and evidence support that not only is this happening in the United States, but in Europe, as well. We believe there is a critical need to obtain valid, accurate, clinical information for the public's decisionmaking.

In my opinion, there are two problems. The first is a lack of acceptance by most physicians towards the research and use of complementary medicine, and the other is the lack of basic and clinical research in this country. Researchers are not responding to the public who are utilizing complementary medicine without benefiting from clinical and scientific studies.

Because we feel this is so important, the Samueli Foundation has funded two major programs. The first, we created the Susan Samueli Center for Complementary Medicine at the University of California in Irvine. The center status was awarded in December 1999, and we are presently in the second full year of operation.

The mission of the center is twofold. One is to focus on high quality scientific research, and the other is the education of medical students, health care professionals, and the community about complementary

medicine.

There are two key approaches to the research component. One is the awarding of competitive grants in basic research and complementary and alternative medicine to members of the faculty of the College of Medicine.

These projects are expected to be focused on integrative biology and outcomes research that have direct clinical applicability. Amounts of up to $100,000 can be awarded and thereby serve as seed money. The intent is to help the investigator develop enough preliminary data to strengthen subsequent proposals submitted to other research-funding agencies, such as the NIH.

The response of the faculty to this opportunity has been impressive. Nineteen applications were received in February 2000, of which the peer review committee awarded 6. This calendar year, 14 grants were submitted, and 5 were awarded.

The other key approach is the research component in the creation of an analysis unit team. This group conducts systematic reviews of the literature, assessing all of the various media now available for the

purpose of identifying and writing a variety of complementary and alternative therapies.

Their findings are archived with the potential for dissemination to both health professionals and the public. The education aspect of the center also has both a public and a health professional purpose. The latter includes a commitment to curriculum development for medical students, integration of complementary and alternative medicine skills and knowledge into the appropriate primary care residency programs and an annual symposium for the medical and nursing community.

The public education programs provide information through a combination of community forums, a website, and position papers, which analyze research reports.

Now to our second major effort. This has been our creation of the Samueli Institute for Information Biology. This institute is currently being created as a free-standing entity without direct or indirect affiliation with any other academic or other nonprofit organization or facility.

We anticipate it will be operational July 1st

of this year, and you have in your notebooks a single-page handout, which is the current vision statement of the Samueli Institute. As you know, Dr. Wayne Jonas, a member of this commission, will be the director of the institute, and Dr. Ronald Chez, who is here with me today, will be the deputy director.

At the present time, these two physicians serve as consultants while completing their tenure and full-time academic positions in their respective medical schools.

Per the handout, we are using the term "information biology" to refer to the interaction of biological systems with non-molecular signals, particularly those signals which are separated from their molecular and electromagnetic carriers. The five bullets indicate the major categories under that definition.

We will not be exclusively focusing on supporting research only in complementary medicine, rather, research in these categories lend themselves to overlapping between complementary and conventional basic science.

For instance, conventional science research

could include biophysics, cell signaling, and neuroscience. The primary purpose of the institute will be to support basic research in the four areas noted under the heading of Science and Discoveries.

We are particularly interested in supporting the work of senior authoritative investigators who have a proven track record in their respective areas of research. We believe these grants could be as long as three to five years and be designed in such a way that they investigators can enjoy a relative freedom of exploration as a research evolves.

Initially, we will be soliciting grant applications from a number of colleagues with whose work we are familiar. These applications will be reviewed by a Scientific Advisory Council in the fall of this year. The Scientific Advisory Council will be composed of individuals with outstanding credentials in research and scientific method, although they may not necessarily be identified primarily with complementary and alternative medicine.

Similar to the NIH system of study sections, each application will be critiqued by a primary and a

secondary reviewer, and this information will be presented to the entire council. In some instances, because of the area and the need for specific expertise, the primary reviewer may not be a member of the Scientific Advisory Council.

Different from the NIH system, the principal investigator will be invited to his or her portion of the meeting for the purpose of making a presentation and to respond to questions. If the grant is approved, we will assign a experienced investigator in the same field to be the primary reviewer of the investigator's progress reports. The Scientific Advisory Council will review each grant on a yearly basis for the purpose of deciding on continuation of financial support.

We are designing a plan that extends over a 10-year framework. Our dominant goal is to grow the number of investigators over that time frame. One of our long-term goals is a translate the information obtained from this funded research to human applications.

This will most likely involve the field of biosensors, digital pharmacology, conditioned healing spaces, and perhaps electromagnetic and homeopathic

treatments. The ultimate focus of the Samueli Institute is not only to advance knowledge, but also to enhance patients' quality of life, support their wellness, and treat their illness.

In addition, the other activities of the Samueli Institute will include the implementation and/or co-sponsorship of annual or semiannual meetings of relatively small groups of scientists, visionaries, and philosophers, and just plain thinkers to explore various topics.

As you see listed in your one-page handout, these topics may include aspects of causation, placebo effect, homeopathic action, spirituality, and multidimensional spaces.

There were several other questions in your invitation that I would like to address at this time.

I believe there are several real and potential obstacles in achieving our goals. Access to money is always a primary one. But second to money is the ability for productive investigators to publish their research in peer-reviewed journals.

I have been told that extremely competent,

world class experts in complementary and alternative medicine have repeatedly had their data and even their analysis and reviews of the literature rejected by peer-reviewed journals whose primary readers are allopathic physicians.

Therefore, I am delighted to see on your agenda a commitment of time and thought to this fundamental issue. At the Samueli Institute, we have every intention of working together with other foundations in our areas of research interest.

We anticipate most of the senior investigators, who will be applying for funds from us, are already supported by other sources. We, ourselves, will be seeking partnerships with other foundations to pursue specific projects of mutual interest.

Our approach to working with the federal government is a proactive one, and we will engage in specific liaison activity. We know that aspects of information biology have specific interests for various branches of our government, and we want to ensure awareness of our efforts and potential.

In closing, please allow me to thank you for

this opportunity to present this information, and thank you all for the important work you are doing.

Panel Discussion

DR. GORDON: Great. Thank you very much. It is wonderful to feel the energy, feminine energy, sort of moving out ahead, and not waiting for others, including the government, to lead. So, I really appreciate that tremendously.

I wanted to ask one question to begin with and then open it up, and that is, Susan Braun, you raised the issue of collaboration, and I know Bridget Duffy is very interested. I wonder if the four of you could talk a little bit about how you would see foundations working together to set agendas and help move the whole field ahead.

MS. BRAUN: With what we do, for example, in breast cancer research, we are a part of a couple of different consortia of funders where we get together on a formal and an informal basis to discuss priorities in funding, for example, criteria for review.

I think there are certainly those possibilities that are somewhat conventional. I think there are

opportunities, though, that might even be a little bit less conventional, for us to talk about, what the various areas of research themselves really need to be, and specifically, who, by virtue of their mission and to whom they might be answerable, would be able to fund such things.

As I talk about the Komen Foundation, we are fairly unencumbered in a remarkable way in what we can fund because we answer to the public primarily. We don't have government funds, and we aren't funded by any particular industry, and I think that is a type of collaboration that we could look at within these groups to say, okay, what does the whole puzzle look like or as much of it as we can define, and who is best suited to pose certain questions and/or fund the answering of those questions.

DR. MILLER: When you take a look at the field of health philanthropy, you will find organizations that have varied agendas, some that focus just on health, some that focus on community organizations, et cetera, but I think that there is an opportunity for the Commission to look at ways in which they can provide education for the

field of health philanthropy through an affinity organization called Grantmakers in Health.

It is an organization that the Robert Wood Johnson Foundation has been very active in, Medtronic, as well, and also Susan G. Komen. They have a series of policy and issue briefings that take place three to four times a year, usually based here in Washington, that give the opportunity for committees or commissions, such as yourselves, to sit down and to talk with health philanthropies about interest, evidence based, so that there can be an educational process there, so that we can I think develop more interest in CAM, and I would take a look at that recommendation.

DR. GORDON: I would right now, on behalf of the Commission, like to say we would welcome that opportunity for all of us or a small group of us to come.

DR. DUFFY: We are already working to put a panel together on this subject soon.

DR. MILLER: Yes, and I am on the board of directors for Grantmakers in Health, if anyone would like to have any individual discussions about that.

DR. GORDON: That would be great. Thank you.

DR. DUFFY: In answer to your question, I think there is great opportunity for philanthropy to collaborate, and I am just struck by the number of philanthropists, large organizations, small organizations. I think that there is a need for a clearinghouse, so that we know who we are and where we are, and can identify our specific areas of interest, and then divide and conquer.

Several of us here in the room had an opportunity to participate in something like that three weeks ago, where one philanthropist in particular, a woman, Penny George, was frustrated, she felt like Sisyphus holding the boulder at the side of the hill with her grant dollars, and she said I want to do more and I want to make it happen more quickly in health care.

So, we convened 15 philanthropists and 15 leaders in health care to have a conversation about that very question, how could this collaboration help move this faster.

So, I think there is a need for that and we need to do something about it.

MS. SAMUELI: We are the new kids on the block,

so I think we are hoping because of what we are doing is so innovative and creative that we are going to be able to draw from other foundations to collaborate with us.

DR. GORDON: Great. Thank you very much.

Dean.

DR. ORNISH: My first comment is just one of appreciation, how exciting it is for me, and I think for most of us here, just to hear of the work you are doing, and just acknowledge it, how important it is and what a difference you are making. So, thank you.

I was also going to ask about this issue about the consortia. Bridget and I talked about this briefly before, but if there is any kind of forum, whether it is Grantmakers in Health or in any other format, it would be wonderful if it could be both experiential, as well as didactic, because I think that one of the things that is the most influential in getting people motivated and understanding some of the power of these simple techniques is to experience them themselves, and I would just ask you to consider that.

