do the third one, which will give us actually 14 members. And then Stephen mentioned that we're hoping to expand the Commission to 20 members. So the additional six will be coming in the next few months.

MR. GROFT: I think now that we've launched, probably the appointments will come quickly. And for those of you who came in yesterday, things happen very quickly.

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MR. GROFT: I put these three people under considerable stress last Friday. And my public apologies to these people. We got them cleared and everything is okay, so thank goodness.

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SISTER KERR: I think he just needs a round of applause.

(Applause.)

DR. GORDON: Steve, did you want to add anything?

MR. OTTENSTEIN: Just good luck with everything. I was glad everything that has happened and we are on the right track and, hopefully, we'll get the other members done shortly, and your report will be fabulous. I'm looking forward to working with you.

DR. GORDON: Great, thank you.

MR. CHAPPELL: My graduate training is in religious philosophy, but I see the correlation here, as I look back over the globe, and my training is that we're the youngest society on the globe. And in the case of alternative medicines, we're adolescents in comparison to the years and years and years of knowledge of many of these other modalities.

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And the reason that consumers are kicking back is that they know they can get what they want

alternatively to the system that we've developed over the years here. And so if we're going to increase knowledge, it's important to me that we find out what it is the consumers want answers to.

I'm on another board, and the dean of that board announced that the university was going to modify its curriculum. And I asked him who was going to do the modifying. And he said, "Well, naturally the academicians." I would like more than the specialists determining what knowledge we want to determine. I think consumers need to be consulted, and that's a very easy and practical process.

DR. GORDON: That's our plan. And I'm hoping that we will have at least one or two of these meetings before the research panel to get some more of that input. And, hopefully, tomorrow we'll have some, as well, from any people who are sitting out there or in the area. Fortunately, in this area, most of us are consumers as well as practitioners, so we have that advantage too. Let's see, Buford first, and then Joe.

MR. ROLIN: Thank you. I just wanted to follow up on what I've heard here, and certainly Tom just alluded to what I wanted to mention here when he talked about the consumer and that aspect. But from my perspective in dealing with this, in our community we're approaching this now from the holistic approach, in line with what

Charlotte has said, which has to be inclusive of the methodologies.

But we also have to get back to actually, when we are talking about all of this, bring in the nutrition aspect in all of that, and dealing with the wellness aspect as well. And that's where we're beginning now, and we have to. In order for the Indian communities to survive, we've got to. And we've begun there to do that.

And I think it's important, not only for this Commission, to be aware of that we're dealing with the same issue with the public as well. And we've got to do that. I just wanted to make that comment.

From the holistic approach, you know, that's going to get to spiritual, as we talked about earlier, and the mind, the body. And it's going to bring in, as we've talked about, the botanical aspect. We're going to find the methodologies to deal with all these issues. But I just wanted to add that comment. Thank you.

DR. GORDON: Thank you.

DR. FINS: I just want to say that on this historic day there is an element of paradox to this. CAM has really come into its adolescence and it's a really momentous moment. But just as complementary and alternative medicine poses some element of challenge to conventional mainstream medicine, the mainstreaming of complementary and

alternative medicine, which I think is embodied in the formulation of this very panel, is going to be a challenge to what is the best of what Sister Charlotte had talked about.

So I think that what we really need to do is really keep a focus on the public health, the interests of patients and consumers, and try to see this as an opportunity, as you said, to kind of recraft what it means to be a healer, whether it's conventional or traditional, but appreciating that there are risks and benefits to this mainstreaming process. That we have to not throw out the baby with the bath water and can maintain what's best in what has brought this movement this far this quickly.

DR. GORDON: Joe, I have a question for you. Do you see any of those specifically related to research that we ought to address?

DR. FINS: Well, as I'm thinking about mainstream academic medicine, there is still a skepticism and concern. And I think that there is going to be resistance. And I think we have to reach out to those communities to ensure that, as I think Dr. Ornish has done and others have done, to maximize the utility of this area.

And I think also there are certain proposals and grants that will go to entities that are outside the national center in other parts of the NIH where it may not

be as responsive to this kind of inquiry. And so I think that there may be resistances in other agencies and other parts of other funders in the private and public sector.

