Whenever there is some hot area of controversy in medicine, we tend to hear about from people and get opinion articles. I am wondering why we are not getting much about alternative medicine and CAM, and I wonder if it is because CAM is actually a lot less controversial than some would say. It is there; it is accepted by people that use it.

Perhaps people have some perspective on it. Physicians are well aware of its popularity and may not be as threatened by it as is sometimes said. Perhaps it is not as controversial. This does not mean it is accepted as effective, but as a part of our system and of what the consumer wants.

DR. LAINE: Part of our aim in inviting a series of papers, the papers in the series are much of the type that you describe. There is a little bit of reviews that are not as critical as we would like, but most of the papers in that series of papers aim to describe the context with which alternative medicine exists in the medical community and the larger society. So, economic issues, ethical issues, medical, legal issues, that have some relevance to our readership.

So while we are still waiting for the right for the rigorous scientific evidence about specific therapies, we hope that those sorts of articles help conventional physicians understand the context that this whole discipline exists in.

As a sideline, I think there is a perception, like Dr. Relman said, that the conventional medical journals are biased against alternative medicine, papers just reporting on alternative medical therapies. I don't think we are. In fact, one of our hopes is that this will show that we are interested, and maybe will stimulate people to send their research to us. Then, of course, it has to go through the review process.

But one of the reasons we don't publish much, is we don't get much. The second reason is, of the stuff we get, a lot of it has methodology problems, but that is no different than a lot of the original research that we get on conventional therapies.

DR. GORDON: Thank you. My thought was that there may be some articles that are equivalent to discussions of the hypothalamic pituitary adrenal access, for example, summarizing the data that may be

interesting, and certainly would be interesting to readers of mainstream medical journals, as well as, perhaps, opinion pieces.

Dean, and Joe, and Effie, and Wayne.

DR. ORNISH: Well, again, I want to thank the people for such eloquent testimony. I really appreciate it.

Several people have said that a distinction should not be made between CAM and other medical modalities, either from the standpoint of funding or publication. I certainly completely share that ideal and your commitment to doing good science. It is certainly how I spend most of my time, but we have heard testimony from several people who have testified before our Commission that certain journals are more likely to publish an article showing a negative finding from a CAM modality than a positive one.

I am addressing this question to Dr. Campion. In the three priorities that you outlined in your testimony a few minutes ago, the top one was to give priority to those few complementary and alternative medicine methods that can cause harm.

Do you also have the same commitment to articles that show safety, efficacy, and effectiveness?

DR. CAMPION: I think, as Dr. Roman outlined, the basic principle is, we will consider any manuscript on it merits. If the subject is important, if the intervention is important, which means it is something that is in wide use or has potential benefits, we will consider it. We don't get many of those. I am not sure if we have gotten any.

We do publish a fair number of negative studies, over 20 percent of the randomized, controlled trials that we publish are negative studies. Those are of conventional medicine. We think that negative studies are more important than people realize, both with respect to CAM and with respect to conventional medicine.

DR. GORDON: Joe.

DR. FINS: Dr. Fontanarosa uses the phrase "a reputable journal," and as a conventional practitioner, when I see something in the Annals or JAMA or the New England Journal, I feel much more comfortable in feeling that it is true, at least by the standards that I have lived and practiced by.

Dr. Relman, this question is directed to you, but to any of the editors, I know there is a consortium of medical editors that have a working group that have published standards.

Is there any outreach to the CAM journals, or at these other medical journals? What are the criteria, and how do we know what is a reputable journal? Because I think that is really the threshold thing.

Yesterday or the day before, we were talking about reimbursement for benefits if things were in a peer-reviewed journal, but the question is, what is a peer-reviewed journal; what is a reputable journal.

How do we establish what the threshold is, and does that organization, that entity of journal editors, have a role in establishing what the cut-off might be?

DR. RELMAN: Although I was one of the founders of the Vancouver Group, more years ago than I can quite remember, and as of the time I stepped down 10 years ago, there was no attempt to define what was a good journal or what was a bad journal. The membership in that group was fairly arbitrary, and it didn't have much to do with quality. It had to do with other relevant editorial

things.

So I would ask my colleagues who are now active members of the Vancouver Group whether there is any attempt to define quality, but I would also say that I would be very dubious about any such attempt. It has got to be very arbitrary. At the very least, you have to say it ought to be peer-reviewed if it is going to publish original research.

If it says, no, that is not what we are about; we are going to publish commentary, then you don't need, necessarily, peer review, but if you are going to publish original research, it has to be peer-reviewed. So that would be my only observation.

DR. LAINE: I have more recent experience than Dr. Relman's with the Vancouver Group, because it met Thursday and Friday of last week in Philadelphia. So I spent two days with the Vancouver Group. That isn't its role. It is a volunteer group of editors from medical journals who came together to create a document called the Uniform Requirements for Manuscripts Submitted to Biomedical Journals to create some standard guidelines that journals can, or choose not to, buy into.

I think, from speaking with people who have been on the Vancouver Group since it started, it sounds like originally it was more focused on the format of the references, and the nuts and bolts of putting together a manuscript.

In its current inclination, in the revision of that document that is in progress, a lot of concern with ethical issues that relate to publication in biomedical journals, but not to give editors some place to refer to when they are trying to sort out difficult issues related to conflicts of interest on the parts of authors, reviewers, and the like, but not in any way setting criteria for what is a good journal and what is a bad journal.

DR. FINS: It is not unrelated because the other issue is the firewall issue, and advertisements and supplements in some of the CAM journals.

DR. LAINE: Right.

DR. FINS: So there may be a role for the Vancouver Group. For CAM journals, if they were to accept membership in this consortium, it might lift the standards of the ethical issues, the homogeneity of

references, and there may be some cross-over effect.

It is just an issue that might be worth --

DR. LAINE: Right. That is an interesting point, because one of the things in this document are recommendations about advertising and where it should sit, and where it shouldn't sit, and what types of products are appropriate according to this volunteer group of editors to be in biomedical journals. That is an interesting point.

MS. WOOTTON: If I could just make the point that the blue journal, the Journal of Alternative and Complementary Medicine, does not accept advertisements at all. This was a conscious policy right at the very beginning at its inception because it is such a tricky area for advertisements. So we are clean.

DR. RELMAN: Let me interject. I think that is just great. If I had had my way when I first became editor of the New England Journal, I would have said to the owners of the journal, live on our modest profits from subscriptions and classified ads. We were probably the only journal that could have made a profit from just subscriptions and classified ads, but fortunately, not

yours.

MS. WOOTTON: Absolutely.

DR. RELMAN: Most journals are now caught in the economic vice of advertising income and conflicts of interest. This is not irrelevant to your concerns. Conflicts of interest between those who profit from the sale of alternative therapies and alternative devices, and so on, and those who set policies, set government policies, and constitute advisory groups, are rampant, and you ought to be worried about that.

DR. GORDON: Dr. Campion, please.

DR. CAMPION: I would just add in response to your question about journal quality, there is no stamp, and there should be none. Journals can change over time, but journals have to be judged on the process, on what they publish, and on their place in the scholarly community, how readers, the critical audience responds to them.

One indicator of that is the impact factor, how often do other researchers and scholars quote articles from any particular journal. That is just one rough indicator.

DR. GORDON: David.

DR. RILEY: We send all authors the Uniform Requirements for Manuscript Submissions and the Consort Guidelines in terms of publications. Now, of course, they don't always follow it, and lots of times, that is probably the primary reason for rejection of original research articles.

DR. GORDON: Effie.

DR. CHOW: Thank you very much for your input. I have got many questions, like Wayne usually has, but I will restrict them to one or two.

DR. GORDON: If you have too many questions, we won't have much lunch.

DR. CHOW: Regarding Dr. Campion's remark that it may be more accepted than we believe it is, coming from an era in 1970-something when acupuncturists were jailed, and homeopaths were jailed, some of the leaders were jailed, and Christopher Hill from holistic health was jailed, and we were helping to get them out of jail.

I would say it is more accepted now, but it is acceptance on the public level. Now it seems like we have the challenge of influencing or educating the top

level echelon of scientists and policymakers and so forth. In your reviews of the papers -- 9,000 reviewers, that is really a lot -- you talk about physicians being the managers of CAM processes and so forth.

How much education do you think is enough to educate the physicians and the health professionals who know, really, basically, nothing about energetics or any of the practices?

That is our educational question, too. This goes into research. So I am curious, and I think we would like to be enlightened as to, how much education do you think will make a physician and a nurse, a physical therapist, et cetera, qualified to judge the value of a particular practice.

DR. RELMAN: May I respond to that? Education has to follow, not precede, the evidence. You will not influence what the leaders of American medical education teach and what they believe without presenting, without having available persuasive scientific evidence.

That is why it is so important to support research, to publish good research, to teach those who believe in the value of alternative medicine how to do

good research. That is the only way. There is no other way that you are going to influence the real leaders of American medicine, and there is no other way that you should want to do it.

DR. GORDON: Dr. Campion, did you want to respond?

DR. CHOW: We do believe in research. I just wanted to say that. That is a big issue here.

DR. CAMPION: I believe that education of physicians should mainly focus on trying to be better physicians. There is plenty for physicians to learn already, and there is this huge, poorly defined area of a million different types of CAM, which everybody knows, there is not a lot of objective data there.

Hence, I don't see need for trying to inject the medical curricula with quasi data, or some pretense of data when there isn't any. I think physicians need to be aware of what their patients want, where their patients go, what other practices are involved, particularly when they come in direct competition.

DR. GORDON: Phil.

DR. FONTANAROSA: I would like to respond

briefly, if I may. Your question about how much education is enough is a very difficult question. Being involved with teaching two courses to the first-year medical students at Northwestern, I can tell you that time in the curriculum is rare for adding on any additional materials.