DR. DUFFY: Dean, my greatest obstacle in building this was really internal, and so for a year and

a half I tried to get this big device company on-board, and it wasn't until we did a site visit to a center where, instead of sitting in a boardroom all day looking at slides on integrative medicine, these enlightened physicians had my board lay on the table.

They came out that afternoon, they are in the back of the limo on the way to the airport, and their ties are to the side, and they said to me, "Bridget, we finally get what you are doing and what this is about," and I was like yes.

So, that is when I realized it has to be experiential. You know, in an airport Hilton, I can't inform 200 sales guys from Medtronic about what it is their patients are seeking. I think people have to experience what it is that their patients are seeking and paying a lot of money for.

DR. GORDON: Thank you.

Joe.

DR. PIZZORNO: I would like to ask for your help. I think what you are doing is laudable, and I think all of us in this room want to see medicine advance and see conventional medicine regain some of its soul.

The reality is that 600 million visits to complementary and alternative medicine care providers is being provided by CAM providers, over 200,000 of them in the United States, and they are the ones who are experts in this, they are the ones who have kept this medicine alive for a century and a half, when conventional medicine has done everything it could to destroy it.

Now, we have talked about integrative care clinics. That is a great idea, but in reality, this care can be provided within communities, integrated within communities, which means conventional practitioners working with CAM practitioners and physicians.

We need your foundations to pay attention to the CAM professionals and the CAM institutions, as well, because we need to advance these healing arts. Again, the majority of the care will be provided by us CAM professionals. We need your assistance also. How can that happen?

I am speaking from experience as the Founding President of Bastyr University that foundations have virtually always said no to every request that we have made. This has to change. How can we do that?

MS. BRAUN: I realize that is probably a rhetorical question, but one comment about that, again, as we look at our mission, it is to fund those issues of science, but that are of most pressing concern and need to our lay constituents, and within the world of cancer and within the world of breast cancer that we specifically operate in, we know that some of the most pressing questions are what else is there in my healing.

I understand a bit about chemotherapy, a patient might say, and chemotherapy is perhaps one of the most toxic of all of the kinds of medicine, traditional medicine that are employed, so they seek to have, not only an understanding of their healing, but how do they deal with the traditional healing.

So, we know that these are people, we know from studies and we know from anecdote, these are people who make a great deal of use of complementary and alternative providers. So, we are pushed by them, and I think what we can do is tap into what is truly a public demand if we are going to then embrace and wrap the science around it, so that we come at it from both sides.

DR. DUFFY: We have to fund some pilots that

work, and there is one we are trying to build in Minneapolis. There is a Powder Horn Community Clinic that I think is probably one of the best models in the world, and it is the only one that doesn't require you to see a physician, it is not just a bunch of CAM practitioners with a bunch of M.D.'s all put in a box together and trying to alter reimbursement, which is what a lot of the models are.

So, I think what the goal is, is how do we connect individuals to the community of healers that they need to heal, and it may not be that we have to open a clinic that has an M.D., an acupuncturist, chiropractor all in the same place. It may be a way that we connect them in different ways and we have to figure that out.

I can't agree with you more, and I don't know the answer to your question, but we need to try.

DR. MILLER: I think from the perspective of Robert Wood Johnson, as I said, we have a translational agenda in terms of our programmatic funding where the evidence base exists. We are very interested in funding projects that will help in widespread implementation.

If you take a look at the projects that are in

your appendix in terms of both mind-body and other areas where an evidence base exists, that we have done some work in that area, but I think that you pose a very important challenge and possibly we need to do more.

DR. GORDON: Wayne.

DR. JONAS: I want to echo Dean and other's sentiments, thanking you all for the spirit in which you operate, one of philanthropy and generosity. I think the quality of the resources has somehow changed by having that spirit and may, in fact, go farther than other types of resources in getting towards understanding healing and having healing as a fundamental concept.

I was glad to hear that I heard at least four times the word "healing" and focusing on healing to help us understand what it is all the way from the basic science level up to the actual application level in terms of personal interactions because I think if anything is going to help us in our current chronic illness, it will be supplementing our current medical system with the practice of healing as a way of approaching and treating chronic disease.

My question to you is how is your effort any

different than what goes on from the government, or how does it relate to what goes on from the government. We are primarily involved in making policy that comes from the government. Are you in some sense supplementing what the government can't provide, but going along the same lines, or are you doing something fundamentally different, or is your process in some way fundamentally different that makes it more likely that there will be breakthroughs or utility? Any, all?

MS. BRAUN: Two things. One is at the Komen Foundation we follow and we are one of the NIH-accredited, I guess, grantmaking organizations, so we do follow the model with respect to our basic peer reviewed grant program, but in addition to that, we have a couple of other mechanisms for grantmaking, so it may be that that is one differential.

We have an ability also to change topics, not on a whim by any means, by certainly in keeping with the demand of the public. So, I believe that that is a little bit different is that ability to change direction perhaps a bit more quickly.

Then, the other thing again, as I have said, is

our funds are for the most part unrestricted, so that we can work in the precise needs that have been identified, and I guess complementary to what the government does, at least in our model, we work with especially the National Cancer Institute and the Department of Defense in our case because they are both the major funders of breast cancer research, and work them to see what they are doing, and not to be duplicative.

There are also some things that they will forthrightly say to us we can't fund this, can you, because it is not something as a government agency we can do, but we feel it is important to be done. So, we work in that way collaboratively.

But I think back to the community and the question that was raised. We also fund a huge number of programs within the 115 communities where we exist, and I think that is also something that is remarkably different from the government model, is that reach within the community and the way that things bubble up, as well as filter down, so perhaps that is a mechanism.

I think you will see that most philanthropic organizations do have that strong reach into the

community.

DR. GORDON: I wanted to say just a couple of words about that. As I chaired the Committee on Research Grants and CAM last year, I think that is precisely a group that CAM practitioners should apply to. We looked at the grants, there was no particular discrimination or prejudice because of the degrees, it was simply the expertise of the participants.

So, I think part of the issue is making more widely available some of the information about foundations that is out there, so that a dialogue can start about some of these issues, and some of the misconceptions can be cleared up.

The other thing that I want to say about Komen is that your turnaround time is about 1/50th of the government's.

MS. BRAUN: I didn't really want to raise that.

[Laughter.]

DR. GORDON: So, it is very effective. You apply, you either take the grant or you don't take the grant, and you know in a few weeks. I think that is a great blessing especially in this field where things are

moving very fast and we are really trying to go with what is important at that time. So, I just wanted to mention that.

George, you had a question.

DR. BERNIER: Yes. I would like to comment that it is very striking that three of the four of the presenters really deal with fairly narrow, potentially solvable problems, and I am sure that is part of the attraction.

I do wonder, though, if down the road, you would consider, and I guess, Dr. Duffy, you would be the most likely one, that you have gone from a one area of interest to two areas in the relatively recent past.

Do you see this as an evolving process whereby you may well start touching territory in areas outside neurosciences or cardiology?

DR. DUFFY: I think most likely not, because the core mission of the company is to provide life-long solutions for people with heart and brain disease, so our foundation tries to do things complementary to what the corporate side does, however, I think the volume of people that we impact with heart disease and neurologic

conditions is so large that I don't see that we can hardly make a dent in it, so we have got a lot to do.

So, it is frustrating for me because I do see people within the community and a lot of grass-roots efforts who I believe are really making a difference in building the model, but because of the people we serve, I tend to have to go with cardiovascular centers and neurologic centers because it is in line with our mission.

But I believe that through collaboration with other foundations and philanthropy that we could identify some key next partners or projects to fund that would be complementary to what we are doing, so I would see a role within a hub of people that looked at exploring, reaching out more broadly.

DR. BERNIER: I would like very much to compliment you and thank you for your contributions today.

MS. BRAUN: May I just add one comment to that, as well, that we found because the interest in breast cancer, I guess, has remained so strong, and we do focus exclusively on breast cancer, but because we have been

relatively successful in garnering public interest and support, that it is also incumbent upon us to, as we do things within the world of breast cancer, structure them such that they can either serve as models for other diseases or for other cancers, and pave the way for others to hopefully, as they go along, whether it is within research of community outreach, to have to do less work, and we have actually structured our organization such that the core competencies that we have will be made available to other organizations, so that they will not have to reinvent wheels as they go along, but can focus upon their mission.

So, I think that may be a way rather than reaching out specifically into other diseases or areas that you will see foundations working, is to trying to provide what they have learned to those entrepreneurs who are coming into other areas.

DR. GORDON: Wayne.

DR. JONAS: I was hoping some of the others would comment on whether there is any kind of qualitative difference in what you are doing compared to what the government is doing. I mean you often hear from, not

just CAM researchers, but a lot of people in research who are trying to do very innovative things that they can't get it from the normal processes because they are rather restricted in terms of what they will fund, not really into high-risk type of innovative areas.

I am just wondering, are your foundations addressing this in any way.

DR. MILLER: A lot of it depends upon the foundation, and because of my work in GIH, I have got a bit of a scope on what philanthropies do and their approach to grantmaking. At RWJ, 75 percent of the work that we do is through a targeted, solicited authorization, usually programs that have been developed in-house, but we do reserve 25 percent of our annual grantmaking for unsolicited, over-the-transom proposals as long as they fit into one of the general goal areas of access - chronic care or substance abuse.

The issue that Commissioner Gordon raised a little while ago regarding flexibility is a very important one in terms of turnaround time for proposals. We are not as fast as Komen, but we are certainly not as slow as the federal government in terms of funding

projects.

But the other issue that I think is a very important one for health philanthropy is the issue of risk taking, and funding things that the federal government cannot fund.