DR. GORDON: I would like to get just a little input and then we'll move on. I'm wondering if we want to be asking the different agencies and private funders something about their criteria and why they are using those criteria. And then perhaps amplify the criteria or develop new ones. Is that something that --

DR. FINS: I think that would be an absolutely good idea because, outside of the select entity within the NIH, this could be construed as an orphan topic. And so I think we have to engender support in these other agencies and in the private sector so that the research dollars and talent is there.

DR. GORDON: Okay. Thank you. Bill?

DR. FAIR: We talked a lot about having research integrate the various modalities and not looking at one particular approach. And I would like to make a plea that we also integrate the results of modalities. In other words, Tom used the term "illness," and I don't know whether that was a specific choice or not, illness as opposed to wellness.

But, again, making reference to Michael Ernst, Michael talks about the difference between disease

and illness. Disease is a physiologic process affecting the body, and illness is the person's perception of that disease. And physicians will tell you they may see two people with seemingly identical disease, and one does well and the other does poorly. And we can't explain it solely on the basis of the disease process.

And I think when we evaluate things, in oncology for instance, we're always looking for the response of the tumor. But that may not really tell you the response of the patient. I think that we ought to make an effort in research, when we evaluate the results of any of these modalities, we have to evaluate the total effects, not just using an isolated marker of effectiveness.

DR. GORDON: Bill, do you have any thoughts about how to pursue those kinds of studies or how to present, how we can get our hands around that and address it?

DR. FAIR: I think a lot of people know more about this than I do. The most obvious thing that's receiving a lot of interest right now is the quality of life measurements at the same time. But I believe that there are other things that could otherwise be measured. Tai Chi. I mean, maybe the tumor doesn't shrink, but the individual is much more supple and much more interested in life, and things like this.

Mr. Groft
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DR. GORDON: One of the issues this brings up for me is the whole field, which has not been looked at very much, and certainly by the mainstream, but biochemical individuality and uniqueness. And I'm wondering if this isn't an area that we also want to be taking a look at? (Many nod affirmatively.)

DR. GORDON: I'm seeing some nodding heads, so that may one way to approach it, biopsychosocialspiritual individuality. Okay. Other issues or other comments? We have some time. Is there anything else that anyone would like to add or questions you'd like to raise about this point? Yes, Effie and then Conchita.

MS. CHOW: Just one point. Just to allow the practice to be practiced as spiritually as possible, instead of squeezing it into a certain mold to get outcomes. The outcomes should be -- you know, if you squeeze a practice into a white-walled, sterile place, the results will be different. It's very different then, say, in a natural habitat. And that research should be done first to gather statistics, outcomes in its natural habitat.

MR. GROFT: Has anyone run into any problems with institutional review board clearance of research? I mean is this something that we need to look at as well?

DR. GORDON: Did "natural habitat" bring that up?

Mr. Groft instead of Dr. Groft

DR. GORDON: One of the issues this brings up for me is the whole field, which has not been looked at very much, and certainly by the mainstream, but biochemical individuality and uniqueness. And I'm wondering if this isn't an area that we also want to be taking a look at? (Many nod affirmatively.)

DR. GORDON: I'm seeing some nodding heads, so that may one way to approach it, biopsychosocialspiritual individuality. Okay. Other issues or other comments? We have some time. Is there anything else that anyone would like to add or questions you'd like to raise about this point? Yes, Effie and then Conchita.

MS. CHOW: Just one point. Just to allow the practice to be practiced as spiritually as possible, instead of squeezing it into a certain mold to get outcomes. The outcomes should be -- you know, if you squeeze a practice into a white-walled, sterile place, the results will be different. It's very different then, say, in a natural habitat. And that research should be done first to gather statistics, outcomes in its natural habitat.

MR. GROFT: Has anyone run into any problems with institutional review board clearance of research? I mean is this something that we need to look at as well?

DR. GORDON: Did "natural habitat" bring that up?

Mr. Groff
instead of
Dr. Groff

MR. GROFT: No, no, no.

(Laughter.)

SISTER KERR: I would think, absolutely, it's critical.

MR. GROFT: What I'm trying to get to would be the types of speakers and programs that we need to have come and talk and explain, you know, get to a common point of understanding about different things. Not to divert from what Effie was saying, but looking at some of the potential areas.

I was thinking of having HCFA come here and talk about what are the requirements to get a product eligible for reimbursement. I think that's what we need to hear, also, as we go along. So we do have some more time to talk about those things.