In fact, if you add something, something else has to get bumped out. There are so many hours and so many ways that you can do it. So I would agree with Dr. Relman, that decisions to add things to the curriculum must be based on existing evidence and a good reason for those being introduced, and bumping out something else.

From the standpoint of how much education for physicians in practice, a lot of that is self-directed, of course, by continuing medical education. I do think that physicians need to be aware of the various CAM therapies, their limitations, their applications, not that they are going to practice them.

I think it would be just as much a mistake for a physician who is not trained in acupuncture to perform it as someone not trained in orthopedic procedures to set a broken wrist -- there needs to be that expertise -- but

to be aware of the current information available on these therapies is important so that when patients ask their physicians these questions, they won't just dismiss the question because of their lack of knowledge, and they will be able, more importantly, to see how the CAM therapies might interplay with the conventional therapies, drug/drug interactions and so on.

DR. GORDON: Wayne.

DR. JONAS: Thank you for some very, very wonderful comments by everyone. That was a good discussion and panel. I hope I can formulate this. I will put my question first. How about that?

Do you think anything needs to be done in this area that, we as a federal body trying to look at federal regulations, need to do?

I don't personally see anything that needs to be in this particular area. It looks like the process is going on like it ought to go on, both with the biases and the lack of evidence. I think anyone who reads the historical literature and the sociology of science sees that journal publications is the world in which biases are fought out.

We get data and we have editors and reviewers that are biased, and then there is, hopefully, an open and full discussion, and eventually some of the good stuff forms to the top. There are multiple examples of this. Parapsychology is fraught with them, chiropractic has documented this recently, Ernst has documented both sides of this problem in publishing, the marked publication bias in favor of positive studies in the complementary medicine journals, very marked.

The reverse of that, the reviewer bias against some complementary therapies among the conventional reviewers. So I think this exists, and Davidoff [ph], actually, at a previous conference, said this directly. The question is, is there anything to do about this, because the bottom line is, there isn't very much good research.

So if the goal for all the journals is to get high-quality, rigorous research -- and let that be the arbitrator of this -- if that doesn't exist, is there anything that we have in relation to this, other than what we have already discussed, which is, let's try to get better and more research infrastructure going, and

actually outcomes, so that we have a better selection among all journals to pick from?

I am wondering if any of you have an opinion about that. Is there anything that should be done about these issues, from the publication point of view, anything that we should be doing?

DR. GORDON: Please, respond.

MS. WOOTTON: Can I respond to that one? I think I would go back to the idea of innovative methodology. This is what the CAM journals can do best, is to nurture new methodologies that are rigorous but bring in new ideas, new approaches

To go back to my recommendations, I think probably the middle one, that there needs to be more research money for practitioner training schools because they are the ones with the knowledge and the insights that can bring forward these appropriate methodologies.

At the moment, there is a dearth of training there. I think Richard Hammerschlag addressed this one extremely well. That would be my recommendation.

DR. RELMAN: Dr. Jonas, I am on your side. I preach the same sermon that you are preaching. We need

more good evidence. In the fullness of time, with good evidence and full publication, the reliable will be sorted out from the unreliable; the true from the false.

I would take exception to my colleague, Jackie Wootton's, suggestion that we practitioners ought to be taught how to do research. That is a special skill. It requires a different kind of discipline, and neither in so-called conventional medical research, nor in alternative medicine research, I think, can you expect that the average practitioner is going to play an important role.

They can be part of a team, but the team has to be directed and disciplined by people who are professional investigators and who understand the discipline of clinical research.

MS. WOOTTON: Could I just come back, quickly, to correct any misapprehension. I am not saying that practitioners should be taught research methodologies. I am saying that practitioner training schools should be given encouragement to develop new, innovative methodologies, because I think this is where the innovation will come, not by channeling and focusing down

the same route that the conventional biomedical research is going in at the moment, whilst at the same time, sustaining the rigor and the basic principles of scientific methodology.

DR. GORDON: Thank you.

Other responses to this question? Dr. Fontanarosa?

DR. FONTANAROSA: Dr. Jonas knows this all too well, from his previous experiences at OAM. I think that the two places that there might be a way to improve this is being sure that the grant review process is such that there is prioritization of important, answerable research questions. So clear prioritization of grant funding.

The other seems, probably, easier said than done. There are, I can't remember how many, national independent centers for CAM research around the country, each sort of focused on its own area of expertise, and I wonder if some better collaboration among these centers might help to answer questions more efficiently.

DR. GORDON: I wanted to ask you all, too, to follow up on Wayne's question, whether there might not be a place for the editors of some of the journals to give

seminars to help some of the investigators develop more appropriate tools for presenting research and papers, a kind of outreach, perhaps, at some of the conferences or some kind of independent meeting.

Would that make sense?

DR. RILEY: I think if people focus on the Uniform Requirements for Manuscript Submission and the Consort Guidelines. The Consort Group meets regularly. There are other guidelines being proposed now, the Moose Guidelines for Outcomes Research.

The information is out there, but it probably needs to be provided more to CAM investigators, or CAM authors when they are writing up data for submission.

DR. GORDON: I was thinking of something more interactive, actually, a kind of encouragement and a kind of working with on developing papers of higher quality.

DR. LAINE: I think developing the paper might be too late a step, because once the data are collected, the data are the data. If the paper has good data and is addressing an important question, as an editor, you can fix up the presentation. That is a big part of our job, but you can't fix fundamental study design.

So I think there may be a role for the sort of activity you are talking about, but it has to be earlier in the process.

DR. RELMAN: Dr. Phillips, in describing the program at Harvard, was telling you that one of the things they try to do is train people interested in alternative medicine to learn how to design good studies to find out whether what they are doing works or not. That should be part of the education of people who want to make a contribution to the field.

DR. GORDON: Thank you.

Tieraona.

DR. LOW DOG: It is quick, because everybody is hungry.

DR. LOW DOG: Thanks for all of your comments. My question relates to the database and self-described experts, or what they self-describe their expertise in.

There has been wonderful articles in all of these journals, but some mistakes continue to be repeated, especially in the area of botanicals, which I think physicians are interested in because of potential herb/drug interactions, and because they are

pharmacologically active substances.

So we get articles that are published that have the wrong species identified. So we say Siberian ginseng is actually Panix ginseng, which is a completely different genus, or we have an herb/drug interaction article published that talks about hepatotoxicity of echinecea, but having some mistakes around the biochemistry.

So I think that those are errors we wouldn't have in conventional medicine because we are more familiar with the pharmacology. Have you thought about getting botanists, or trying to expand the database a little bit more, so that they have specialized areas, just to make sure that those errors don't occur?

DR. LAINE: Yes. That is something that we constantly do when we go to our reviewer base. We don't have any process or the resources to go check into people's credentials. Once they have done a review for us, each reviewer is graded, and that information is included in our database. Somebody whose done a lousy review for us is unlikely to be chosen to do another review, but we have to rely on what people tell us their

area of interest and expertise is.

We do go out and try to find reviewers in CAM therapies, and in other areas, too, where there seems to be a paucity of expertise among our reviewer database, but mistakes will always get by. I think it is probably just as common in conventional medicine, although in areas where there are lots of reviewers with that background and expertise, it is probably less likely.

Particularly, in alternative therapy, it sometimes seems like we are hitting on the same reviewers over and over again, and then the potential is there for their biases to creep into the reviews, which is another problem, different, but maybe just as great as inaccurate information.

DR. FONTANAROSA: I would agree with Dr. Laine for the most part, and I would add one thing, that in addition to appropriate reviewers for papers, and this is true of any paper, if there a new mutational analysis for a genetic predisposition, you try to get someone familiar with that methodology, the same thing.

I would also add that editors have a responsibility in reviewing papers, not solely to rely on

the reviewers comments, but to do independent work on his or her own, to pool research articles, to try to verify, independently, names of drugs through various textbooks or other resources to find that out.

Once something is published, it is really out there. There is no pulling it back easily. So to try to be sure that these T's are crossed, I's are dotted, the right drug is named -- or, the right herb is named, excuse me -- is very important, and I think it is also the editor's responsibility, in addition to the reviewer's information.

DR. GORDON: Thank you. Thank you all very much. This has been a wonderful panel, and we have really enjoyed the discussion and look forward to continuing to work with you all.

We are going to take a break now for lunch. We will come back at 1:45 for small group meetings. Small groups will meet until 2:45, and then at 2:50 we will come back here for the large group.

[Lunch recess taken at 12:50 p.m.]

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AFTERNOON SESSION

[2:55 p.m.]

DR. GORDON: Which group is going to present first? Tieraona.

Group IIIA: CAM Research and Publication

DR. LOW DOG: My panel, we had Tom, and we had Joe, and we had Julia, we had Conchita, we had George.

So our first question was, evaluating the research literature. So we tried to look at barriers and obstacles that were involved, and we divided it up into two groups, one was evaluation of research literature by practitioners; how could they use it to change their practice habits, and then we also divided it up into reviewers, people that were actually reviewing the literature.

For the practitioners, we feel that everybody would benefit, conventional medical doctors, massage therapists, acupuncturists, chiropractors, if all practitioners had training in school, or through continuing education from people who are already graduated, in how to critically evaluate published research.

That would include conventional practitioners having some familiarity with unique aspects of evaluation of CAM. It would also allow CAM practitioners to have a better handle on how to critically evaluate the research that they read in other journals. So we had that.

Also, for practitioners, sort of in that area, we wanted to encourage the continued development and support for training CAM professionals who can teach research methodology and evaluation, because part of the problem is, who is going to teach in these schools. If we are saying we want the chiropractors or the naturopaths or the acupuncturists to be able to evaluate the research, we have to have people that are capable of teaching them in their schools.

To that end, we encouraged collaboration between the conventional academic institutions and the CAM schools. So there is a wealth of people who are well-trained in research methodology at universities to be able to help teach in these schools.