We have done a lot of work and actually at one point were the sole founders in the areas of both tobacco and also end-of-life work at the Robert Wood Johnson Foundation, and I think that if you are able to create that kind of leadership or niche within a particular foundation -- I know that Fetzer was not able to attend the meetings today, but think about that kind of focus and helping to lead a foundation and a foundation's board in a way that can help to promote the field would be very useful.

DR. DUFFY: I agree. I think that we target people that take risk and are innovative, and, in fact, I think that what you are doing is really cutting edge, and one center that we are funding couldn't get funding from any other place because they are looking at issues of energy research.

I think there is an opportunity, when couched

in an organization that there is very conventional treatment and they have visionary people who are looking on the edge, that we can help get them to a place where they can then qualify for funding through the government to take that research to another level.

I think that the other thing that we can do is help make inroads to other entities that are doing research in this. For example, I presented on a panel with Dr. Eisenberg and some others at the National Academy of Engineering and Science a month or two ago.

There were 400 people in the audience, mostly men, and we were on after the talk on nanoelectrical, microprocessor chip something, and I thought we are going to get laughed off the stage. Our talk was forces driving patients into models of health care, and at the end of our presentation, we were mobbed.

I came home with like 20 cards in my pocket from these basic science researchers who are looking at the bioelectrical chemical mechanism of connections between the heart and the brain, and energy, and I was just blown away by what is already going on out there.

I think that we can play a role in connecting

these people doing the research that can get to a level where the government will support it.

MS. SAMUELI: If I could add just one more thing, the creation of the institute was to do just that, we wanted to seed innovative and creative projects, so that the government could see what is out there and that people were willing to seed these projects to add to the credibility of CAM.

So, that is exactly what we are trying to do is to be innovative and flexible.

DR. JONAS: Dr. Duffy, would you mind giving those cards to Dr. Samueli?

[Laughter.]

DR. GORDON: I want to thank you all. I want to make a couple of suggestions and ask for your ongoing help. The suggestions are one of the things that is very important to us in reaching out to foundations, and several people have said it or hinted at it, is that if we can be there to share with you, and share the experience, as well as the knowledge, hopefully, the wisdom as well as the knowledge, that that will go a long way, and that can be very important to all of us.

Secondly, I think that you are in a wonderful position, all of you, to speak with other foundations, and the foundation people, as you know, trust each other or at least get along with each other in a way that is different from people who are potentially coming for money from you.

So, part of what we are doing in a sense is entrusting part of our mission to you, is to reach out and to share with people your experience and the possibilities that you see, and the implications, not only for complementary and alternative medicine, but for informing medicine and health care and healing that you see.

Finally, we would love to talk with you further because as we come out with recommendations in the Interim Report and in the Final Report, that is only going to go as far as the people in this country take it, and you are, in various ways, in touch with many people in many different ways.

So, we would like to have the opportunity to share with you that information to get your input about it and for all of us to partner in trying to move the

field ahead.

So, thank you very much for coming and for sharing so much with us.

[Applause.]

DR. GORDON: We are going to take a 15-minute break and then we will come back with the next panel.

[Recess.]

Panel Session III

Approaches to Evaluating Research Literature

Presenter: Donald A. Lindberg, M.D.

DR. LINDBERG: Good afternoon. I am happy to appear before you. If you like, I will make a statement and then take questions. Is that suitable? Okay.

In writing, you asked about the policies of the National Library of Medicine with respect to scientific literature on complementary and alternative medicine.

At a previous hearing, you already met with Sheldon Kotzin, one of our technical people at the Library, and he has given you a briefing, so I will attempt to go somewhat beyond that in what I say, but I would be happy to take questions on any portion of our work.

The National Library of Medicine is the biggest medical library in the world. It actually began its existence in the United States in 1836, so it has been in the business of collecting physical prints and photos and journals and books for all of these many years.

It pioneered the use of electronics and indexing that literature starting in 1964, and made those available throughout the world basically starting in 1970. I will say a little bit more about recent advances.

But I mention this because it is the mission of the Library to acquire, organize, and disseminate the biomedical knowledge of the world for the benefit of the public health, so we, of course, include the area of your concern along with the other older areas.

In fact, I have been there only since 1984, but in those roughly 16 years, a number of new institutes have been created, a number of new fields have been created, a number of regrettable elements like AIDS have been discovered and are being attacked. We are returning to the attack on malaria, an old enemy.

So, things have changed and the Library changes

with them, and we always ask ourselves two things when we recognize a new field, as we did with complementary and alternative medicine - firstly, what is the status of our collection; secondly, what is the status of the electronic indexing; thirdly, is the terminology we are using to describe this field suitable.

So, that is sort of our approach to it. As you, I am sure, realize and would approve, libraries don't write books, they organize them, and we don't write journals, we organize the literature.

The literature is pretty big. We add, for instance, the MEDLINE 450,000, say, half a million articles per year, and the terminology to organize those things is roughly 500,000 to a million terms or concepts.

In recent times, the advent of Internet and World Wide Web and the electronic technologies have allowed us to include in the list of users, patients, families and the public, so that since starting to make MEDLINE available on Internet in '97, and making it free since 1998 -- Mr. Gore did the first search, as a matter of fact, first free search -- our usage has gone from 7 million a year to, within a year, 75 million, the next

year 120 million, the next 240 million searches per year on the database.

Mostly, this is the United States, but in areas like molecular medicine, it is half and half, perhaps a little bit larger overseas, but, of course, half the data comes from overseas, too.

So, more specifically with respect to the CAM area, at the time that Wayne Jonas was director of the National Center, we offered him the opportunity to talk with our Board of Regents, and in the course of that, he described to us a list of journals, which was then 695 journals that he and his colleagues had felt were important for CAM.

So, we sent that list. We did two things. We, first of all, began to examine our own collection, asking the questions that I mentioned to you, do we own these things, and so forth, and then we sent those out to 14 research centers in CAM, in the U.S. and abroad, to get an opinion on which are most important and give us some guidance.

Well, it turned out that we already owned 79 percent of all those journals and had since their

inception, and it is a big library.

Based on consultation from the Centers, we immediately added roughly a dozen journals to the routine collection and reviewed the question of which are to be indexed electronically. In more recent days, of course, Dr. Strauss has taken over the Center, and working with NCCAM and NIH, we have jointly produced a database aimed at the public for the most part, but also practitioners and scientists, of complementary and alternative medicine articles on MEDLINE, so that is to say we are working as partners.

This has been very, very helpful to us because we can look to him and his colleagues and consultants and funded centers for guidance as to the quality, if you will, and we know how to do the electronic part. So, I think it is a pretty good result.

There are roughly 230,000 citations on that sort of pared-down, high-quality database.

Now, questions that, Mr. Chairman, you asked in writing to me had to do with the process for selecting new journals either for the collection or for inclusion in MEDLINE, so perhaps just for the moment I will tell

you about that.

There is an NIH-chartered committee, that is to say, compliant with the various federal advisory committee rules and regulations, proper committee, in other words, called the Literature Selection Technical Review Committee, LSTRC.

It reviews all new journal titles that we undertake to include. They meet three times a year. The skills and backgrounds of the persons vary, but they include a host of medical specialties, medical librarianship, public health, basic science.

It isn't, of course, like any study section, necessary to include all knowledge in the heads of a few people around a table or a dozen people around the table, so they will also get collateral reviews whenever a particular journal warrants it.

In addition to that, each year we review one or two major fields. So, for instance, last year we did pharmacology, and this year we are doing public health, and I can describe in more detail how that is accomplished.

What else would be of interest to you - the

success rate. I think I mentioned that they look at roughly 140 new journals each quarter that they meet. I mean it is rather amazing how fast journals come into existence.

They don't go out of existence with quite the same speed, so there is an accumulation, but there is a lot to look at, and the success rate is roughly 25 to 30 percent, so it is almost like grants, and we will undertake to include those which are the most important or of highest priority, perhaps I should say.

You also asked, Mr. Chairman, in writing, what are the criteria which we would use to judge a journal, and so forth, so I should tell you that the most important one centers on the content of the journal, the scientific content of the journal, and it is desirable, of course, that -- I guess the terminology we would use in our published criteria are we look at the validity, importance, and originality of the contribution.

My colleague, George Lindberg, who used to be editor-in-chief of JAMA, said it in a much snappier way. He said when we get a submission of an article, I ask is it new, is it true, is it important, and if it is all

three, it might get in JAMA, also won't. So, I suppose we are really looking at much the same criteria.

In general, the editorial work on a publication is of some interest, as well. You want it to be well presented, you want it to be on acid-free paper, for example. There is no point in subscribing to and buying stuff that is just a liability.

I think I mentioned that 55 percent of the journals themselves in MEDLINE are from outside the United States, so we attempt, as I said, to bring the knowledge of the world to the U.S.

In closing, there is an additional effort that NLM is making that you might possibly have an interest in, even though, of course, you didn't ask for this specifically. We have taken a great shine to the idea that we would like to try to do as good a job for the public, for patients, families, and the public as we have historically done for scientists and doctors. I mean it is much more difficult to serve the public. So, we are still learning quite how to do that.

Most recently, we have started working with public libraries because there are databases that we

produce - MEDLINEplus is aimed at the public, clinicaltrials.gov is aimed at the public, but it is said that only about half of Americans actually have computers and connectivity, so the others we wish to serve, as well, and so partly the public library program is aimed in that direction.

In each case, we will have a medical library, a public library, and then a study to see how can we -- we are trying to help both of those -- enhance the ability of members of the public to get biomedical information. There are more public libraries than medical libraries, obviously. So, we have funded I think it is 64 grants in 34 states, thus far with a very encouraging result.

While we are not pushing CAM or pushing anything else, we are pushing ourselves to try to increase the likelihood that a user can get what he or she wants in the way of information about science and health from the library system.

I think you probably share this goal with us, and I thank you for the chance to be here.

DR. GORDON: Thank you very much for your work and for coming here, Dr. Lindberg.