DR. GORDON: Steve, you brought up institutional review boards. What is the kind of question you think we might or should be interested in?

MR. GROFT: I guess the question is, in any of your experience, thus far, has it involved difficulties in getting studies approved and accepted through IRBs? Does this problem exist?

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But I want to follow up, I was going to suggest the same thin. But I think, particularly since we're here in the HCFA building, to have some of the people, the likely administrators, the chief medical officer of HCFA, come here and talk about what is their resistance to these approaches. And many are of their issues are legitimate and many are just fear.

I would ask people from Dr. Varmus, you know, a very vocal critic at the NIH of alternative approaches, to come, both, so that the critics feel included in the process, which I think is very important. When people are included in the process, they tend to be less vocal in their criticism of the final outcome. But also because I think it's very important to have a better understanding of exactly what are the concerns that are being addressed.

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DR. ORNISH: I think it's a bigger issue than either one. I think it's more of a mind set, you know, resistance to approaches in general and this in particular. And, you know, logistically it's just a few floors down and so I think it would be an easy thing to do. At what point, I would defer to you on that.

DR. GORDON: But that opens up a very interesting issue of whether early on we should address some of the resistances. So, let's say while we're doing the research panel, if we had two and a half days, what about spending a half a day addressing different areas where there are resistances, concerns, trepidation, whatever --

DR. ORNISH: I personally like that idea very much because there is nothing that clarifies your thinking as much as having somebody challenge you. And that's really what the scientific process is all about. This is why I'm a scientist, because I like the process of not having the true believers but having your assumptions challenged, having our assumptions challenged. And I think it would focus our panel to have those people come early on so that we have a fair sense of the -- you know, we're not just preaching to the choir.

DR. GORDON: I wanted to ask if there are others who this might be a good idea as well?

(Many affirmative responses.)

DR. GORDON: Okay, good, thank you.

MS CHANG: Also, after that, there is also the need, I think, to consider hearing from other researchers out there that are not necessarily doing the kind of research that -- they are not part of a grants program. These are people who are practicing CAM modalities in secret -- not practicing but researching them in secret.

And the CDC, for example, I wish Wayne were here to talk to us a little bit more, but the CDC, for example, has tried to do some type of what we call "investigative research," where you go out into the field and you are doing field studies in the environment, as Effie said.

And the problem we're having is the resistance on the part of the practitioner to make known what they are doing because they are afraid that they are going to be closed down once the authorities become involved.

DR. GORDON: I just want to second that. At our most recent cancer conference, one of the very interesting things that we had is people, who are doing what may be extremely promising work, presenting their data rather poorly, for two reasons. One is that they are not expert in presenting data, which is a whole other issue that I think we need to address, how to help the CAM or health

world present their data better.

But the second issue is exactly the one that you mention, that people were afraid to say, "I'm treating cancer." Because then they were using natural substances, these were foods, they were not supposed to be treating a disease.

I'm going to be talking with Bob Wittes, at NCI, in the next couple of weeks about this issue, because they are concerned about it too. They saw it at the meeting and want to move this forward. I think it's a great idea for dialogue. Conchita first and then let's go back to Charlotte.

DR. PAZ: That's interesting that you said that because what I was going to mention a while ago was that I think part of the bottom line is looking at some of the research and some of the people that are receiving alternative therapies, and sometimes we can lose focus as the fact that sometimes some of these may go against what we call "traditional" therapies.

And sometimes, at least in my own practice, I've received some really adverse outcomes that have happened with people who have had some alternative therapies in places that I could not document.

And so I guess what I wanted to mention was that sometimes in getting this information, it's really

tough to sometimes get that kind of information from folks, because they don't want to divulge the fact that they weren't doing real well with whatever therapies they were doing, so they are coming to where ever I happen to be at with that outcome.

And so sometimes we do have difficulty getting that information. But also to realize that, you know, sometimes our patients health really does come first and we need to really keep that in focus.

DR. GORDON: Charlotte?

SISTER KERR: Having engaged in this point and even made comments, I now have the question, which is this. What objective do we seek as regards all we've just been talking about? What objective do you seek in doing this?

And my second statement, I almost want to say something to you as chair, or you and Steve, I feel and I may be wrong, again I need to pause. Are we just recreating what the NIH has been trying to do? And, again, what objective do we seek? What good is it going to do us as a Presidential Commission to be updated, having some questions answered on what's going on?