Also, we wanted to encourage funds that could help support and sustain library types of materials. A lot of times, large academic institutions have endowments

and funds that are not available to CAM schools, and that there should be some sort of funding available or set aside so that they could have access to journals, MEDLINE, computers, et cetera.

DR. GORDON: Question. In this first one of training people to evaluate research, did you have any particular pathway by which you thought that could be done?

DR. LOW DOG: Well, part of it is already being done through NCCAM, who is helping to teach CAM practitioners research methodology, but we also feel that part of this is going to have to be done in the short term through collaboration with universities and academic centers where you will have Western-trained people, basically, going to CAM schools to teach research methodology.

The ideal, actually, would be to have people that are specialists in their own modality go through and learn research evaluation. We are hoping that they could use that through NCCAM, such as what we heard today, through NCCAM means.

I hope I answered your question.

DR. GORDON: Sort of like NCCAM having a training program.

DR. LOW DOG: With the sole purpose not to train researchers, but to train people who teach practitioners how to evaluate research. So a little bit different there.

Then again, we wanted to make sure that we earmarked funds to accomplish, making sure that practitioners could have access to this.

Then we separated evaluating research literature, looking at barriers and obstacles, into reviewers, people that just review the evaluation of this literature separate from publication. We have carved out this niche.

We just, again, wanted to encourage that there be at least somebody who is reviewing it on the team that has familiarity with that CAM-specific modality, so that they would know if that was even appropriate; was it appropriate to test this herb for that purpose so that there is somebody specific.

DR. GORDON: I'm sort of lost. What is the context in which you are talking?

DR. LOW DOG: When you are evaluating research literature, like for doing a systematic review, when you are doing a meta-analysis, when you are gathering data, that those types of reviewers need to also have some sort of expertise, or have some sort of collaboration with somebody who knows about CAM.

We didn't have much on there. We just sort of thought that came before the published issues. That is all we had for evaluation of research literature.

Was there anything I forgot, guys? No?

So the next question was, publication of research results. Again, here, we tried to look at ways that we could promote and improve the availability of research being published in peer-reviewed journals.

One of the things that we really did want to encourage, because you can't mandate, but we just wanted to recommend that peer-reviewed journals involve at least one person on the review team when they send an article out for review that was specifically familiar, or had expertise in that CAM modality. They don't have to be experts in the research methodology. They have other people for that, but just the appropriateness of the way

the study was done involving that modality.

Part of what we tried to consider about publication was, one, we don't want complementary and alternative medicine to be seen as second class. We would like us to try to get more of the articles into peer-reviewed journals, but we thought, perhaps, since we do believe there is some bias at this point, which may be just because we haven't got to the place where we have good enough studies, that maybe NCCAM could do something like, either consider a quarterly journal, less frequently; more frequently, or do what we call a "year's best," where they take the best studies that have been done in CAM for that year, or six months, or however frequently it is done, and publish that and make that available, similar to what ODS does now, so that you know what the 25 bests were for the year.

We thought that that might be a way of making people more aware of the research that has been done because maybe they didn't get into the New England Journal or JAMA.

We also just bandied around other ways of getting that information out there, and wanting to

encourage NCI, CDC, Office of Dietary Supplements, HCFA, people who are already taking trials and summarizing or putting them on their sites. We would like them just to consider the inclusion of CAM trials that were well done, and putting them in their sites, because sometimes we think there is just an exclusion of them for no real reason, maybe just a reminding that good trials should be included there, too.

Anything on publication stuff that we had, that we bandied around?

This took a lot of time. We had a lot of work on those issues, about where things should be published and who should pay for what.

Questions 3 and 4, we sort of put together. This was looking at issues around non-profit support, people that are not for profit, and private sector support.

Based on some of the previous testimony that had been given to us, we came up with a couple of ideas that we liked. One was that there is a lot of private foundation money and not-for-profit money out there, but nobody knows about them. So, how would a CAM researcher

even know they existed?

We thought that NCCAM might be able to just have a site under their researcher site, where they just actually list contact names for foundations, so that if you are an acupuncture wanting to do a trial, there is a place that you could go to that you could get information of other foundation that might be willing to sponsor it, and that they could maintain that as sort of a liaison.

We weren't sure who it would be, this ambiguous, appropriate government body, but we wanted to have an appropriate group to serve as a coordinator for a group of public, private, and governmental agencies who convene to discuss how to better coordinate CAM research. We think there is a lot of duplication. We think there is a lot of discoordination, that there is precious little money, and the money is sometimes not being used in a very coordinated fashion.

So if there was a group that could come together that could help coordinate the public money, the private money, the government money, the foundation money, we might be able to get more work done in a better and more quick fashion than in this disjointed fashion it

is now. We didn't know if that was NCCAM or who, so we just left it open.

Finally, for foundations and not-for-profit, we wanted to recommend that we try to get a group of them to pool monies together, so that they put a CAM pot together, if you will.

Some of them, we heard, they are only willing to put so many dollars in; so that we get them to contribute a group of dollars, and then they could announce a competition, and then could take applications in and get the best few that could compete for these CAM research dollars. We might be able to get some bigger studies funded, instead of $10,000 here and $42,000 there. If we could get some of them to come together and pool their research money.

We didn't address Question 5.

DR. GORDON: Either additions from Tieraona's group, other points that anyone in the group wants to make, or questions for her about this? Wayne, go ahead.

DR. JONAS: What was Question 5?

DR. LOW DOG: It was CAM research and regulatory process.

DR. GORDON: Other questions for Tieraona? Because I have one, and I don't know whether this fell into Wayne's group or yours, or somewhere in between.

Oh, you wanted to ask a question?

DR. JONAS: Yes. I just wanted to make a comment and add something that has worked in the past and could work in the future, and that is OMAR. They are the ones that do consensus conferences. When we were originally looking at the whole list, gee, what ought we do through OMAR.

A lot came up. We did the mind-body stuff, we did the acupuncture area, but there were a whole bunch of herbal products in which the question was, gee, is there enough research to currently recommend under what conditions that these are safe and effective.

It is exactly in those controversial areas that consensus conferences are held, to have the debate and the discussion, and also bring out the current evidence. So they, I think, would be an area of focus in terms of some of the areas.

DR. GORDON: I want to ask Tieraona, both you and Wayne, the question, yesterday when AHRQ and Brian

were talking about different ways of producing information. Was it your task to figure out how all that should go together? Was it your group rather than yours? It was not, okay.

DR. LOW DOG: I am sure it was Wayne's. I know it was Wayne's.

DR. GORDON: I don't think we can necessarily do it here, but I would like to hear some more thoughts, like the consensus conferences, which I think is really important, about an overall strategy, because I think what we want to do is make some recommendations, should we go in some of the direction of outsourcing, in a sense, to private groups, like the Cochrane Collaboration. The production of information, should it go to AHRQ, should it be NLM, or NCCAM. I would like to hear a little discussion here about that.

DR. JONAS: There is a real debate within NIH as to whether they should do that. They have done it in the past, and there is a real debate as to whether they should continue to do it.

For example, they contract with groups to do special databases to produce research on health services

research and cancer, and a variety of other things, toxicology.

Some of the areas they are not particularly happy with having to do that, but on the other hand, they do it a lot. One of the things that might be useful would be to actually contract with a group that does an ongoing summary of current information, past information. I think that would be a very useful thing, and it wouldn't be very expensive. We actually looked at the cost of that, and it is not very expensive.

DR. GORDON: Yes. I would like to hear other people's thoughts about that, because I think this is a really important issue. I think this may be one of the ones we want to address in the Interim Report. It may be complex, but it is reasonably straightforward at the same time.

DR. JONAS: One of the issues is that, often, people will look at those sites and say, that is the authoritative site, and therefore the individuals that want to market a supplement, if it is listed on that site, then they will say, okay, now we have an authoritative body that has said this is worthwhile, we

can market it, and they will use that through the courts and things like that. So there are complications to doing that.

Again, the government is nervous, rightfully so, lest they be interpreted as recommendations in some way.

DR. GORDON: But AHRQ does that, in a sense.

DR. JONAS: AHRQ no longer does that, actually.

DR. GORDON: But they do these, what are they called, evidence reports.

DR. JONAS: Yes. They do do those, exactly. The Cochrane work does do that. So they do do that, and they have a whole process for making sure that you don't take this as a recommendation, that they are available for groups that want to then make guidelines out of those, if they feel that they warrant them. But it is possible to do that. That becomes very expensive, however.

DR. GORDON: If AHRQ does it.

DR. JONAS: Yes, because if they are doing those evidence reports, they are much more elaborate than simply summaries of current reviews, just with a

database, or even systematic reviews, than what Cochrane is doing.

DR. GORDON: Tom, and Joe.

MR. CHAPPELL: I just wanted to maintain a principle in the choice, the ultimate choice here, that CAM research has access to practitioners and to the public.

DR. GORDON: Exactly.

MR. CHAPPELL: So that the more public the domain, the entity that is doing the evaluation and the publication, the better.

Now, if the public entity decides to privatize but still maintains control, that would be fine, too. I just feel that we need a public entity assessing the evaluation of these trials and taking responsibility for publication to various channels of groups.

DR. GORDON: Great.

Joe.

DR. FINS: I very much want to endorse the "year's best" concept that you folks came up with. I think that is really a way of bridging the gap between the alternative medicine journals and the New England

Journal level, and it gives it a kind of validity, and I think that would be very helpful.

The other thing, the practice guidelines, or recommendations for reaching out with the clinicians out there, is through the specialties societies, through the American College of whatever. They often have board review, documents, or annual updates. If there could be some kind of linkage with what NCCAM, or whomever is going to do that, with those entities in reaching out so it gets distributed widely, that would also be very helpful.

DR. GORDON: Okay, great.

Other thoughts?

Tieraona, go ahead, and then George.