Douglas Kamerow.

Presenter: Douglas B. Kamerow, M.D., M.P.H.

DR. KAMEROW: Thank you, Mr. Chairman. I am pleased to be here representing the Agency for Healthcare Research and Quality, which is the smallest agency of the Public Health Service.

If you look at your list of speakers, you will see that you have listed the old name of the agency, which is the Agency for Health Care Policy and Research, so we have changed our name, and my e-mail address is also wrong in there, so if you want to e-mail me, the correct e-mail address is my name at AHRQ.gov.

I have got handout that I think was distributed to you as a set of PowerPoint slides, and I want to go over that very briefly. I will skip around a little bit because I don't think I can cover it all in 10 minutes, and I do want to get to the questions that you asked us.

As I said, the agency is the smallest in the Public Health Service, and our job, like NIH's, is to do research, but we focus specifically on health services research. As you can see from the third slide, basically, what we do is support the research that

improves access to care, reduces its cost, improves its outcomes, tries to improve its quality, and appropriate use of health care services.

There is a cute little water faucet down there a little below that tries to show the pipeline of our research, and if you have good eyes, you can read what is inside of that. If you can't, the idea is that we move through new research on priority health issues, through creating tools and training folks, then translating that research into practice, and the goal coming out of the faucet is improved outcomes, better quality, greater access, and appropriate cost and use.

The agency really has focused very little on CAM activities. We have done a bit of research in that area. What we are doing mainly now is two things. One is surveys. That is, we have a large Medical Expenditure Panel Survey that is the biggest health expenditure survey in the country and the most accurate.

One of the nice parts of that survey is we ask people about their use of various practitioners, and I have got some slides on that, so if you want to know about that, it is a useful way. As the survey comes out

in various iterations, we are now in the '97 survey that is being released, '98 will be out soon, and then followed by '99 as they lag a little bit, but you can find a fair amount about who uses CAM practitioners and for what concerns that they saw them.

There is nothing on outcomes of care in that survey. We have done some outcomes research, but not a whole not. It has mainly been in the area of chiropractic, mainly in the area of back pain, looking at acupuncture and chiropractic medicine.

The focus of our activities besides those two has been on what we call synthesis here, and the part of the agency that I am in charge of does that kind of synthesis. If you turn over the page to the next one, to the very bottom of that page, that is page 2 in the handout, you can see that it has a little logo and describes our evidence-based practice centers.

About four years ago now, we created 12 centers around North America, and their job is to produce systematic reviews. Systematic reviews is not like the kind of general literature review that you see in a journal, at least not the kind that you used to see in

journals, and if you go to the middle of page 3, you will see a definition of the word "systematic review."

They are concise summaries of the best available evidence addressing sharply defined clinical questions, using explicit and rigorous methods to identify, then appraise, and then synthesize the studies.

So, you don't just gather them up. First of all, you systematically gather them up. You have to in a lot of cases -- and CAM is a good example -- really dig around to find things, and I will come back to that in a minute.

Then, you have to set up some sort of rating scale to decide how you are going to evaluate those studies. Once you do that, you are going to rate the studies and then come to some sort of conclusion.

Sometimes that means using fancy techniques, such as meta-analysis or decision analysis. Sometimes you can't do that for various technical reasons. You basically just display in a series of tables what you have found and try to come to some conclusions.

We call these things evidence reports because we don't make recommendations. The agency used to make

clinical practice guidelines that had recommendations, but what we do now is try to supply what we think is the front end of these kinds of recommendations, so that organizations, whether they are clinical organizations or states, or whether they are health plans, whether they are groups of practitioners, whoever they are, they can then take the stuff that they ask for, because we do these when we are requested to do them, and they can make their own recommendations.

What we do is try to supply to them and to everybody on the web, evidence reports and good syntheses, so what they look like - here are a few that have been done, and I will be glad to pass them around.

Here is one on garlic. They come in two versions, the turgid and the brief, the mercifully brief. So, I will pass the two around, and you can take a look. Here is one on milk thistle and it is whether it works to help liver disease, and we have some other ones that are coming out, as well. I will just pass them around.

I guess the point that I want to conclude with, and I will be glad to answer your questions after we have finished, are a couple of things. First of all, we have

got an agreement with NCCAM at NIH to do this work on selected topics that they are interested in, and you will see on the last page of my slides that we have chosen one of our evidence-based practice centers.

This happens to be the one in Southern California, which is a consortium of folks led by Rand, to do a number of topics for NCCAM when they ask for them, and you can see the topics that we are working on now, some of which are done, some of which are in process.

They have asked us for these, not so much because they expect to find the answer, that is, they don't really expect that after a systematic review, they are going to find that this particular substance is perfect and should be used for treating that, although that may happen, and occasionally it will.

What they are really looking for, and I think in some ways most excited about, is to find areas where more research is needed, the areas where there is good beginnings of evidence, something that lets people know that there is probably something to this idea that people are talking about, whether they are maybe small trials or

other kinds of case series that really wouldn't pass the test of very strong evidence, but something that NIH can then turn around and do a carefully done trial, because we don't have the resources at the agency, we don't do many clinical trials. It takes a lot of money to do clinical trials obviously. But we help them, we think, set their research agenda for doing that.

The third thing we can help them with is methods and bibliographic research, so that we can try to push forward the ideas of how you go about analyzing data like this, because there is definitely an art, as well as a science, to finding the CAM literature.

For instance, we just completed one on Ayurvedic medicine, which is, at least in its origins and still a lot of it is practiced in India, so Rand had to get someone to India and go through libraries there to find language, English language and other kinds of literature about Ayurvedic medicine.

They found a lot, and they found more on diabetes than anything else, but still there was no true answer, but there was a lot of interesting indications in a report that is still forthcoming, we are not quite

finished with it.

But it is an interesting process, it has taken us a little bit of a departure from how we set up this program, but we think it is one that has been useful in NIH and we hope useful to others, as well.

So, that is all I wanted to say and I am glad to answer questions when we are done.

DR. GORDON: Great. Thank you very much. I certainly understand more now. That is great.

Brian Berman is next. Brian is going to assume two different identities or two slightly different identities. He is going to talk both about the Cochrane Collaborative and also about doing research in an academic medical center, so he will have more time than the other presenters.

Brian.

Presenter: Brian Berman, M.D.

DR. BERMAN: Thank you, Mr. Chairman, members of the Commission. I am honored to be given the opportunity to speak with you today on the evaluation of CAM research literature and the role of the Cochrane Collaboration, and as Jim said, the issues in bringing in

research into an academic health center.

I am a board-certified family physician and pain management specialist who has been integrating a number of these CAM modalities into my practice over the past 18 years.

I am also Director of the University of Maryland's Complementary Medicine Program and principal investigator on an NIH specialized center research in complementary medicine focused on arthritis and principal investigator on one of the large clinical trials in osteoarthritis and acupuncture, so today I will be wearing more of my research hat.

One of the main activities of our center is the investigation of the safety, efficacy, and mechanisms of CAM therapies for pain-related problems. We design and conduct original research trials in addition to systematically distilling the best evidence available worldwide and disseminating these also to the public and scientific communities.

So, the first half of what I will be talking to you about is the Cochrane Collaboration and evaluation of the literature. Some of you may be familiar with the

Cochrane Collaboration. It is an international nonprofit organization that prepares, maintains, and disseminates systematic up-to-date reviews of health care interventions.

It started in '93 from a challenge by Archie Cochrane, an epidemiologist in Oxford, England, who recognized that people who want to make more informed decisions about health care do not have access to reliable reviews of the available evidence.

So, the Cochrane Collaboration aims for information that is evidence based, easily accessible, internationally developed, quality controlled, clinically useful, and periodically updated.

There are a couple of points there. International, we have researchers, clinicians, consumers from all over the world working together in this collaboration. It truly is a collaboration. It is especially important in this area of complementary medicine where about 80 percent of the world uses it as their primary form of care.

Evidence based, the reviews, as was mentioned before, they are prepared systematically, and a special

feature is that they are kept up to date and to account of the new evidence.

I would say that the Cochrane Collaboration has embraced this field's approach to look at what is effective and not effective, and many of the leaders from this group have really taken this on-board.

A couple of years ago, in Lancet, it was compared, the Cochrane Collaboration in general compared to the Genome Project.

One of the questions was the role of consumers in the Cochrane Collaboration, and I would say they place a high priority on consumer input throughout all levels of activity. There is a consumer network that has been developed based out of Australia, and they have many roles.

They make abstracts and reviews more readable and more accessible, so they have developed a way of having a synopsis of these systematic reviews, sort of half-page, and they by now have done about one-third of the thousand systematic reviews that exist in the database.

They also have a seat on the Executive

Committee. They help research identify important questions to answer, they comment on drafts of reviews, and they help disseminate the results.

For the complementary medicine field, the consumer representative is Clara Allen from the U.K., and she has taken a very active role in taking some of these systematic reviews and writing summaries for the public.

The products for the Cochrane Collaboration, the main products is the Cochrane Library, and this has in it a database of systematic reviews, as I mentioned, over 1,000 reviews are in it now.

In the Controlled Trials Registry, there are over 300,000 randomized controlled trials. This is all aspects of health care, not just complementary medicine. But that is more, as I understand, since he is sitting next to me, more than what is in MEDLINE to date, and not bad for an organization that is only eight years old right now.

The complementary medicine field was started in 1996, was registered with the Cochrane Collaboration in part due to Dr. Wayne Jonas' encouragement at the time for our center to really get involved in that, and it has

developed a specialized registry of trials in complementary medicine, developed a registry of systematic reviews, and facilitate new systematic reviews, to coordinate the field and work with groups both inside and outside the collaboration, and then disseminate the results.

