getting some kind of joint understanding of what needs to happen. So, this is not just for Conchita's group, but for everyone.

If there are national organizations, whether of institutions like hospitals or groups or interest groups or organizations of individuals, we need to know who they are and know which ones of you are connected to those groups, so please, if everyone would pay attention to that and give us feedback about that, then, what we can do is ask those of you who are connected to help be the bridge to the organizations.

Anything else anyone wants to add or any questions about recommendations that this group has made?

[No response.]

DR. GORDON: I wanted to get filled in a little bit about the idea of coverage, if you have gone any further in the idea of coverage for all therapies for which there was good evidence in peer-reviewed journals, any thoughts about how one would organize that process at this point?

DR. FINS: I think the emphasis is really on peer review, and not necessarily peer-reviewed journals,

but that it is scientifically valid, and in my personal view, that it has to be as efficacious and as safe as things have been demonstrated to HCFA to be worthy of reimbursement, so there is a kind of a comparability standard is what I think some of us in the subcommittee endorsed. I don't think it was universally agreed upon.

DR. GORDON: How would that tie into the recommendations that have been made by several people, and most recently by Max, about having the database, do you see that as coming out of that?

DR. FINS: The thing that I think we probably need to spend more time on thinking about is how do we operationalize that global principle, and we did say, and I missed part of Conchita's presentation, but that there is going to be a mechanism of peer review that would look at these RFAs for demonstration projects that would have expertise of the methodologists, the traditional and the CAM providers, and that group would in a sense by endorsing the project would also help to endorse whatever results came out, which would then lead to an accumulation of data that would then lead to HCFA and other funders saying we have reached a threshold and

crossed a threshold that allows for reimbursement.

I think it is really the incremental approach that Max laid out cogently before that I think we need to sort of operationalize.

DR. GORDON: Julia, did you want to add something?

MS. SCOTT: No.

DR. GORDON: Joe.

DR. PIZZORNO: As I think you astutely observed, realized this was a topic of considerable discussion, and on the one hand, we could recommend to all the federal agencies to utilize language, such as that in Washington State, to cover every category of provider that is licensed in that state.

Obviously, ultimately, that is where we want to get, but our thought was rather than to establish that social mandate, get some hard data first and base it on evidence, and that by specifically requesting that these federal agencies collaborate to develop the kind of evidence that is needed, we feel that it would provide a much stronger foundation for long-term success.

DR. GORDON: Okay, great. Thank you.

George, do you want to present?

Group IIA: Coverage and Reimbursement for CAM

MR. DeVRIES: Thanks, Joe.

Our charge was to consider coverage and reimbursement for CAM by employers and health plans and state agencies, and we started with the question what are the barriers, why are health plans not voluntarily doing it today, why are employers not mandating coverage for CAM as part of their benefits.

We felt like let's understand what the barriers are first before we can make recommendations. So, we went through really a list, and first is education and information that perhaps the purchasers don't necessarily have all the information necessary to make a good decision.

Cost. We have been hearing that for the last couple of days, that the additional cost of adding CAM is unacceptable, that there may be perceived relationships with current providers which may cause them hesitancy to cover CAM.

Current belief systems. Perceived lack of availability of providers. Access to services. Lack of

personal experience by the buyers of CAM or by the buyers of health care benefits. Quality - that there is a perception on the part of buyers of benefits that CAM perhaps isn't safe or not clinically effective for treatment of certain conditions. Providers, are they licensed, and employer liabilities.

As we really began to go through this and began to understand what the barriers are to providing reimbursement and coverage, it is coming down to bottom-line issues of quality, cost, access, and education, which if we think about what our charter is as a commission, we can really begin to qualify that the issues related to reimbursement really come down to these major issues.

We are making the assumption that we are not moving from the perspective that CAM benefits are mandated by health plans or employers. We are making the assumption that this is an incremental approach where we are providing the proper foundation for the purchasers of health care to make decisions based on the information they have to go ahead and include CAM voluntarily as a covered benefit, so it is a different approach, which is

a more incremental approach.

First, areas related to cost. The key issue related to cost as you talk to health plan purchasers, they are going to say CAM is an additional benefit, it is going to cost me additional dollars.

Now, I think for those who are involved with CAM, we have to ask the question is it going to cost more money, is it going to cost less money, is it going to save money, is it the same, or even if it does cost more, how much more. We don't understand that.