DR. LOW DOG: In the AHRQ, they have the really big, thick technology report, and then they have that brief summary, but it is still not consumer-friendly. It would be nice if somehow there would be some funding. That information is public and it is from the government, and it would be nice if there was a lay version of that for the consumer that was just one page, or on a website that would be available as well.

DR. GORDON: I think it is up to us to fashion exactly the kind of information we want to have out there about the research. So these points are going to help us make that recommendation.

George.

DR. BERNIER: We had tremendous exposure today, I think, to the leadership of medical journalism. I would like to point out, and this sort of came up in our conference today, that very people publish what they are interested in in the New England Journal of Medicine. It is really hard to get into, and you say, if I get one of those every 10 years, I have got it made.

So it is not a bad sign to take something less than the Annals and the New England Journal, but I think we have been believing it is.

DR. GORDON: You mean it is not eternal damnation if you are not published there.

[Laughter.]

DR. BERNIER: That's right.

DR. GORDON: Okay, thank you.

Other comments? Joe.

DR. PIZZORNO: I appreciate that comment,

George, and it gets back to the question I asked Brian, and that is, where is the bar. One of the concerns I have is that, if you look at the New England Journal, et cetera, a very high bar. If you look at the Cochrane Collaboration, a very high bar. If you look at the AHRQ, a very, very high bar.

My concern is that, while at some point we want to reach that bar, there is some standard of evidence that is appropriate for us to utilize when treating our patients, and I don't think we know where that bar is. If we could, in our wisdom, come up with some recommendations, or at least a process, for determining that, I think we could do a lot of good.

DR. JONAS: May I just comment on that?

DR. GORDON: Yes, please. Go ahead.

DR. JONAS: One of the things, again, we just mentioned, is the possibility of a specialized database contracted out which reports on current research. It simply reports on research. NLM does this a lot. They are not in the role of evaluating it, they simply report it, and report it accurately.

DR. GORDON: In a sense, what you are saying

is, you report on it, and you report to height of the bar as you are reporting on it, you say how good the research is.

DR. JONAS: No. They don't even report the height of the bar. All they do is just describe it in a clear, precise way. They do summaries of it, and they produce it and put it in one place where if someone wants to get that research, they can go there. It is ongoing, so it is real-time with the current research.

DR. GORDON: Joe, go ahead.

DR. PIZZORNO: Something that we have done, and a project that we are working on, is, we actually developed, by looking at what the Cochrane Group did, a ranking system for the quality of the research.

I am wondering, maybe if we had some kind of central repository which looked at the research that was out there, and basically each study was ranked, just how good is that study, how reliable is that study, that way, we could at least get a sense for where the body of research is shifting or establishing itself.

DR. GORDON: I think what we have been hearing is that people need some estimate of the quality of the

research. The researchers need it to some degree, but certainly the public does need that.

DR. JONAS: The way most conventional journals do this, like Annals has JPC Journal Club in which they report abstracts of ongoing research. Most of the time, they have commentaries, because having a score, tagging a score, is very unreliable, and there is no standard score that everybody accepts. There are fatal flaws of even high-quality studies, and good studies that are low quality, and so they have a description of that. Then that gets into a little more complicated --

DR. GORDON: Joe.

DR. FINS: There is a lesson from the death-and-dying movement, which had a textbook project that Steve McPhee [ph] from UCSF headed up. It looked at the death-and-dying care content of the leading textbooks. It has also been done for nursing as well.

Maybe we can reach out to the kinds of places where conventional practitioners go for authoritative information and try to get some infiltration of the kind of basic themes that we talked about in the December meeting, about what the conventional doc needs to know.

I think if it is there, it gives a tremendous legitimacy. Of course, it would be a conservative part of the entire spectrum of CAM, but it would be an initial foothold.

DR. GORDON: Tom.

MR. CHAPPELL: Dr. Heirich, in his first proposal, says, "Congress should instruct public agencies, that is NIH and AHRQ, to gather data, both on clinical effectiveness of various CAM approaches and on the relative costs of more conventional allopathic, and of CAM treatments for the same condition.

"This information, supplemented by other information found in peer-reviewed journals, should be brought together and made available in an easily accessible website, which is updated constantly as new data becomes available.

"The public agency responsible for the website should be instructed to draw this information to the attention of insurance companies, managed care organizations, HCFA, and the continuing medical educational programs and schools on an ongoing basis."

So I just refer you to that as more specific.

DR. GORDON: Right. We are looking at several different kinds of data. We are looking at research data, we are looking at practice data, we are looking at cost data. It sounds like many people would like that information made available.

Wayne.

DR. JONAS: There are plenty of examples of how this is done; HIV-AIDS clearinghouses.

Steve, you put together a Rare Diseases Clearinghouse, the Health Services Research Database. There are many examples that could probably very easily be modified.

DR. GORDON: Thank you, Wayne, for that.

Maybe one of the things on this issue, in particular, is that staff could put together some possible, specific recommendations for ways to fulfill this general mandate to produce information for the public and researchers. Then we can pull that together and take a look at it, and come up with recommendations based on that data, and make that data available for everybody. Then we can talk more about it.

It sounds like we are all pretty much in the

same ballpark, feeling the importance of this, the importance of some kind of discussion, if not necessarily a numerical evaluation, the importance of not only making it available to researchers, but making it easily available to the public.

Joe.

DR. FINS: One other thing. I don't know if there are any editors from the CAM journals here, but if there could be sections in the journals specifically addressing methodology and the design of studies in the literature tutorial, deconstructing good studies, explaining what were the elements, as a way of doing a kind of continuing educational effort, I think the readership would probably benefit from that.

DR. GORDON: That is a separate item.

DR. FINS: A separate issue.

DR. GORDON: A separate item, but on the same general topic of information about research. Thank you.

Any other issue related to these topics, related to journals or philanthropy, that anyone would like to bring up at this point? Yes, Tieraona.

DR. LOW DOG: Just the whole issue of the

public. We certainly didn't adequately address it, and I am not sure it has been, really, adequately addressed overall, is, how do you synthesize the research to the public that is truthful. When you take a study and it says something, what does it really mean, and synthesizing it, because it has to be more than just this study was done and it showed this, because they can't interpret it.

So I do like the AHRQ, and trying to come up with some body that can give truthful information about the research in a lay sort of way. We really focused more on practitioners, reviewers, and sites, and things like that, but I think that that is one of the biggest jobs that we have, is, how do we get the information to the consumer.

DR. GORDON: I think, if the staff can bring up some of those models to us, we will see the different ways that it has been done. One of the things I think that has been clear throughout is that there has not been enough information for the public. It is not easily available, and it is not answering most of the questions that they have.

DR. LOW DOG: It is often tied to a product, too, which makes it hard for them.

DR. GORDON: Right, exactly.

Anything else on this? Great.

Wayne, do you want to talk about your group?

Group IIIB: CAM Research Methods, Training, and Concerns

DR. JONAS: We were tasked with methods, training, concerns, federal agencies, academic health centers, and design. I made a mistake when I read these, and I thought it was methods and framing. So I started with that.

So we had some assumptions that we thought should frame the whole research discussion that we have heard a number of times. There is a close consensus among some of these. They are fairly simple. Research is important, we should be doing research; it is key, it is important. The research has to be high-quality, it has to be good, and it should include multiple methods. There isn't, simply, a mono-method approach to understanding complementary and alternative medicine, or any medicine, for that matter. There has to be multiple methods.

Now, given the fact that there are multiple methods, we felt like, or, at least we outlined, six major areas that we heard discussed both in the prior research discussions that were in the summary your book, as well as over the last few days where people wanted to see emphasis on certain kinds of domains, if you will, and other domains.

That included systematic reviews; consensus conferences; meta-analyses; summaries of current research; randomized, controlled trials; basic science research. We heard that. We heard a lot of emphasis then on health services research, especially looking at costs.

Cost effectiveness was something that was emphasized this time; outcomes research and observational data; and then one that was only mentioned briefly, but I put it in there because I thought it is very important for public input, and that is qualitative research, to really get at some of more subtle items that are difficult to capture in complementary medicine, or address issues that the public finds important that, maybe, is not captured in some of these other methods.

So qualitative research is an important area, also. We just wanted to frame that.

One of the things that we did not address is the whole prioritization process, how do you decide how much you put into health services research and what areas, and should we all do randomized, controlled trials, or how much basic science research and that type of thing.

So this perhaps, then, is an item which is addressing prioritization. Perhaps, one of the things that needs to be done is to have a prioritization process developed, if you will, that is explicit and clear, and that includes all the major audiences that are involved in complementary medicine to make sure the kind of data that they need is produced in research.

So that was the framing idea, and actually, this is the kind of thing that the Institute of Medicine does. They have actually already written a number of reports on this, including one we heard from in the first conference, which said that the public should be especially more involved in this prioritization process.

For complementary and alternative medicine, we

all felt that that was a very important area, because this is a publicly-driven phenomena. So, how to do that is a question.

In terms of other mechanisms, we thought it was extremely important that research be done in multi-disciplinary teams. That includes not only scientific teams, experts in a variety of sciences in these areas, but experts in the actual methods, the complementary and alternative medicine practitioners who actually do this and are trained in this, as well as public participation.

I think that most people have agreed that there needs to be good research methodologists, experts in the clinical area that is being examined, in the complementary medicine area that needs to be examined, but how to get the public really involved on the research team is a key issue, and again, probably you need a special item for complementary and alternative medicine.

We had a discussion of outcome measures, selecting outcome measures as being important in complementary and alternative medicine. Several of them that were mentioned that appear to be important in this area are: quality of life; patient satisfaction; adverse

effects; and then a category that we struggled a little bit with coming up with the terminology, but special outcomes specific to complementary and alternative medicine, such as energy or qi, for example; measurements, or the more subtle aspects that are difficult to capture and may not have a Western conception, even, and therefore not a Western outcome measure; and then also, ways to capture unexpected or serendipitous outcomes that occur from interventions that are focused on healing. A lot of times, things that happen are unexpected.