The field is coordinated by our center at the University of Maryland, and we also maintain the CAM registry through the work of Mac Beckner, and we receive funding from the NIH, first, at the Office of Alternative Medicine, and now at NCCAM.

One of the first aspects of what we got involved with was to develop the Fields Trial Registry. This registry aims to be inclusive of all randomized controlled trials in complementary medicine, published or unpublished, in any language.

The trials and tribulations of finding and developing studies are outlined in the article that I have included for you, the JAMA '98 article and some of those difficulties of capturing all the complementary medicine studies through standard MEDLINE searches and the incomplete search terms up to the early 1990s.

There wasn't a MeSH term of alternative medicine, it was actually therapeutic cults. That was then changed in the early 1990s to alternative medicine, and there are, I think, 25 search terms in there. We used 250 search terms. So if you used one of our 25 terms, you would get about a yield of 45,000 articles. If you use the other 250, you would get about 150,000 articles.

We also need to identify and search comprehensively the electronic databases worldwide. And then, many of the journals are not indexed in the National Library of Medicine, although it is increasing, as we have heard. There is also the need for hand-searching the journals.

We now have 5,300 randomized controlled trials in this registry and another 4,000 possible randomized controlled trials have been identified.

One of the questions that you asked was about the criteria for inclusion as complementary medicine, which is a difficult area. What we did was we took the definition of complementary medicine that was developed in the NIH/OAM Methodology Conference back in 1995, which

is in your written testimony.

We then used this definition as an inclusion criteria, and then developed three exclusion criteria. So, we said that an intervention will be excluded from the registry if it meets two of the following criteria:

One. Is the intervention, when practiced in this manner, at this dose, with these patients, almost exclusively practiced by those with conventional medical qualifications.

Number two. Is the intervention, when practiced in this manner, at this dose, with these patients, a recommended treatment.

In other words, a significant number of standard medical or paramedical references refer to use of therapy as routine.

Number three. Does the intervention fail to involve any theoretical divergence with mainstream medicine or science.

The search strategy we developed and the list of included the therapies are in the addendum that you have. I would say the value of the search strategy is seen from the graph that you also have in your testimony,

where, if you take a MEDLINE alternative medicine MeSH search for randomized controlled trials, you will get a yield of about 2,400.

If you take a more comprehensive MEDLINE search of the 182 terms that we tried to take, you get almost double that, 4,700. Then if you take the Cochrane Registry, where there has been some hand-searching and other electronic databases, you get about 5,300.

So, how does Cochrane Collaboration assess the quality of the research it includes? That was one of the questions for us. Well, it is accomplished through systematic review, which is the main product of the collaboration. The CAM systematic review registry contains 208 systematic reviews to date, and as we heard, these reviews answer sharply defined questions through a comprehensive search, assess the quality of each trial, and synthesize the data.

I have found that they are a powerful way to keep up to date, handle the information overload, give practitioners and consumers answers to what works, what doesn't, what is safe, and tell us where the gaps in the knowledge are.

One of the important steps in the systematic review is to critically appraise each study to evaluate the quality of the study's methods. As the computer industry says, garbage in; garbage out. Often a checklist in the scale, such as the Jadad scale, was used.

This looks a three main issues. One, is whether the study was randomized, and if so, was the randomization process adequate.

Number two, blinding. Was it double-blind, and did they evaluate the success of the blinding? This obviously tends to favor drug trials, but you can always blind the person evaluating the outcomes, as well as the patient.

Then there is the third, the attrition rate, was it reported and why did the subjects drop out.

The fourth one, has become very important, allocation concealment. After the randomization, how were the groups hidden; was it put up on a board where everybody could see which groups they were going into; was it computer generated; just how was that done.

Other features of the study often evaluated

are, was the primary endpoint measure defined. For all studies, it is evaluated at 25 percent that that has been done. That is in all conventional, as well as complementary medicine.

Very important is the quality of treatment; was there a description of the intervention; and what about the qualifications of the treater. I saw that, recently, in a paper that was submitted to me for acupuncture, looking at rheumatoid arthritis, it was a well-designed study. However, the intervention itself was sorely inadequate, one or two treatments for chronic rheumatoid arthritis. So the adequacy of the treatment.

The sample size is important. Was there sufficient statistical power; was the analysis appropriate; did researchers assess compliance; and what about co-interventions to were other things done that maybe made the difference, and then, do the conclusions follow the evidence, or were the hyped up.

So, why do all this? Well, we know that poorly executed trials tend to exaggerate treatment effects, and they have important biases. Sometimes they have effects as much as the treatment itself.

You asked for some policy recommendations, and I would say that the work of CAM literature evaluation in the Cochrane Collaboration field has just begun. I think the importance is that these systematic reviews are useful to consumers to cohere evidence that may sometimes go in different directions.

They are useful for policymakers to define, sometimes, what to fund, as well as for practice guidelines, useful for practitioners to answer specific clinical questions, and for researchers to summarize existing data.

The effort in producing systematic review needs to continue, and the scope of the work and its impact needs to be broadened. Specifically, I would recommend that the infrastructure and collaborative work with the Cochrane Collaboration field be allocated ongoing support, allowing for continued maintenance of the registry and coordination of the field.

With sufficient support, the field can increase its current work and significantly add to its value in the following ways:

Number one, it can set up a working group to

further define and broaden the scope of modalities included under alternative medicine, medical subject candidates. Some of our people worked with the National Library of Medicine a few years ago, and I think it still needs to go a lot further than that.

Number two, to increase the availability of reviews and their potential value in a number of ways make them available in the offices of policymakers, in public libraries, community health centers, through online subscription of the Cochrane Library; to develop executive summaries of the systematic reviews that clearly and concisely state the results of the reviews; to develop electronic jargon-free versions of systematic reviews with hypertext links to allow readers with various backgrounds to access information at different levels of complexity; to expand the area of the complementary medicine field website to include access to review summaries and to include consumer-friendly information.

Then, to identify the need for working with organizations such as NCCAM clearinghouse to find out what are people calling for, on a monthly, basis that is

really important to them, and then commission topics for review so that the questions addressed and the information developed are relevant to the users of these treatments.

Finally, to develop methodologies to evaluate non-randomized controlled trials, thus broadening the pool of information that can be drawn from them. I think, with support, the field would be able to undertake an ambitious program of generating and disseminating high-quality information to the public.

DR. GORDON: Do you want to take a breath and put on the other hat?

DR. BERMAN: I actually had a Terps hat and a Ravens hat, but I left them in the car.

The second part of the talk, a different subject, is the challenge of integrating CAM research into conventional academic institutions, and the training of CAM practitioners as research investigators. This is really focused around issues ensuring that research in CAM meets the highest scientific standards, and there are a couple points about this.

One, it is important to tap into our country's

academic institutions for their infrastructure and intellectual wealth, and two, we must make sure those involved in CAM research know about the therapies they are investigating, including their unique paradigms.

Our center at Maryland has been in existence now for 10 years, and we are well aware of some of the challenges of bringing CAM research into an academic medical center. I think our taking an evidence-based approach to CAM has been an extremely important part of our developing positive relationships with the institutions and the people therein.

We collaborate now with Departments of Epidemiology, Medicine, Pediatrics, as well as Schools of Pharmacy, Dentistry, and Nursing on preclinical and clinical research, as well as other people, both in this country and abroad.

Just as important is we have built up trust and respect, and nurture the common curiosity and finding out what works and doesn't, and how this translates into improving our patients' lives.

So, I was asked, well, what are some of the challenges in doing this. I would say, number one, the

lack of knowledge and understanding of CAM amongst the medical community is one of the first challenges facing any CAM initiative in the medical school or university and with this, a lot of bias can still occur.

Number two, sometimes, even if there is a willingness, the interest can be driven more by chasing sources of funding. This can, at times, lead to a highly experienced researcher designing and being funded for a study that isn't sensitive to the way a therapy is practiced. Also, researchers may not have a good understanding of what are the key questions that need to be answered, the sort of big bang questions.

Another issue is the importance of a clinical base in order to build a program of clinical research in CAM. At our own center, we have a fully functioning outpatient clinic staffed by practitioners who are duly trained in conventional medicine and complementary medicine, as well as a number of highly qualified CAM practitioners.

We found the clinic to be vital as a nurturing ground for research questions that are firmly based in clinical reality, however, establishing a clinic of this

sort within an academic medical environment is not always welcomed or readily supported by the institution.

I think complementary medicine research has suffered from the lack of CAM practitioners who are knowledgeable about research. The value of an academic-based center is the possibility of developing a team to design and conduct rigorous complementary medicine studies that draws on the expertise of methodologists, clinicians, and CAM practitioners, a critical mass of people.

However, the role of the center should also be to train CAM practitioners to become skilled CAM researchers. These researchers, in turn, will ensure the future leadership of the field. So as an example of that, we have recently submitted an application, through the Fogarty, to take people from Beijing University, who are trained in traditional Chinese medicine and now want to become clinical researchers.

They will come into our university, they will get trained with a Master's in epidemiology, set courses that are there, and then with a focus, with our people in our own center, to work on particular studies in the area

of complementary medicine.

But even with the best team and with highly skilled CAM investigators, there are many practical issues common to almost all researchers conducting well-designed studies, and these are the issues of limited funding resources for the type of large randomized, controlled trials that are needed.

Some of the many challenges of seeing a research trial through to the conclusion include the usual complaints of space, paperwork, especially now as it get increased with IRB demands and funding bodies, and the difficulties of keeping patients invested in the study, especially if they are randomized into an arm of the study that does not include a CAM intervention.

Some recommendations, that good science is a key component to evaluating the role CAM can and should play in the health care of Americans. In turn, education and training are the key components in creating a community dedicated to rigorous evaluation of CAM.

So, a number of recommendations for achieving these aims would be, one, to fund a network of centers of excellence at academic institutions dedicated to the

investigation of CAM.