We have good research out there that says here is how much it takes if a chiropractor treats a particular patient versus a medical physician, but that doesn't tell you cost effectiveness in the context of saying here we have a pooled population, and they are covered under these health benefits, which provide coverage for general medical.

We have another pool of the population that has coverage for general medical plus they have CAM benefits. What is the cost of providing those benefits for each pool of patients, and the recommendation is that we truly need cost effectiveness research, cost effectiveness

research that will say it either doesn't cost more to add CAM, it saves money to add CAM to a benefit plan, or perhaps here is the incremental costs.

The recommendation is really that this research can happen through AHRQ, it could be demonstration projects through the state, through HCFA, through Medicaid, NIH, or NCCAM. In fact, one of NCCAM's request for grants recently was related to cost effectiveness of chiropractic.

There is even the potential for private foundations to be involved in this type of research, that these represent both private and public initiatives, and bottom line is we are looking at comparative health research.

It is still a concern on the part of the health purchaser who is basically saying I am not convinced that CAM is either safe or effective, and so really, it is continuing on the recommendation that there needs to continue to be substantive research on safety and effectiveness of CAM, and that really this is happening through NIH and NCCAM, through CDC field studies, through systematic reviews by AHRQ, and Cochrane Collaboration.

So, this is really the issue. Again, we are dealing with foundational issues related to reimbursement, what is going to cause and encourage and support reimbursement of CAM services, and what are the barriers.

A review of DSHEA, this was encouraged because at this point, there is various perspectives. DSHEA doesn't go far enough to protect quality or properly monitor marketing of dietary supplements.

There are others on the other side who would argue it does go far enough, it is just that the regulatory agencies that are responsible for monitoring these activities aren't doing their job as is required under DSHEA.

Finally, probably one of our most controversial topics was the issue of licensure. We heard the other day, Dr. Korn, the chief medical officer of Blue Cross/Blue Shield Association, basically state a theme, which is basically saying if providers aren't licensed, they will not be covered as a benefit.

So, this comes back to a reimbursement and coverage issue, that licensure is an issue of coverage

and reimbursement. Without it, you cannot get coverage. This is truly a black and white issue in the sense that even regulators, like Department of Insurance, Department of Managed Health Care, who license benefits plans, will not approve coverage or insurance plans for non-licensed practitioners.

So, I won't say there is an agreement to recommend a specific statute coming out of our group, but I think there is an understanding that this is an issue that, as we look at a preliminary report, and understanding states rights, understanding license and regulate health care providers, the federal government doesn't do that.

This commission needs to be careful of any recommendations it makes, but it is recognizing that there needs to be the recommendation and encouragement, really, the encouragement to states to pursue state licensure for those provider groups that are safe and effective.

There is actually a very good recommendation also, and I guess this is particularly happening in the State of Illinois, where instead of the state boards,

having separate state boards for chiropractic, acupuncture, and various other professional groups, it is a State Board of Complementary Health Care, and that is an interesting model to pursue.

Access. Again, the issue of licensure is a critical issue under coverage and reimbursement, and there is also a perceived lack of availability in terms of access to CAM services, but I think that really leads us to education.

The recommendations related to education are really multi-tiered. First, there is a recommendation that we believe would help in terms of improving coverage and reimbursement of CAM services, that the CAM perspective be included in decisionmaking and advisory capacities in various state and federal agencies, that really there is an expert multi-disciplinary perspective, it is a professional perspective that is being given to that process.

We heard a recommendation this morning, which was recommendation that NIH/NCCAM maintain an Internet site, which becomes a repository for CAM research data and information, that that can provide a separate source

of information that an employer can be referred to when they have questions regarding quality, everything from quality, safety, efficacy, licensure, cost, that this would provide excellent resources for those buyers.

Finally, there is a continued recommendation regarding broadly based public education. I think ultimately, the concept of the education recommendations are coming back to, that over 40 percent of consumers utilize CAM in a given year, over 60 percent of Americans have used CAM, and those individuals are making the buying decisions, they are the ones who are running human resources and corporate benefits across the country, whether they are Fortune 50, and they are also running the buying and benefits decisions for health plans.

If we lay the right foundation, provide the right education, provide the right information, that coverage and reimbursement will follow.

DR. GORDON: Thank you very much, George. It was very cogent.

Any other comments from anybody from that group at this point? Linnea.

MS. LARSON: George was very clear in what we

did discuss. I think that we really do need to revisit the issue of licensure in a very, very systematic fashion, and not just -- I feel this way. It is what is the evidence, and do it in five minutes.