So again, that is where qualitative research comes in, to try to capture things that you can't anticipate, don't have a measurement item for.

We felt that one of the main focuses, in terms of setting a research agenda that could go fairly quickly into policy, is the area of safety, that we need to look at safety specifically in the areas of supplements. We have heard that over and over again, and there are several ways that that might be done.

Again, many people say that DSHEA somehow needs to be either fully implemented or modified, or discussion

of DSHEA in order to identify and allow it to get at the safety issues that appear to be inadequate, currently.

We started to get into different ways to do that, and then kind of retreated and said, no, we don't want to get into modifying DSHEA; it is too complicated, but we want to acknowledge that it is important to do and that this should be done in some way.

Safety also includes the monitoring of adverse effects, and also the quality of products. There are particular ways in which that could be done, and we should empower groups like the FDA, the CDC, the NIEHS, USP and industry, to move into these areas to make sure the quality is improved and that there is monitoring for adverse effects interactions in that way.

I suggested but we didn't really discuss, but we have heard it in the past conference, that the level of evidence, or type of evidence, should, in some way, be stratified by risk so that those that are higher risk require more data, more evidence than those that are lower risk.

This is done, actually, in the government. We heard from the FDA Devices Division, in which they have

an explicit way of doing this. This should be looked at in a broader way, because certainly some things that are low-risk need different types of evidence than some things that are high-risk.

Also, in safety issues that needs to be addressed, is the indirect effects from incompetent practitioners, although that is slightly different. That is more in the training issue, and certification and licensing, but it is an important component of safety. So there should be research looking at safety, and that should be a highlighted item.

There was a discussion of trying to get at those things -- again, this was a little bit difficult, and maybe, Joe, you can help me with this -- getting at the meaning aspects, information about meaning, culturally relevant information, including anthropologists, social science involved in providing information about complementary and alternative medicine research as being very important.

National Endowment for the Humanities, I think, was suggested as a place that, perhaps, this could be a targeted. So that was a suggestion.

We then looked at stimulation of support in research in federal agencies, academic health centers, and foundations, which was not our charge, but we felt it was very clear that we needed to encourage funds, stimulate more federal involvement in research. That could be done through multiple methods, RFAs, Special Emphasis Panels, money.

What else did we say, perhaps opening up coordinating offices, either in Health and Human Services, initially. Then maybe in other agencies that are not within Health and Human Services' purview, perhaps this could be done in a stepwise manner, so you do, first, one in HHS, and then subsequently, you open up as those areas develop to try to specifically encourage research in those areas, similar to what happened at the NIH when the OAM was started and that began to gather a lot of attention, and kind of develop those areas.

One very touchy area is that, first of all, I put up there, "should be blank percent of future budget increases should go to integrative medicine research." I was hoping they would fill in the blank for me with a number. They didn't do that, they said, well, there

ought to be more, but it should be a significant portion.

There are many ways to do that, but we don't feel like we should specifically say how much that should be. There are a variety of methods that could be done, line items, appropriations in language, requiring reporting on the amount invested every year in these areas in complementary medicine.

DR. GORDON: Wayne, could you just define what you mean when you say "integrative medicine"?

DR. JONAS: Integrative medicine involves the use of complementary and alternative medicine within the conventional health care system as part of our health care delivery in some way. It doesn't necessarily mean it needs to be in hospital, it just needs to be part of the individual's health care complex.

We listed a number of agencies in which that could occur. Joe just mentioned to me that we didn't address the whole issue of targeting specific vulnerable populations, areas like end-of-life, but my feeling is that if we played on the strengths of these agencies, that many of them have special populations, like HRSA, that they deal with, and that we perhaps would then get

encouragement across the board in terms of different types of research, especially areas that are outside HHS. DoD, the VA, has a lot of research capacity and is willing. We heard from them, and they are willing to do research in these areas.

Let them build on the strengths of what they do best. Of the six general areas that we framed in the beginning, different agencies do different aspects of those better than other agencies. AHRQ, for example, does the reviews better than anyone else. They do health services better than anyone else. NIH likes to focus, and does a lot of good work in randomized, controlled trials, basic science research. That should, perhaps, be an emphasis for them in other areas, et cetera.

Finally, we also asked, how can there be stimulation of research in other areas besides the federal government, academic health centers. I think one of the things we thought was especially important that we heard over the last couple days was investment in infrastructure in academic health centers. These academic health centers include complementary and conventional health centers.

They may require different mechanisms, different approaches to that, but they all need training, they all need equipment, they all need expertise in methodology, they all need to take a team approach, they all need informatics aspects. The federal government has a number of ways in which they invest specifically in infrastructure to get a critical mass of researchers, and those should be encouraged.

Under foundations, I think you addressed this. We didn't talk about it too much, but we agreed, relatively easily, we could facilitate coordination among foundation, private and federal, through meetings and things like that, so that they are at least talking to each other, and talking about the kinds of things they are providing.

In the private sector, there were a number of mechanisms that policies could be targeted towards. Some kind of market protection was mentioned for private groups that invest in research and products and particular practices. I put down patents. That is a major issue. It hasn't been discussed a whole lot here, but again, that is another way of coming up with market

protection.

DSHEA, we have already mentioned. Modification or implementation of DSHEA in a way that encourages research, rather than discourages it; tax incentives, SBIRs. The orphan drug approach was thought of as being a way of providing some kind of market protection, or as an example of providing some kind of market protection.

Training. Since I misinterpreted training as framing, we didn't talk about it. Never mind.

Regional collaboration was felt to be extremely important. In other words, getting complementary groups and conventional groups to work, such as in the Northwest, was brought up as an example of where that is occurring, and should be encouraged.

We didn't really didn't get into details about how to get state and local governments more involved in the area, but thought it was important, and having a repository of research methods, facilities, resources, et cetera, that have an interest and are doing work in complementary and alternative medicine, an information source for research itself, not the results of research, which is information, but actually, the funding sources

and approaches, and types of things they are looking for among these agencies, would be useful.

Oh, yes, we did mention paradigms, and we assumed that for 20 cents on your tax dollar, you could get a couple.

DR. GORDON: Thank you, Wayne.

Tom, and then Joe.

MR. CHAPPELL: I am wondering if we could begin a drafting of something for the area of herbs, botanicals, and so forth, as an interim report to postpone this. We are beginning to get a better understanding of this, and had a lot of testimony. I think it would be wise to begin to draft a set of recommendations regarding this whole area of concern.

Since the committee, this working team, has identified it as a problem, could we begin to draft some language?

DR. GORDON: So, what is the problem?

MR. CHAPPELL: The DSHEA. So whether DSHEA is sufficient or insufficient. Do we have sufficient laws. If not, what are our recommendations going to be?

DR. GORDON: Dean.

DR. ORNISH: This is one of the things that came up in the discussion we just had, which is whether we get into that level of detail, or whether we just simply say that we think there are issues within DSHEA that need to be addressed. I think that if we get too much into that level of detail, it might be polarizing or distracting from what our overall mission may be.

DR. GORDON: Did you want to address DSHEA?

DR. FINS: I think I agree with Dean. I think the notion is, we have identified problems. Whether it is resolved with an amendment, a repeal, better implementation, I don't think we are in a position to address, but I think it is valuable to simply put it out there that there is a problem, and not to get to the specifics.

DR. GORDON: My thought is, there are two levels to DSHEA. One is, there are certain things that have come out consistently in these meetings about DSHEA. One is that there needs to be good manufacturing practices. Second is, that the labeling needs to reflect, which is related, what is inside the bottle. The third is, the FDA has to have more authority, not the

same authority that they have, and more money to enforce the provisions of DSHEA.

So I think there are some basic recommendations we can make, that we have heard from every part of the spectrum, about DSHEA as it presently exists, and I think we may or may not want, depending on an analysis of what is there, to take a look at other possibilities.

Tieraona.

DR. LOW DOG: I just want to remind us that the first two things you said are already in place, though they are not enforced.

DR. GORDON: That's right.

DR. LOW DOG: The first thing is, it has to be what is in the bottle; it has to be what it says on the label. That is by law. I know it is poorly enforced.

The second is, GMP, which, the FDA is eventually going to publish and release those findings. So GMP is there. It is a matter of giving and empowering the FDA the power to be able to enforce, or perhaps looking at rather they should have pre-market kind of authority. The FTC for label claims, the FDA, if it shown to cause harm, and too, if it is not meeting

claims.

DR. GORDON: That is what I was basing my analysis on. The point is, that I think it is important for us to take a strong public stand on these provisions that are already in DSHEA. So if we try it and we really do it, we may find it works rather well, or we may not. Then there are the whole complex issues that you are talking about of DSHEA.

Joe, and Tom. Anyone else?

DR. FINS: I would suggest, because I think there are other issues that we need to talk about here, that maybe we ask the staff to draft what you just said in the Interim Report that will be circulated, and then we can deal with the specifics. I think there are wide areas of consensus, and I think it would be helpful to have a real text in front of us.

If I could move onto another -- no?

DR. GORDON: Let's finish up with the DSHEA, and then come back.

DR. JONAS: I agree with what you said. I want to add one item that relates to this research area, and that is, it should also be looked at in terms of its

ability to facilitate research, not inhibit research, in addition to those others.

DR. GORDON: Tom.

MR. CHAPPELL: I think we need to add safety to that list of three that you identified that needs to be looked at in this Interim Report, and we need to look at the question beyond DSHEA and the FDA in terms of the efficacy.

I think Dr. Grollman's proposals, specifically Recommendations 3 and 4 relating to funding efficacy trials at NIH, are very important here because the problem is, it is very hard to find the mechanism of action when it deals with this category. It is a far greater research burden to approach efficacy than it is to approach safety.