Some of this work is already going on at the NCCAM, and it is beginning to create the infrastructure necessary to support large and far-reaching research programs, as well as educate and train a growing pool of investigators dedicated to the CAM field.

The scope and number of these centers needs to grow. What I have heard here, which you are certainly aware of, is to encourage collaboration between the CAM community, government, industry, philanthropy, and academic health centers through forged partnerships and joint funding.

Number 3, to fund career development initiatives that would include research fellowships, including didactic teaching, hands-on training with appropriate mentoring aimed at creating skilled CAM clinical researchers, and also a Masters of Science degree in epidemiology with a CAM clinical research track.

The third, would be a critical appraisals training, focused on finding and assessing the scientific literature, and I think that kind of a workshop -- we

have had a number of those over the years -- have been very successful, and I think that is the kind of thing you can take as a traveling show, both for the CAM community, as well as the conventional people wanting to get involved with this.

Then the CAM tracks at medical schools and residency programs, allowing interested individuals to focus on CAM, which would include experiential elements, as well as the clinical uses, and then methodological issues in CAM research.

I would also put in one as the creation of a centralized database of curriculum topics and information material to facilitate the integration of CAM into existing courses, so that people at different universities who actually want to bring this into the courses that exist will have ready material to draw from.

I think my time is up, so I thank you very much.

Panel Discussion

DR. GORDON: Thank you, and thank you for being so gracious. Brian couldn't be here tomorrow, so his part two would have been, ordinarily, under Training of

Conventional and CAM Investigators.

So thank you for preparing so well and doing them both at this time.

I would like to open with one question, and then the Commissioners may have other questions. You three represent two government and one non-government agency that are very important in providing information and good information about CAM.

Do any of you, or all of you together, have any thoughts about how the responsibilities might best be divided up among the various government agencies and non-government?

For example, where is the boundary with NCCAM and the National Library, the Agency, and the Cochrane Collaboration? Who do you think best does what?

DR. LINDBERG: I think what Dr. Berman was describing is the scholarly production of critical reviews, and that has always been a very, very important part of the scientific literature, very much admired and sought. That, certainly, is what they are doing. That is certainly not what the Library is doing, or will it ever do.

On the other hand, we are sort of, I would say, committed to solid information infrastructure, and with respect to these clinical trials, I agree with Dr. Berman, these data are hard to come by, particularly if you go back in the old literature back in the turn of the century. I don't spend much time back there, frankly.

We, NLM, and FDA are required under the 1997 FDA Modernization Act to create a database of all clinical trials for, let's say, significant disease in the U.S., and our first step has been to make clinicaltrials.gov, focusing on those that have NIH support. That currently numbers 5,500 trials in 5,500 places. I am only talking about existing ones that patients can call a telephone number and enroll in, or at least consider.

That was hard to do. Our next step, of course, is the privately supported ones, drug houses and otherwise, those we will go hand in hand with FDA, because we want to be certain that they are properly described. Beyond that, of course, is overseas.

So, there is plenty of work for everybody to do, but our part of it, I would say, is the

infrastructure, and it is not writing clinical reviews.

DR. GORDON: What about, for example, how evidence reports would relate to systematic analyses?

DR. LINDBERG: If they are published in proper journals, they are in there.

DR. KAMEROW: The evidence reports that we produce, our systematic reviews, when you compare them to a Cochrane review, what you find in general is that the evidence reports are broader. You might think of them as comprising several different Cochrane reviews. That is a generalization, but it is generally true.

We also always have someone who has suggested the topic to us. So it is very important to us to take the review when it is done and give it back to the folks who requested it. It may be a government agency, it may be a group of physicians or other practitioners, it may be a health plan.

The hope, then, is that they are going to do something with it, and we generally ask them before they ask us, or as they ask us to do them, what will you do with it, create a guideline coverage decision, some sort of quality improvement program, something to put it into

action.

Of course, because we are a federal agency, everything we do is in the public domain. So, of course, it is put on the Web, and available, as well.

DR. GORDON: Where is the boundary with AHRQ and NCCAM?

DR. KAMEROW: Well, they are partners with us. They have asked us, just as we have groups in the private sector who ask us to do topics, we have become in just four years to the point where about almost a half of our budget is contributed by fellow federal agencies, sister, whatever the gender is.

DR. GORDON: How much is your budget?

DR. KAMEROW: We have about $3 million a year from agency funds that go to fund the evidence-based Practice Centers Program. So a group such as NCCAM will come to us and say, we would like reports on X, Y, and Z, and we talk about trying to get some funding from them, and then we do them.

DR. BERMAN: There are some ways that I think they can work together, and are working together as well. With the National Library of Medicine, I think the

abstracts of systematic reviews from the Cochrane Collaboration now go into MEDLINE.

I think that started about a year ago automatically, and I think they also download the central registry, which is now in New England, to MEDLINE, so they get that way.

I know a number of the Cochrane Collaboration have been involved with some advising on the complementary medicine field side within NLM, and the same with AHRQ. When they started, there were evidence-based reports. We know the field, we know the people who are doing it. So some of the people, like Cynthia Murrow [ph], came to us and said, who do we know that could act as either content experts or involved in systematic reviews in there. I think that is one of the ways to work.

The Cochrane Collaboration has the ability because they have so many people worldwide, and they are interested in different things. So it depends what they are interested in, but they can do many different systematic reviews. So in the four or five years that it has been receiving funding from NIH, I think we have

accomplished about 100 systematic reviews, and I know there are people interested to do a lot more than that.

DR. GORDON: What would the next steps be in collaboration, if you could look ahead?

DR. BERMAN: I would say, to help with NLM; how do they build an even stronger, finer net to capture the relevant studies might be one way of working together, and then on the systematic review side, I don't think the evidence-based reports are going to be able to do all the systematic reviews that need to be done.

DR. GORDON: I'm sorry, Brian. I didn't understand.

DR. BERMAN: You might correct me if I'm wrong, but I think these evidence-based reports are in-depth and, as I said, there may be several systematic reviews, as well as, I think, other information. So the evidence isn't really ready for that kind of a report. Yet, it is ready for a systematic review. It is very necessary to do that to find out where the evidence is.

DR. KAMEROW: We are trying to find ways to work with the Cochrane Collaboration. We co-located several of our evidence-based practice centers with U.S.

Cochrane centers four years ago, and so some of the personnel are the same.

We always make sure that we search the Cochrane database as we begin one of our evidence reports because why reinvent the wheel. That is the whole point of this. The Internet, of course, makes that a lot easier to do.

So, we are still trying to find a way that we can collaborate better, I think, with the Cochrane Collaboration.

DR. LINDBERG: It seems to me the critical reviews are a very good contribution. If it is possible to make nicely written explanations that patients can understand, we link to those kind of things through MEDLINEplus provided that they are from legitimate sources, either agency or voluntary health organizations, that they are kept current, that it is clear what biases are present, but we welcome the opportunity to link patients to good explanations.

So, I would say that is a possible area for expansion. NLM has actually been known to ship a little money to you guys, and I haven't seen any checks come back, so I imagine that is a reciprocal arrangement that

could be continued.

DR. GORDON: Wayne, Joe Fins, and Bill.

DR. JONAS: The panel not only represents government and non-government, but it represents the spectrum of data, information, and knowledge. Hopefully, we can take it even further, to wisdom.

One thing that Brian didn't mention along the line of what Dr. Lindberg, you just mentioned in terms of public information, is that the Cochrane Collaboration now is actively working on developing lay summaries of their reviews also that will go right along with the evidence reports and the regular summaries specifically working with public input on how to produce those summaries, so that it will be easier for the public and more valuable for the public.

Before I ask my question, I want to digress a bit and thank Dr. Lindberg for the support that he gave our initial attempts to try to assess this literature. He had me to the Board of Regents, and began immediately to assess the current journals to look at, where were their quality journals that were not being indexed in MEDLINE.

To my great surprise, the vast majority of them were somewhere in the collection of NLM, or many of them already indexed. It was quite a surprise to me because everybody had always said, gee, there is all this stuff out there that is not there, and actually, a lot of it was.

Also, in the evidence-based centers, Doug, as those were getting developed, I think we weren't sure exactly what they were going to be able to do in the area of complementary medicine. I am happy to see that you have taken, really, a bold step in looking at something as complicated as Ayurveda because one of the obstacles was, is that literature accessible, and is it any good. The general attitude was that it may not be good, but at least we need to look, I think, and know.

My question relates to that now. At the time it didn't appear that it was ready to really launch kind of full blown into the assessment of evidence. We were still trying to develop the methods for doing that including in the Cochrane Collaboration.

I am just wondering, do you feel that the field is ready to begin to do kind of an overall assessment of

the literature?

After all, it really isn't that big in terms of the amount of research literature that is out there relatively speaking, and I know that many of the things that we had talked about here, that people have requested, is if we just had some central authoritative source of the current literature evidence and how it existed, that this would be a useful starting point for a number of activities.

I am just wondering, do you feel that the field is ready for that, and would an infusion of support and funding be able to adequately begin to address this? Or, is it even needed at this time?

DR. KAMEROW: Is that a question for me?

DR. JONAS: It is for all of you, but, yes, I think, Doug, you could certainly start.

DR. KAMEROW: I am not an expert in CAM, so I can't really tell you, for sure, the answer, but it seems to us that it is a step-by-step process, that we clearly need to move into some new methodologic areas to be able to do this right, but that we were also able to use the current processes I think to do a pretty good job.

Ayurveda was a good example where it was kind of hard for those of us trained in Western medicine to -- I will speak for myself -- to put my mind around the concepts that were put out very carefully and pretty clearly by the Rand Corporation when they did the report, but you have to really shift into frames.