Would it be then our objective to advise Congress, to then say what else we think needs to happen? Because if that's so, it's almost like we're asking for, and

I'll make up this word because I don't know what the right words are, an "executive summary" from all the people doing research, or people who affect research, like the things Steve brought up about who refused the study request. When and why are we going to do all this as the Presidential Commission?

DR. GORDON: Why are we going to do all of this?

DR. PAZ: Yes.

DR. GORDON: I think because many of the issues that have been -- and I'll just give my add, I think answers will emerge from all of us over time, and from all of the people who will come in and talking with us.

There are questions here that are not being addressed by anyone right now. Many of the questions that we raised are simply not -- there is no forum for addressing them. Whether it's the issue of combining herbs, or the issues of standardization, or the issues of resistance, or IRBs, just to pick out four, none of those are being dealt with.

Most of what's happening at NCCAM is they are sponsoring certain kinds of research studies based on studies that are proposed by different people. And they are doing some other things too, and it's clearly very important work, but it's not taking a broad look at the whole field or

suggesting ways of modifying the way we are all thinking about research.

DR. ORNISH: Just to add to that, any form of healing, you have diagnosis, and then we have prescription or treatment. And I think before we can make any recommendations regarding policy, we have to first know what's out there and what needs to be done.

DR. GORDON: Joe, and Tom, and Bill.

DR. FINS: Just to respond to a few things that came up. One is whether or not we should have critics of CAM in to give us their point of view. I would just say that we're discussing CAM as if it were sort of a homogeneous set of interventions, and there are some that are more contentious than others. And I think we should know the distinction between things that are benign, moderately benign, useful and extremely useful.

And another issue that is related to the research question is I'd like to know perhaps from medical journal editors what sort of information finds its way into journals and why, what the criteria are that they are using. Because I think research, at least in the academic medical arena, is the coin of the realm and it confers legitimacy.

Acknowledging what Sister Charlotte says about the broader picture, if we want to integrate this sort of stuff into the mainstream, we have to get published in

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Should be
MMWR

journals that are prestigious.

And, finally, Dr. Paz said something that I thought was very interesting about tracking bad outcomes. I think to be credible, we have to acknowledge the good and the bad. And I'm suggesting, and perhaps Michele could comment on this, but the CDC has a weekly report, NFWR, that talks about bad outcomes. Perhaps that's an expanded role for the CDC, so that we deal with the good and the bad.

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MS. CHANG: Just to quickly respond to Joe, yes, the CDC and the FDA have for some time been looking at how to systemically begin to report the adverse outcomes. And they are really struggling with it because there is currently no workable and efficient way to collect all the adverse outcomes, research them, assess them, and then publish them.

As you know, CDC, most of NFWR is about what the Government has to do, a fast turn around on outbreaks and things like that, so it's not meeting the need right now. So it's a very good point and I think we should hear from the folks at FDA and CDC who are working on this specific realm.

DR. GORDON: Thank you.

MR. CHAPPELL: I'd like to have us consider whose property this new knowledge or increased knowledge would be. And if it's going to be public domain, then who

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DR. GORDON: Thank you.

MR. CHAPPELL: I'd like to have us consider whose property this new knowledge or increased knowledge would be. And if it's going to be public domain, then who

are going to be the forces that want to prevent this knowledge from being brought to light?

If it's not private property, if it's public property, then I'd like to know what are the forces in our society that would like to prevent this knowledge from being brought to light.

DR. GORDON: When you say "this knowledge" do you mean research?

MR. CHAPPELL: Increased knowledge. Coordinated research to increase knowledge.

DR. GORDON: And could you say more about how you would look for these forces or how you would address that whole issue?

MR. CHAPPELL: Well, I'm thinking of the issue of private property. Is this patentable? If it's not patentable, what threats does a more approved and credible product or service --

(Sister Charlotte Kerr leaves.)

DR. GORDON: Excuse me one second. Charlotte, good bye. Great to see you.

MR. CHAPPELL: -- if it's not private property and not patentable, what threats does a public domain of an openly marketed product -- that is, by "openly marketed," I mean this knowledge is public domain -- what threats does that present to those base their illness

business on private property, intellectual property?

DR. GORDON: In this context, in this Commission, how do you see addressing that?

DR. GORDON: Well, I guess I would just like us to identify the forces in our culture that would prefer that this kind of research not become publicly available and marketable.