So I think safety and efficacy need to be treated on different levels, different recommendations, and I don't think it is too complex for us to deal with, so I am glad you are willing to begin the drafting of it.

DR. GORDON: I think it is complex in every way, especially politically.

MR. CHAPPELL: Well, that is okay, but that is

why we are here.

DR. GORDON: No, I understand. So what I am saying is that, for the Interim Report, I think we need to lay out where we have consensus, and then for the Final Report, if we start looking at some of the issues, then we can have some time to discuss them and figure out where we stand.

MR. CHAPPELL: Thank you.

DR. GORDON: Joe.

DR. FINS: I just want to make passing reference to the idea about the NEH, the National Endowment for the Humanities. I think one of the things that we really haven't addressed, that I think we really need to address more fully, is this phenomenon, this social movement which is CAM and what it means for American society, good, bad, and indifferent.

I think that the reason I really favor the NEH is that it is a different kind of scholarship. Conclusions that are drawn in the medical humanities do not necessarily have to adhere to the scientific method because they are asking different kinds of questions. The sociology, our cultural values, why this Commission

itself was created at this time and at this place.

I think future historians will really be appreciative of the fact that we made a nod to the NEH and the humanities to address these broader issues, as well. I think a small amount of resources directed towards the humanities will have enduring effects that will outlive any of us in this room.

I just want to make an appeal for that. I know Linnea feels strongly about that, and some of the other Commissioners. So I hope that that gets some traction.

DR. GORDON: Joe, could you say a little bit more about what you mean by NEH?

DR. FINS: The National Endowment for the Humanities.

DR. GORDON: No, I know that, but what are you thinking of?

DR. FINS: Well, they fund a lot, and there are state humanities councils that actually go out and foster the fine arts, literature, history projects, the kinds of things that really address the cultural richness of our society. I think that the evolution of CAM is part of our cultural inheritance and the legacy that this

generation will leave to future American generations.

So I think we just need to understand what it means in a different kind of way. I am a big proponent of the scientific method for scientific questions, but I think that these are different kinds of social, cultural, anthropological kinds of concerns.

DR. GORDON: Joe.

DR. PIZZORNO: Jim, I would like to second what you said about DSHEA. What we have in place needs to be enforced, and the FDA needs to be funded for it.

However, I also would like to take one step further, and that is, I believe DSHEA does not have adequate safety components to it. I think before a product is allowed on the market, there should be basic safety documentation, and that is not required right now, and I think that is a serious flaw.

DR. GORDON: Do you think we have enough consensus to put that in the Interim Report, or do you see that for the Final Report?

MR. CHAPPELL: You have my consensus.

DR. LOW DOG: Can I say something?

DR. GORDON: Sure.

DR. LOW DOG: There are 2,400 botanicals sold, if you include all the herbs in commerce, 2,400. They have not all been tested adequately for safety, and that is going to cost an awful lot of money to test them all. It will limit acupuncturists in their ability to prescribe and use many of the Chinese remedies because they have many in them that have very little data that would be accepted or used here.

I agree, DSHEA absolutely missed the boat on safety, but I think we want to be very, very thoughtful in how we go about defining our recommendations. If we are going to undertake that, I think it is one thing to say, we do not believe that DSHEA has adequately addressed safety.

I think it is quite another thing to try to say or come up with the recommendations for how they should go and fix that, because I think it is a huge issue. That's all.

DR. GORDON: Dean, you had your hand up.

DR. ORNISH: Again, especially in the Interim Report, we should try to find areas of consensus, and if there are people who have strong feelings, rather than

trying to resolve the differences, I think we ought to just take note of the differences, see where we can come to consensus, and then leave it for later to try to resolve them. I think it is just going to take too long otherwise.

DR. PIZZORNO: Tieraona, I agree with you on the one hand, because there is a lot traditional medicine we don't want to lose access to you and I both use.

On the other hand, there are a lot of products out there that are adulterated. We have had experiences in Seattle.

DR. LOW DOG: That is GMP.

DR. PIZZORNO: Pardon?

DR. LOW DOG: That is a GMP issue.

DR. TIAN: That is a quality issue. That is not a safety issue.

DR. PIZZORNO: I concede. In terms of the expense of safety testing, it is not that expensive. There is now microbiological testing that can be done that is not particularly expensive. Any manufacturer who is bringing these products into the market can spend a few hundred dollars for these real basic screening

processes.

DR. GORDON: Joe, I think it is much more complicated because something may be safe in a biological system, and may not be safe for humans.

DR. PIZZORNO: We have to start somewhere.

DR. GORDON: But I think that the issue here -- I have to say one sentence, Effie, and then you and Ming can speak -- the issue here is that it is very complex, and I just don't feel comfortable at all getting into it in the Interim Report. Safety is an issue, but how to --

DR. PIZZORNO: For the Interim Report, I am okay.

DR. GORDON: Ming.

DR. TIAN: I agree with you, Jim. I think this is really complicated issue, because whenever we say anything, it just cannot cover everything. If I understand, most herbs and dietary supplements are generally considered as safe. Maybe some things are not safe enough, but when you set up the standard for all the dietary supplements, there is going to be a problem.

Who is going to do that? That is the second thing. There is no such standard that we can test all of

them, because we are talking about quality control, GMP. The second one we are talking about is safety. Number three, efficacy. When this is so effective to treat any disease, then the dietary supplement is not considered as a dietary supplement, it should be as an OTC drug.

DR. GORDON: I would like to get off this topic, because I think it really needs a lot more discussion, and I would like to get back. We only have about 10, max, 15 minutes more, if that is okay, Effie. Or, do you have something --

DR. CHOW: I agree with you that I think we need to be very sensitive about that, particularly when there are other groups that are dealing with it. I think to make final recommendations that say we should be communicating with them, or recommend that we communicate with the other groups, take it very carefully. I don't believe that in this Interim Report, we should say much.

DR. GORDON: Okay, thank you.

So let's go back and let us focus and see if there are other issues in this Research Report that we want to deal with.

Anybody else, any thoughts about this? Well,

one thought that comes to mind, in addition to framing, I would like to talk about training.

[Laughter.]

DR. GORDON: I think we need to make some recommendations about training. I think some of the things that we have heard today about training, if everybody is comfortable, we can put together a kind of synthesis of what we heard from the training panel and what we heard from the Commissioner's questions, and perhaps even put forward some recommendations to consider for the Interim Report.

If there is anything anyone wants to add to it now, that is great. Wayne.

DR. JONAS: Training, in one way, is part of the infrastructure, development of the infrastructure. I actually had it up there, I think, if not, I will stick it up there.

DR. GORDON: Yes, it is up.

DR. JONAS: However, the other kind of unique thing about complementary medicine is that the training needs to be in order to bridge the standard research methods and individuals that have knowledge about

complementary medicine. It is to address the two cultures, if you will, as was mentioned in there, or to provide what David Eisenberg calls dual-skilled individuals, and that should be the focus of the training.

DR. GORDON: Right. Okay, good.

Other research issues that either have been raised by Wayne and his group, or that you think we need to be addressing?

Some of them we have talked about before. I just want to bring a couple up, and maybe they will lapse over, or maybe emphasize the whole issue of integrative medicine, or, if you will, complex, many-modality approaches. I have a sense that we a consensus on that, that that is an important area that we want to urge investigation of.

Is that correct? That is, approaches that not just are just single procedure, but complex approaches that may involve acupuncture and diet and exercise.

One of the areas, and maybe we want to wait on this, is the whole area of so-called "frontier science". Maybe that is one we need to think through more and talk

more about, but in terms of making recommendations for more investigation in this area of energy medicine, areas of distant healing. I am thinking aloud now.

DR. ORNISH: I guess, Jim, part of that, if we agree that we should take certain methodological approaches, as several people testified today, they can be applied to a number of different things. The only methodological issue becomes, is it measurable or not, trying to measure qi, for example. How do you do that?

I am not sure where you are going with that. Are you saying we should devise new methodologies for new problems? Or, are you saying that we should make sure that a variety of things be studied in addition to the traditional ones.

DR. GORDON: No. That is a whole other question, about new methodologies or new instrumentation. No, I wasn't talking about that. I think, just as with the creation of the OAM, it focused attention on certain approaches to medicine and healing that were not being generally considered, so the creation, the recent NCCAM RFA for a center on frontier medicine began to focus the issue on some of those other approaches to healing.

It is not that the techniques of evaluating them are any different, and perhaps we ought to just put this off and let this go, but whether or not we want to come out strongly on the side of looking at approaches that are beyond the generally accepted, even though we accept them as part of CAM, everything from shamanic practice and studying shamanic practice, to understanding and studying healing at a distance or healing by intention. That is the thought that was going on.

So it is not a difference in method, it is just an emphasis on another subject.

Wayne.

DR. JONAS: I think this is very important to put in, and the reason is because this addresses the paradigm issue that we didn't talk about. Many, many complementary or traditional medical systems do not share the same assumptions about fundamental science and reality that we do in Western medicine. They are literally outside the paradigm of causality and a variety of other things. Yet, they are an integral part of their system, the practitioners use them, they frame their therapies based on them, et cetera, et cetera.

So, how can this get addressed? So I think to frame it in terms of the fundamental assumptions that currently lie outside the paradigm; are there ways in which we can use the scientific microscope to examine these, and is there a way in which the government can support that.

The other thing that comes into that is that there is a lot of the public very interested in these areas, and yet the scientists aren't. So it is another area of public-scientists interest gap, and I think that justifies it.

There are places where we could encourage that to happen. I think it is in the basic science areas, through groups like National Science Foundation, et cetera, using the standard procedures that they have for trying to develop and encourage good research in those areas.

DR. LOW DOG: I just wanted to say, that is, again, where you want to collaborate with your medical anthropologists who have been studying all of this in traditional cultures, looking at how they diagnose, how they treat, and their whole system of belief, and how

that influences, then bringing your basic scientists and that. But that is where you want that collaboration.