Still, though, there is the need to have a defined outcome of some sort, a divine intervention of some sort, and something to compare it to. I don't think that you can get around that. I think that is the question and can you define them and come up with ways to do it.

One of the things that Rand is doing is trying to figure out ways to statistically correctly and methodologically provide an overview of non-randomized controlled trials in a way that can be helpful, because a lot of this literature isn't a randomized controlled trial. Some would argue it can never be.

There are certainly some interventions for which that is true, but many, that is not true, and so I think that the idea of investing in one of the centers over a period of a few years, giving them a number of

topics, getting them familiar with sometimes it is a foreign language or whatever it required, a lot of the language is German, that that may be necessary, can move us along, both in terms of the actual topics, but also the methods that are needed.

DR. JONAS: What I am hearing you say is that resources really are not the issue even now, it is really the methodological development.

DR. KAMEROW: Oh, NCCAM has provided us most of the resources, it is not coming from AHRQ money, we just don't have that much, so if they are willing to support it, we, I think our centers can provide useful information.

DR. JONAS: The assessment of observational data, non-randomized trials, isn't that something, though, that is of interest and is being explored all over in medicine, not just in complementary medicine?

DR. KAMEROW: Well, it is an attempt to try to figure out how to combine those data in ways that we already know how to combine in randomized controlled trials, and that is, at least to my knowledge, still an unsolved problem.

DR. JONAS: So, the method really isn't developed yet to begin to venture in to do good evaluation using that kind of data.

DR. KAMEROW: But it is also one wants to stimulate the kinds of research that we do know how to evaluate. The problem is that is costly research because if you are talking about large trials, they are going to have enough power to be able to come up with the answers to the questions especially if they are relatively close in terms of the outcome, that, you know, it is slightly better, but not a whole lot better, so a large study you need.

DR. BERMAN: I would say, Wayne, also, that a little bit of that work is happening, you know, with people like Klause and the Cochrane Group where they have been working for several years on a review of reviews, and I think three of those have been accepted in Biomed Central, you know, one in acupuncture that I am involved with, and one I think in herbs, but it is piecemeal because there, there is a funding issue. You know, it is mainly a volunteer thing, and that would be I think extremely helpful to have those kinds of overviews

together.

There is also in the Cochrane Collaboration, you know, there is the Methodology Working Group, and there are people that are really interested, not just from the Cochrane's medicine side, but both sides, to see how we can look at some of these observational studies and do it properly.

DR. LINDBERG: I don't think that we should be limited by sort of one mental model of what this field is all about. I am reminded, just this morning I was reading an article in Science. It may not have been the latest one, but it was the latest one at hand. It had to do with malaria, because NIH has taken under Harold Varmis' prodding a good interest in malaria in Africa in the application of molecular biology to that, and, Wayne, you probably remember that.

So, NLM is involved in it because of our ability to facilitate communication. In any case, what the article described is what no doctor could ever fail to recognize, the power of botanicals. In this case, it is an Artemisia extract, artemisinin, which is active against falciparum malaria. You don't need a big

clinical trial and six years of statistical analysis to be excited by that.

We now know that you have to use those drugs in combination with others, but I mean this amounts to a spectacular breakthrough, and it apparently has been written about using a Chinese term for the extract for 30 years.

So, I mean a lot of I think what this commission is after is sort of an attitudinal change in attitude, keeping an open mind to these matters, so that the benefits will come from a lot of points where we are not expecting them.

DR. GORDON: Joe Fins, and then Bill next.

DR. FINS: On that attitudinal theme, we have heard from a number of constituencies during our deliberations who just reject the evidence-based approach. They see it, they cast it as their right to choose whatever therapy they want. They will contest the data that you folks would come up with, which I, by the way, endorse your approach.

But how do we build trust, how do we achieve an acceptance of these methodologies, as diverse as they may

be, consistent with our dissemination mandate, which is in the executive order, and are there any lessons specifically from reactions from the public to any of the studies that maybe the agency has done that disappoint proponents of one modality or treatment or herb or another? I mean what can we do to build a trusting relationship, so that we serve the public health, we promote safety, and we try to bring things that do work down the scientific pipeline, does anybody have any thoughts on that?

DR. BERMAN: One way I think is to bring the different groups together when we are looking at some of these questions and when we are looking at the systematic reviews, so there should be some consumers involved with what questions particularly are important to them, and then if they are involved with the whole process, as well as through the dissemination, I think that is going to make all the difference in the world.

There is not much point to have somebody in an ivory tower picking out a systematic review of something that really isn't relevant to your average person, but if there are topics that have real value to them, and then

the participatory type of research then goes on, I think that will make a big difference.

DR. KAMEROW: I would agree. I think that having patients involved on these panels helping to select and refine the topics is useful. There is a bit, of course, always of the keys-under-the-lamppost phenomenon where people who are doing reviews want to go where the evidence is, where the literature is, and people, whether they are physicians, other practitioners, or patients, may have different questions that can't be answered very well by what literature is out there. So, there is always a kind of a conflict there, and it leads to, one hopes, good research agendas in that area.

As a family doctor, you know, when I see patients who are interested in these things, nothing substitutes for good information and education on everybody's part, and I think most of us in conventional medicine don't have much education about these substances, treat them with disdain, if not lack of knowledge, and that doesn't help anything.

But we still need to have good information available, so I think that is the problem, is trying to

get more good research, and it is nice that the Cochrane Collaboration has undertaken the attempt to put into lay language their systematic reviews.

That is something we talk about, but haven't done yet. It is not a trivial matter.

DR. GORDON: Thank you. Bill.

DR. FAIR: On the other end of the spectrum that Wayne mentioned, there was a great deal of experience and knowledge in this area, but it seems to me that this is really very impressive, but many of the CAM practitioners, at least I am associated with, are over the age of 25, and the computer is an intimidating object to them.

What I am wondering is do we really need something like finding CAM Information for Dummies or something, because I don't think you will find it here, do we need to go back, or is there such a thing?

DR. LINDBERG: We wouldn't use that term, I don't suppose, although it does sell books, but the MEDLINEplus is definitely aimed at patients, families and the public, and it isn't particularly dumbed down, but it is using straightforward terminology and linking to other

sources on the web.

If we can find Cochrane things to link to that explain this stuff, that is great, we will for sure do it. I don't think anyone quite understands the best way. If I could just mention one other thing, I didn't give you recommendations, but the recommendation clearly from the Library is pay attention to make sure that the public can get good information, can get ready access to good information.

I agree with you, not everybody is facile with a computer, so that is why we are trying to work with the public libraries, hoping that, you know, what is whole thousands of other sites that they could go to.

Thus far, it has been pretty well received, and the public library people from the American Library Association have embraced the idea. It may seem obvious to you, but I would say 10 years ago, that the medical library and the public library people really didn't have that strong a partnership, but it is emerging from exactly this scheme to get electronic information to the patients.

DR. FAIR: I think it is a great idea. Are the

locations of those libraries on your website?

DR. LINDBERG: Yes, but some are cities, some are little towns. Initially, our questions were, well, will anyone bring medical questions to a public library, and if so, what kind of questions, how good are the answers, and can we help, and it has turned out that, yes, they do.

Now, if you bring them to a place -- I visited, for instance, a New York Public, Midtown Branch, 96th Street -- well, those people are fantastic. They are not afraid of medical questions or any other kinds of questions. You will definitely leave with good answers.

But on the other hand, and I can't throw this in CAM terms exactly, but when I was there, I tested them by asking about flu shots, and their software was smart and understood "flu" is influenza and "shots" is immunizations.

So it gave all the right information. Then I said, well, where do I get a flu shot, and it conjured, and did its searching and all that sort of stuff, and it said Albany, the Public Health Office in Albany.

So, I mean that revealed to us the difficulty

in linking to local information, which is what the real individual wants, not just crawling around a Web finding out who gives flu shots, but how to package it locally.

So, I guess it is just saying that there is a lot for us to learn about how to serve the public properly, and we are trying.

DR. GORDON: Joe.

DR. PIZZORNO: First, Dr. Lindberg, thank you so much for putting MEDLINE on the Internet. It is an incredibly useful resource.

DR. LINDBERG: Thanks.

DR. PIZZORNO: I also have a concern. There was an article, I believe it was JAMA December '99, that looked at abstracts and compared what was reported in the abstract to what was in the journal, and looked at the major journals, the New England Journal of Medicine, Lancet, et cetera, and found that about 65 percent of the abstracts contain inaccuracies ranging from important information not reported in the abstract, to the abstracts actually misreporting what was in the journal article.

Is there anything that you folks are doing to

try to improve the accuracy of abstracts so they could rely on our MEDLINE searches better?

DR. LINDBERG: No. I understand what you are saying. Obviously, we don't undertake that level of review. That is what they pay editors for, for heaven's sake, but there has been more than one circumstance, even since I have been there, in which the people entering the stuff into the database have noticed that a drug dose was wrong, a wandering decimal point, or even a change in units, so the abstract didn't match the journal.

In that case, we call the editor right away, but in the general case of assuring that they match, I think we would go beyond our limits if we undertook to guarantee that.

DR. PIZZORNO: Brian, I would like to ask you a challenging question. The question is, at what point do we decide that the case has been made for CAM therapy?

The reason I say that is because I took a careful look at all the CAM reviews in the Cochrane Collaboration, and virtually every one said, "inadequate evidence to support its use."

So, I am wondering, where is the threshold,

because it is one thing to say it doesn't work, it is another to say there is not enough research for us to be sure about it. Yet, they both appeared to come out the same as, don't use it.

DR. BERMAN: That is a hard question of, when is there enough information. We also looked at that, actually, in the Cochrane Library for conventional medicine, and we looked at all the systematic reviews, and did a random sampling. I think it was in three-quarters of the time, it showed that it didn't work -- not that it didn't work, that the conclusions were inconclusive.