DR. GORDON: How do you identify them? That's what I'm asking.

MR. CHAPPELL: Those that base their businesses on private intellectual properties.

DR. GORDON: For example, would you like to have representatives of the major research enterprises and drug companies come and talk about how they relate to our discussion?

MR. CHAPPELL: That might be helpful. Are they proponents of the pursuit of this greater knowledge? There are lots of people who have businesses built on the lack of knowledge. Even those in the -- well, I would just leave it at that.

DR. GORDON: Bill?

DR. FAIR: A number of speakers have commented on sort of our unclear understanding of what we are to do relative to CAM, and I should count myself among them. And I find myself thinking, Gee, I wish Steve Straus

were here.

Because I would like to hear from Steve Straus what he views this committee could do to help the functions of the NCCAM, which is basically why we're here. And if you will excuse a surgeon's approach to it, I'd see if I can get Steve here tomorrow, if at all possible, just for 15 minutes.

MR. GROFT: It's better to get this into a forum of formal presentation and give him time to prepare for the next meeting. It's much better. I think we want to get all the parties involved into a cohesive set of presentations to address all of the issues.

DR. FAIR: As I said, surgeons, it makes no difference whether you are right or wrong, just do something.

(Laughter.)

DR. GORDON: I like that. Steve will be one of the first, if not the first people presenting at length at our next meeting. And I talked with him about that, and he and I will be talking between now and then. And so, yes, he is a very important person in this, and he is very eager to share with us his sense of where NCCAM is going and how we can help.

MR. GROFT: And I think it was important also to separate out NCCAM from the Commission. I think that was

one of the reasons why we did not invite Steve specifically to come here today or tomorrow and address some of the issues.

I think it was important to hear from you and the public about the issues. Steve is more than prepared to -- we've talked to him on several occasions about his willingness to participate as much as what we need.

DR. GORDON: I think it's really important too, Bill, the research agenda is much larger than NCCAM.

DR. FAIR: Yes, absolutely.

DR. GORDON: And the research questions that we're raising go far beyond the current purview of any agency. And those are the areas I think are most important for us to consider.

DR. FAIR: Well, that's why it will be important for him to be here because he's probably thought about this question more than any of us in this audience.

DR. GORDON: I know he's thought about it a lot, but he's been doing this work only for a certain number of months. And I think that one of the things that's really important in this area is that gathered around the table are people who've been working in these areas for altogether, I don't know how many years, but it's a lot of time.

And I think that it's very important that, as Steve Groft has said, that this is very much an independent

entity and that our deliberations will, hopefully, be of use to all of the Government agencies.

MR. GROFT: I think to remember, too, that after tomorrow we'll have each of you identify what working group or subcommittees you want to become involved in. And part of that process will be us talking with different people on teleconferences, arranging for the next meeting. And so I think we'll have the opportunity to get all these issues out then to express the concerns.

DR. GORDON: Are there any other comments or thoughts before we close this afternoon's session?

(No response.)

DR. GORDON: So just a reminder, tomorrow there will be time for public comment between 1:00 and 2:00. And we welcome that. And please let Michele Chang know if you are interested in commenting, we'd love to hear you. And if you can't make it, or know someone who can't make it, who would like to submit written material, we'd love to consider that as well. We have a statement by the President here that's just been handed out, each of you has a copy of it.

I want to personally thank everybody for what was a wonderful discussion. I really feel we've come a long way in defining the issues related to research. And we have three more areas to cover tomorrow.

And one of the wonderful things has been how we've used CAM. CAM is our doorway, it's our specific mandate. But I think what's coming out very clearly is that, while we consider CAM, there many other issues and concerns that have to be looked and understood. And then there is a context to this work that we are doing, and we are being to establish that. So thank you very much. And thank you, Steve and Michele and Terri also for the staff work.

MR. GROFT: We do need to know how many of the Commission members will attend the dinner this evening. And so if you could give Michele a quick nod or how about a hand count?

(All hands are raised.)

MR. GROFT: Everyone. And are there any other guests we need to count?

(No response.)

DR. GORDON: And we'll see you back here at 8:30 tomorrow morning. We'll look forward to it.

Whereupon, at 5:15 p.m., the meeting was adjourned, to be resumed July 14, 2000, at 8:30 a.m.)

REPORTER'S CERTIFICATE

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