DR. JONAS: And clarifying, really, in Western terms what those assumptions are in those societies.

DR. GORDON: The question I have here -- Effie, go ahead. Do you want to say something?

DR. CHOW: Just a brief thing. Also, the speaker on psychoneuroimmunology, that is a new science that fits into this.

DR. GORDON: The question I have here is a tactical one. It sounds like we all feel this is an important area. The question is, do we make a recommendation in the Interim Report, or, do we simply raise this area, and then make recommendations in the Final Report.

DR. ORNISH: My question is, who reads the Interim Report? I am still not clear.

DR. GORDON: What, Dean?

DR. ORNISH: Who gets a copy of the Interim Report? Is it just an internal document, or is it a public document?

DR. GORDON: The Interim Report is a public

document. How does that affect your thoughts?

DR. ORNISH: Well, I think if it is an Interim Report, we can include things that we wouldn't necessarily want to see the light of day just yet. My own belief is that we want to really be careful on the Interim Report and stick to areas that we have consensus, particularly at a new administration who is going to be looking at this, and is going to be looking at how people react to this, even more than looking at it directly. If it provokes a lot of controversy or polarization, I think it is going to make it that much more difficult to get our Final Report done.

If, on the other hand, we write something that we can all stand behind that doesn't cause polarization within the Committee, which would be the worst thing, then it doesn't provoke a too heated response from the general public, then I think it is going to make it easier to continue doing the work.

It goes back to the incremental approach that we were talking about and that has been presented to us. I think that, while there is always a tendency that I have to want to do it all right now, immediately, which

is my nature, I am learning a little more in my old age that there is something to be said for taking a longer view of this. I think that in this case, that might apply.

DR. FINS: I really endorse that. I think, up to this current session, we were really very clearly developing a consensus on 80 percent of the issues. I think we have the potential to have problems with the membership on issues that are very complicated, like DSHEA, on specifics about funding. I think we can say that there are problems out there about regulation of supplements but not get into the specific details that have the potential to fracture the recommendations.

So I would, again, urge what I urged --

DR. GORDON: Were you feeling that about this issue, as well?

DR. FINS: Yes, a little bit. I think there is so much that we have come to agree upon.

DR. ORNISH: Yes. I want to echo that.

DR. FINS: I would hate to jeopardize that at this stage.

DR. GORDON: Let me make a suggestion.

Everybody probably wants a little break before Public Comment. Yes?

So the suggestion would be that this is clearly an important issue, that it is one that we at least prepare, and I am looking over at Jim Swyers as I say this, that we at least some material and some points for discussion, but that we not be planning to come out with a recommendation in the Interim Report.

I don't think it is just my feeling that it needs more discussion and needs more solidity to it, and needs more consensus.

DR. ORNISH: Maybe we can have an internal document, just among ourselves, that lists the more controversial areas that we want to explore to see how far we get.

I agree with Joe. I have been very encouraged by how this very disparate panel, who have come from very different places, is moving much more towards consensus than I ever thought we would see.

DR. GORDON: Does that sound okay, that we raise the issue? I think that what we can do is, that when it comes time to formulate it, we can formulate it

in a way that will be heard and that will not create problems; quite the opposite, will gain support.

DR. JONAS: I agree, there are ways it can be formulated in which it will be heard. I think one of the ways to do this is to simply acknowledge that there are assumptions that are part of non-Western cultures that are now part of our culture because there is a multi-ethnic group of the United States, and that these assumptions need to be examined, systemologically or in some manner.

DR. GORDON: So I think, as we are thinking about the Interim Report, we can think about some statements about where we are, what we recommend, because there is a clear consensus, and then other issues that are part of our understanding of the field as a whole that we will be addressing in the Final Report. I would see these other realities as being one of those issues.

Great. Thank you. Thanks for lots of work in this condensed period. Let's take a 10-minute break. We will back at 4:15, and we will begin public testimony at that point.

[Recess.]

DR. GORDON: We will begin with James Sensenig.

DR. SENSENIG: Dr. Gordon and Commissioners, my name is Jim Sensenig. I am a naturopathic physician. I was the founder of the American Association of Naturopathic Physicians, and I have served as the dean of two or our colleges. I am here today on behalf of the American Association of Naturopathic Physicians and the American Association of Naturopathic Medical Colleges.

We need medical pluralism in this country for the same reason that we need diversity amongst the plant species of the rain forest. It maintains the gene pool, enhances creativity, allows for the competition of ideas, and stimulates critical thinking.

Furthermore, we do not know which of those plants in the rain forest or which of the therapeutic systems holds the medicine that we need to heal our health care system, our nation, and the planet. It is likely that they all do.

You have been asked by the President of United States, in my opinion, to not only survey the forest of healing, to identify the species of therapeutic systems,

but also to preserve the diversity of the ecosystem for the benefit of the health of our nation.

While the details of our recommendations to the Commission have been previously submitted and are in the written testimony today, they can be summarized thusly:

First, ask the Congress to commit this nation to medical pluralism;

Secondly, inasmuch as these diverse systems constitute a national treasure, use them to pay down the debt of human illness and suffering in this nation.

Thirdly, nurture the diversity of this ecosystem by pruning back the barriers to access and by fertilizing the ground with the richness of our academic, economic, and scientific communities.

Fourthly, we want to thank you all for having the courage and the energy to put into this project because we know it will change the face of our health care system. Thank you very much.

DR. GORDON: Thank you very much.

Candace Campbell. Candace has a statement that she has ready on the Access to Medical Treatment Act. I have also asked her to speak for two minutes relating to

DSHEA, because I thought she had some information that might be helpful to the Commissioners. So I think I will let her do that in seriatim, so that we don't have to just go to it with the Questions and Answers.

So, please, Candace.

MS. CAMPBELL: I am the executive director of the American Preventive Medical Association, and I came here today to ask you to recommend passage of the Access to Medical Treatment Act, which will be introduced this week in the House, and then the Senate soon thereafter.

You have a copy of the bill in the background materials in the written material I provided.

Why, you may ask, am I requesting passage during a week when you are talking about research and reimbursement? Because we because that Americans should have the right to access therapies as soon as possible, and not have to wait decades for all the research to be in, or for the FDA to approve a drug. We believe that many lives could be improved and saved in the interim years.

The Access bill, for those of you who are unfamiliar with it, would create a federal statutory

right for Americans to use any therapy they desire, so long as they and their authorized practitioner follow the consumer protection guidelines in the bill.

There are four main categories of things that would be accessible, drugs approved and used safely in other countries that are not available here because the companies have not sought FDA approval; drugs in the FDA approval pipeline that are showing promise, but that are not available to patients who do not fit the tight clinical trial guidelines; therapies that are not patentable, and therefore will never go through the FDA approval process; and therapies that would be called experimental but for which there is evidence of safety and efficacy.

This last category would include the unapproved therapy for Lyme disease which cured former Congressman Berkley Bidell, and about which he testified last year.

APMA and scores of other organizations, and millions of patients and their practitioners believe that patients should have the right to make the most personal of all decisions, how to treat and cure their disease. That choice should not be limited by bureaucratic,

political, or unnecessary financial roadblocks.

Do we really want to criminalize the doctors and patients who are seeking safe and effective treatments? Do we want to promote a black market in effective therapies and leave patients prey to unregulated promoters of miracle cures?

We would rather see Americans going to duly authorized health care practitioners in this country, instead of having to sneak across the border to Mexico, Canada, or the Bahamas, to receive treatment in clinics that may or may not be reputable.

We would rather see data collected and disseminated about these therapies so that we may all learn and benefit. We would rather see all Americans have access to the full range of therapies, not only those who can afford to go to Germany for six months or a year of treatment, and not only those who are diligent or lucky enough to discover that they actually have options beyond what the FDA, AMA, state medical boards have sanctioned.

We would like to see a health care system that embraces advancements and accepts science from other

parts of the world. NIH should not stand for "not invented here". We believe that the Access bill provides an appropriate balance between increased freedom and adequate consumer protections, and we believe that Americans deserve health care freedom.

When I was sitting in the audience for the past hour or so, I was biting my tongue during your discussion of DSHEA because, frankly, I wasn't sure if you had heard any testimony about the Pierson decision, which we were one of the parties to. That was a First Amendment case revolving around the FDA's handling of health claims for supplements. What I suggested to Jim during the break is that you need to be extremely careful, if you are planning to make recommendations about revisiting DSHEA.

I would suggest to you that the problem is not so much with DSHEA as with the agency's implementation of DSHEA. Their cries for more power and money are nothing, if not disingenuous. We won that case two years ago, after a six-year, very expensive battle.

The appeals court told them that they must allow health claims, they must define significant scientific agreement, which is their benchmark for

approving a health claim, and which they have yet, two years after the court case, to define.

In order to force them to comply with the laws, we filed five health claims after the Pierson decision. They rejected all five, without having defined significant scientific agreement. We filed two more suits. We won them both, but not after more years, more money. I don't think that supplement companies and the American public should be forced to go to court and spend hundreds of thousands to force a federal agency to abide by the law.

We have met nothing but lies and deceit. They cook the books when they judge the science. They cook the books when they determine how long it takes them to approve a drug approval. There is an incredible institutional bias against natural products, and dietary supplements in particular. We have had landmark victories over the past several years. I am tired of suing the FDA. I think you have huge problem with the definition of "drug," not with DSHEA.

DR. GORDON: Thank you, Candace.

I wanted her to raise this issue so we could

have some conversation now, but also, just to give a sense of the complexity of some of the issues as we get into them.

Diane Davis Cole.

MS. COLE: Hi. My name is Diane Cole, and I am an education coordinator at the University of Virginia in the Cancer Center. I address you on behalf of health care providers and educators who are mandated to educate patients and their families at cancer centers across the country.