There are different reasons for that, that when they did trials, the quality has been improving and the standards have been improving. So we are always trying to catch up, I think.

I think a lot of things that you can say is, if it was a good review, it will show where the gaps are, and it will show where the flaws are and how we can do things better. Oftentimes, it is not that it doesn't work. I think that is a little bit misleading. It is more that you can't say one way or another, because of,

usually, the quality of the trials and that, in what direction to go further.

I guess in the Cochrane and evidence-based medicine, they always say, we are looking for the best available evidence, and it may not be the large randomized, controlled trial or the meta-analysis, but we have to know what it is.

I am sort of going around in circles because there is no good answer to your question. In a particular therapy, say, for osteoarthritis and acupuncture, practitioners out there say it is great that you guys are doing a very large randomized, controlled trial, but it is not going to really change how we practice one way or the other with that clinical trial.

DR. PIZZORNO: Could you give an example of both a definitive positive evaluation of a CAM intervention and a definitive negative evaluation of a CAM intervention, and what the criteria or research was that was adequate to make that decision?

DR. BERMAN: Well, definitive negative, I guess, would be the one with acupuncture for smoking cessation. It is used a lot for smoking cessation, but

when you looked at all the trials, there really wasn't much evidence to show that it worked beyond any sort of a controlled group in any way.

It was a little bit of a caveat to say, well, you could look at it in a different way and do slightly different studies, but basically, you have to look pretty strongly at that to say out of -- I can't remember, maybe it was 9 or 10 -- clinical trials, that there wasn't much there. I think that was useful for that.

A positive one, let's see. St. John's wort would be a good example of that, and that was also an example. St. John's wort in '96, really wasn't on anybody's radar screen, and then a systematic review by Klause Linde in Germany was performed. I think most of the studies were non-English. When they looked at the evidence for that, they said there is quite a bit of evidence to show that St. John's wort has real value.

That led on to one of the TV shows, "20/20" or one of them. They did something on that, and now all of a sudden, it came on everybody's radar screen. Then the next step, which I think was very appropriate, the NIH, said, we really need to begin to look at this, and they

funded a large randomized, controlled trial to look at St. John's wort for depression.

DR. GORDON: Thank you. Thank you three very much. We really appreciate it and appreciate the precision of some of the recommendations, as well.

We are going to take a five-minute stretch break and then we will come back. In the meantime, the next panel can come forward.

[Recess.]

Panel Session IV: Concerns about CAM and CAM Research

DR. GORDON: This will be the final panel of the day, and we thank you for coming and for being with us, Dr. London, Dr. Margolis, and Dr. Grollman.

We will begin with William London.

Presenter: William M. London, Ed.D., M.P.H.

DR. LONDON: Thank you. I am here representing the National Council Against Health Fraud. The Council bases its claim to be a consumer organization on its founding principles derived from consumer protection law and the scientific process.

Included are the beliefs that consumer is not a special class, but a role played by all, everyone in the

free enterprise society has a stake in maintaining high standards for health products and services.

Professionals in the health sciences, academia, law, and business, as well as government agencies, share a responsibility to help consumers protect themselves from deception and exploitation in health-related matters.

Scientific process is essential for discovering truths and validating health claims and information, and we also believe that health products and services should be proved safe and effective before marketing with proponents bearing the burden of such proof. Products and services should be accurately labeled and fully described, and they should be truthfully advertised.

I want to read you two working definitions of health fraud, which is in the name of our organization. The first one is from The Assembly Republican Task Force on Health Fraud and the Elderly from the New York State Assembly, June 1986.

"Health fraud is the promotion, for financial gain, of fraudulent or unproven devices, treatments, services, plans or products (including, but not limited

to, diets and nutritional supplements) that alter or claim to alter the human condition."

Another definition of health fraud comes from the Compliance Policy Council of the U.S. Food and Drug Administration, that was announced in a letter by M.L. Frazier, Director, State Information Branch, June 18, 1993.

"Health fraud is the deceptive promotion, advertisement, distribution or sale of articles, intended for human or animal use, that are represented as being effective to diagnose, prevent, cure, treat, or mitigate disease (or other conditions), or provide a beneficial effect on health, but which have not been scientifically proven safe and effective for such purposes. Such practices may be deliberate, or done without adequate knowledge or understanding of the article. Intent to deceive is not the issue."

The keyword in both definitions is "promotion," and that is where the concern is.

I wanted to discuss with you my call to oppose health fraud when promoted using words "complementary" and "alternative."

According to NCCAM, complementary and alternative medicine cover a broad range of healing philosophies, approaches, and therapies. Generally, it is defined as "those treatments and health care practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies."

The definition has little to do with what the words actually mean, "complementary" and "alternative."

To refer to "complementary" and "alternative" methods is to imply that such methods actually complement other methods or serve as alternatives to other methods. To refer to something as "complementary medicine," implies that it completes what some other medicine does not do on its own.

However, just because someone refers to a method as "complementary" does not mean it actually complements anything else and providing benefit to health. The claim that a particular method is complementary to anything else is misleading unless the claim can be supported by evidence. If a method doesn't add to the outcome, then, it isn't truly complementary,

it just adds to the cost.

What about "alternative?" A dictionary definition, American Heritage Dictionary of the English Language, Third Edition, defines alternative in three ways. One is "Allowing or necessitating a choice between two or more things," and definition 2a is, "Existing outside traditional or established institutions or systems," 2b is, "Espousing or reflecting values that are different from those of the establishment."

The definition from NCCAM suggests that "alternative" is similar to "alternative" in the sense of dictionary definition 2a, and to some extent this is a fair characterization. However, I point out that "alternative" medicine is largely traditional itself and it has become its own "establishment."

Promoters of "alternative" medicine often promote traditional systems of healing. Strong reliance on tradition is one of "alternative" medicine's biggest problems. When I use the term "alternative," I am using it in quotation marks.

Tradition-bound systems resist change. Their proponents selectively seek affirming evidence while

rejecting disconfirming evidence.

Science-based, evidence-based medicine has a different approach. It is one in which practitioners learn to discard unsafe and ineffective methods rather than to cling to them.

My big concern is that I am unaware of efforts, first, by the Office of Alternative Medicine, and later by the National Center for Complementary and Alternative Medicine, to identify methods promoted as complementary or alternative that should be discarded.

In order to provide reliable and useful information about complementary and alternative medicine, it is necessary to identify methods that should be discarded, and I ask that the Commission make recommendations to accomplish this based on principles of consumer protection and science.

I think it is also fair to note that "alternative" is now an establishment. We have many institutions that are part of an alternative medicine establishment, so in that sense, alternative medicine is misleading, as well.

According to a usage dictionary, "alternative"

may suggest adequacy for some purpose, but questionable and alternative and dubious methods are not adequate for their intended purpose, so calling them "alternative" is misleading.

Now, it is unavoidable for practitioners of any sort to use unproven methods. Medicine won't have all the answers. Patients have complex problems. Clinical judgment and innovation will always be important to delivering health care.

The question has to do with promotion, the promotion of unproven methods through methods such as advertising and publicity is objectionable because it is deceptive. It violates the ethical principles of veracity and non-maleficence.

Everyone wants alternatives, but they want genuine alternatives. Many promoters of "alternative" medicine exploit this by calling for "freedom of choice" for consumers. What these promoters really want is freedom from accountability. They support the concept of caveat emptor, "let the buyer beware," but they have a problem with the concept of caveat vendor, "let the seller beware."

Caveat vendor provides a rationale for consumer protection laws to compensate for the disadvantageous bargaining position consumers have in the health marketplace. It is difficult to evaluate claims for health products and services.

We are vulnerable to mistaken perception and deception especially when we feel threats to our well-being and when we are desperate for answers. It is important to protect consumers from both intentional and unintentional deception, and it is also important to preserve true freedom of choice.

Thus, the model of the National Council Against Health Fraud is enhancing freedom of choice through reliable information. I ask the Commission to enhance freedom of choice by recognizing the need to identify health fraud when it masquerades as complementary and alternative medicine.

DR. GORDON: Thank you very much. I am sure we will come back and be asking for some specific suggestions from you.

Simeon Margolis.

Presenter: Simeon Margolis, M.D., Ph.D.

DR. MARGOLIS: First, let me thank you for the opportunity to testify before the Commission. Let me preface my remarks by stating that as a practicing physician, I would enthusiastically welcome any complementary or alternative product or practice that is proven to be effective.

The first question we were asked to address was what were our major concerns about CAM practice, and as you have heard, and will hear, the major problems with CAM, I think are well recognized.

Most CAM products and practices are either untested or their use is based on unreliable research. Nonetheless, they are aggressively promoted, usually with guarantees of success, and yet any experienced physician knows that no treatment or procedure is always effective.

These promotions and promises mean that patients may not only waste money on unproven measures, but also fail to seek medical attention and obtain effective medications or procedures for illnesses that may have serious consequences.

People are urged to use CAM products because they are natural, apparently forgetting that poison ivy,

floods, hurricanes, and tornadoes prove that natural isn't necessarily good.

Finally, because CAM products are unregulated, patients can be subjected to serious risks, and we all know of studies that have shown that a number of herbal products contain toxic constituents or contaminants.

I have chosen to discuss in more detail chelation therapy as one example of CAM. Chelation involves a course of two to three weekly, two-hour long intravenous infusions of EDTA for a total of 30 treatments.

Originally, chelation was said to improve atherosclerosis by removing calcium from plaques in the arterial wall. Now, chelation therapy is reputed to improve angina and painful peripheral vascular disease by binding heavy metals that damage tissues and proteins by oxidizing them. However, there is no data to support either the theoretical benefit or any properly controlled study that supports the effectiveness of chelation therapy.

By contrast, in two randomized, blinded studies done in Scandinavia and New Zealand on patients with