What we know is that 50 percent or more of all cancer patients are using some form complementary or alternative therapy. We are trying to address the quality of that information for the protection of the patient. Our patients are very vulnerable to being taken advantage of by companies and products whose bottom line is profit instead of cure or quality of life.

Many of them trust their health professionals to provide excellent medical care, but the want to do more for themselves that help them feel in control. These patients are making decisions about, and are spending thousands of dollars on some therapies and

products that have very inconsistent data to support their benefit.

When they search the Web, there is no standard on which to judge the credibility of the websites. Many patients will not tell their physicians what CAM therapies they are using, and many physicians do not feel comfortable advising their patients about what CAM therapies to use, if any.

Members of our network hear patients express their frustration and confusion about what they should be doing in terms of CAM every day. In response to this, we have developed a guide to CAM resources, which is not exhaustive, but it gives patients a start. This guide is provided in your packet of information.

Our network offers the following observations for your consideration based on our experience with this particular patient population. Students preparing to be health care professional, as well as those already in the field, should be educated on complementary and alternative medicine practices and interventions. A better understanding of CAM services by all health care professionals is the best way to eliminate barriers and

make CAM service more accessible.

An oversight department in Health and Human Resources must be at the forefront of consumer safety issues, responsible for the labeling of herbal natural products and supplements. Consumers should be able to read a label and make good decisions about possible side effects and/or food/drug interactions.

Medicare and third party reimbursement should be available to include modalities such massage, acupuncture, and visits with other certified practitioners. Research in this area could prove that there is a real potential for tremendous cost savings to the burden of the present health care delivery system.

Lastly, more research is needed in complementary and alternative medicine modalities. Research could encompass case studies and clinical trials that include the study of the placebo effect.

Thank you for the time dedicated to this important topic of complementary and alternative medicine that now occupies a prominent position in the delivery of health care services to or cancer patients.

DR. GORDON: Thank you, and thanks for the work

you are doing.

Susan Pittman.

MS. PITTMAN: Thank you. My name is Susan Pittman, and I am a registered dietician, and I am representing the American Dietetic Association today.

The American Dietetic Association represents 70,000 food and nutrition professionals who serve the public by promoting nutritional health and well-being. Many ADA members are licensed, registered dieticians who provide medical nutrition therapy and preventive care nutrition counseling to hundreds of thousands of Americans each year.

To date, 43 states, the District of Columbia and Puerto Rico have laws that recognize dietetic professionals. ADA members base work on sound information drawn from peer-reviewed nutrition research and credible sources representing scientific consensus.

The members of the ADA generally see nutrition-related CAM therapies as potential components of medical treatment and patient care, where sound, safe, and empirically proven therapies can better serve patient needs.

ADA welcomes additional research that can support broader application of CAM practices. We believe patients who utilize nutrition-related CAM modalities should receive care from those who have appropriate knowledge, training, and expertise. We also believe the dietetic professionals are valuable members of the extended team providers, and play an important role in the integration of nutrition and other modalities of treatment.

Science supports the role of preventive nutrition and the role of medical nutrition therapy, or MNT, in managing disease. However, continued research is needed to evaluate fully many CAM practices, and to provide the substances for evidence-based medicine. ADA urges that any preventive or treatment strategy, conventional or CAM, be supported by sound science and evidence-based practice before it being integrated into a health care strategy.

ADA recognizes that nutrition intervention, such as MNT or the use of dietary supplements may reduce or eliminate the need for more costly medications or treatments. In the case of medical nutrition therapy, we

have science to verify the role dietetics plays in medical care and outcomes research to demonstrate the effectiveness of MNT in treating diabetes, renal disease, and cardiovascular conditions.

To help consumers make wise choices about food and dietary supplements, dieticians can provide nutrition counseling and education, and can work with patients in developing a sound strategy to obtain nutritional health. Dieticians are the best source for consumers who need or desire nutrition guidance, and are most qualified to provide advice about whether to consume dietary supplements, which ones, and in what amounts.

For example, European studies support the use of St. John's wort for mild depression, which can be purchased for half the cost of selective serotonin re-uptake inhibitor. While this herb may be safe and efficacious for some, St. John's wort has shown to interfere with the efficacy of certain drugs, such as Coumadin, cyclosporine, digoxin, and protease inhibitors, and should not be consumed by patients who rely on these medications.

There are many examples of food drug and

supplement drug interactions, which make evident the need for dieticians, especially as more Americans consider the use of dietary supplements.

ADA believes all Americans should have access to nutrition services. Such services are covered through reimbursement payments in some hospitals, home health, and post-acute care settings, but inconsistently among insurance plans, and generally at levels inadequately to meet the needs of many Americans, particularly older Americans.

We hope work will progress rapidly to advance our understanding of the role of nutrition in preventing or delaying the onset of many chronic diseases, and to substantiate through evidence-based practice that coverage of nutrition services is a wise investment in public and private health care programs. Thank you.

DR. GORDON: Thank you.

Audrey Di Maria.

MS. Di MARIA: Good afternoon. My name is Audrey Di Maria, and I am secretary of the Art Therapy Credentials Board, which oversees the credentials of about 3,500 art therapists nationally.

I understand that Linda Gant, past president of the American Art Therapy Association, has submitted material regarding art therapy research. So I am speaking about art therapy training and credentialing.

The American Art Therapy Association, or ATA, regards the masters degree as entry level to the profession. It sets standards for the training of art therapists that include the completion of 45 credit hours of course work and 700 hours of supervised practical work.

Many programs require more. At the George Washington University Art Therapy program where I teach, students must have a minimum of 1,100 hours of clinical work, one year with children, and one year with adults.

Settings range from traditional psychiatric hospitals to hospices, prisons, shelters, nursing homes, hospital waiting rooms, and even corporate board rooms.

Of the 40 training programs nationwide, 28 have thus far obtained ATA approval. Graduates of approved programs must accrue 1,000 hours of direct client contact before applying for registration with the Art Therapy Credentials Board, the ATCB. Graduates of non-approved

programs must accrue 2,000 hours. At least half of the 100 hours of supervision required must have been provided by a registered art therapist, an ATR.

At present, 2,200 art therapists are registered with the Art Therapy Credentials Board, and thus, are eligible to sit for the National Certification Examination.

I would just like to say that the music therapists were very helpful to the art therapists when we were developing our exam. Individuals who pass the exam, are entitled to add B.C. after the A.T.R., becoming art therapist, registered, board certified. Currently, 1,200 art therapists have been certified by the Art Therapy Credentials Board. A recertification program ensures that board certified art therapists earn at least 100 hours of continuing education every five years.

In two states, Kentucky and New Mexico, the state licensing boards use the ATCB certification exam to license art therapists. In 11 other states, counseling bodies give art therapists seeking licensure as counselors credit for the art therapy courses they have taken. In two of those states, the ATCB certification

exam is accepted in lieu of the counseling exam.

Art therapists continue to work for licensure in the other states, as well as in the District of Columbia. Thank you.

DR. GORDON: Thank you.

Judy Simpson.

MS. SIMPSON: My name is Judy Simpson, and I am the government relations associate for the American Music Therapy Association. I would like to thank the Commission for this opportunity to address research needs and reimbursement challenges for our field.

Music therapy is an established health profession in which music is used to address physical, emotional, cognitive, and social needs of individuals of all ages. We have a 50-year history of contributing to the treatment of individuals with a variety of disabilities and illnesses, with more recent expansion of services to include prevention and wellness programs.

Board certified music therapists use both instrumental and vocal music strategies to facilitate changes that are non-musical in nature. After assessment of the strengths and needs of each client, qualified

music therapists provide indicated treatment and participate as members of the interdisciplinary team to support a vast continuum of outcomes.

To advance the awareness of music therapy, I have provided materials for the Commission's review, including a CD ROM containing 35 years of published, peer-reviewed research. This existing research not only addresses direct benefits dealing with specific illnesses, but also demonstrates how music therapy can contribute to the amelioration of pain and distress that sometimes occurs with conventional treatments and invasive procedures. For example, the clinical application of music during chemotherapy treatments has been shown to reduce anxiety and nausea in oncology patients.

Intervention benefits have received attention outside of our association publications as well. In a recent Journal of the American Medical Association, music therapy research in a neonatal intensive care unit was featured. Data on the physiological benefits of music therapy included improved oxygen saturation levels, increased weight gain, and shortened length of stay.

These positive outcomes, however, have not translated into more research opportunities or more access to services. If we know it can make a difference, what steps are necessary to provide and reimburse music therapy in every neonatal ICU. How do we progress from any positive research finding to increased access and coverage for effective music therapy interventions.

The truth of the matter is that music therapy is not just a nice thing to provide to patients, but it is a serious intervention supported by scientific evidence. Even with our long history, we don't have the necessary volume of research projects to make primary reimbursement easy. We have nowhere near what other related disciplines have when it comes to research funding.

The lack of understanding and acceptance by the federal government, along with limited funding for research, direct services, and reimbursement seriously restricts access to music therapy services. Without federal recognition and support, it is difficult to conduct the multi-site, large sample, longitudinal studies that we need to demonstrate the outcomes and cost

effectiveness third party payers require.

The current method leaves music therapists as freelance advocates with each provider an insurance case manager to prove music therapy is a valid treatment worthy of reimbursement.

We know music therapy can make a difference in health care, but we need help in getting that message to decision-makers. The American Music Therapy Association would appreciate the Commission's assistance in securing research funding and third party reimbursement for music therapy. Thank you.

Panel Discussion

DR. GORDON: Thank you very much. Thank you all.

Question from the Commissioners. Joe.

DR. PIZZORNO: Dr. Sensenig, thank you for the eloquent statement about medical pluralism. I suspect you speak for many CAM providers who feel we have so much to offer, and yet are being seen as simply a source of cherry-picking a few therapies.

Going along with the idea of nurturing medical pluralism, what recommendations would you to this