DR. GORDON: I sorry, it is what?

MS. LARSON: What is the evidence, and you do it in five minutes. The other is, it is not simply CAM perspective, it is CAM provider. It has to be someone who has the training and the experience in providing those services, not just someone who laid on new ideas.

DR. GORDON: I have a question about licensure. What information do you all, does everybody feel we need to make some recommendations about licensure, what information other than what we have received so far, so that we can begin accumulating that information?

DR. FAIR: Well, my opinion on that was basically a negative one. I think it is inappropriate. We start off discussing quality and safety of various CAM modalities, which I thought was appropriate, and then we jumped to licensure as a way of getting the CAM practitioners reimbursed, and I think those are two separate things.

I think that our responsibility to the population is, first, to make sure that we are going to recommend something or have some evidence that something is safe and effective before we worry about whether we reimburse the practitioners.

I just think that making a recommendation for licensure and spelling out what professions should be licensed is a very shaky step, shall I say, because I think that ones -- and I won't pick any particular one -- but I think that there are some of us who would have trouble assuming that some of the CAM practices being used are effective or safe.

DR. GORDON: I think the whole issue of licensure is one of the more thorny ones, whether or not we are going to say anything about it and if so, what. So, with that in mind, what else would people like to know about, who else would you like to hear from?

Obviously, we will be having this discussion, and one of the things to remember is that the more thorny long-term issues, strategic issues, we are probably not going to make decisions about in the next few weeks or the next couple of months, so that will be for the final

report.

So, if there is more you would like to know, or people, or kinds of people you would like to hear from to discuss this issue -- yes, Joe.

DR. PIZZORNO: Actually, I was kind of surprised by what I just heard. The issue for licensure, while reimbursement is clearly of significance to both the practitioner, as well as the public, far more important is the issue of licensure as protection of the public safety.

If we have practitioners out there who are providing services to the public, diagnostic and therapeutic, the public needs to be assured that the services persons provide to them are indeed what they are claimed to be, that they know what they are doing, know how to diagnose, and how to refer properly, and when treating with therapies that are safe and efficacious, can use those appropriately, and that is what licensing is about.

MR. DeVRIES: I would like to throw in one more comment, which is when we really talk about licensure, or at least today, I mean we are talking about the fact that

licensure, except for the chiropractic profession, tends to be very inconsistent across the country, and that is for I think things that the Commission would say they are very comfortable with, massage therapy, acupuncture, Doctors of Naturopathy, that it is not that they are not licensed in any states, it is that there is inconsistency of licensure, and that there are some states they are not licensed in, so this is not about creating licensure for broad ranges of providers where there is nothing out there.

This is about really developing consistency across the country, as well as 50 state licensure ideally, for provider groups that already are pursuing and are licensed under many states. I mean acupuncture - 39, massage therapy - many, naturopathy - perhaps there are a dozen. So, that is really the issue at hand, and we do need to narrow the focus on it.

DR. GORDON: Tieraona and Joe. One thing I want to say is this is not a discussion about licensure now. This is going to be a much longer discussion that we are going to have to have over time.

DR. LOW DOG: You asked actually for

information that we might need, and I guess my only -- I am absolutely in favor of licensure, no question, and consistency I think is important, so I know what I am getting as I move from state to state, but I do think that one has to be careful about the language that we use only to remember that, like in New Mexico where I live, there are traditional Mexican-American healers that are not licensed, and there is no way you could license them, and there are Navajo practitioners that do not live on the reservation, that live in Albuquerque, that do still practice their traditional medicines, and there is no school for them.

They don't want reimbursement, I mean so they are not looking at that issue, but I would hate to make any kind of step that might put their practice in some sort of legal jeopardy, that could cause them harm.

DR. GORDON: We heard that concern expressed in Minnesota, and we have heard it in other places, as well, so thanks, Tieraona, for that.

MR. DeVRIES: Please remember that our discussion was related to coverage and reimbursement, what are the barriers to coverage and reimbursement, what

needs to happen to help develop coverage and reimbursement.

We acknowledged in our group the Practice Act in Minnesota, and that there is non-licensed providers under law being able to practice their professions, and recognizing, though, that those professions practicing without licensure, I think most health plans, I think it is clear none of them would reimburse for services.

So, this was a discussion about what it takes to get reimbursed and to cover, not to limit to other providers.

DR. GORDON: Joe.

DR. FINS: I would just add I think that safety is the first principle, and everything else follows, and I think licensure is linked to safety, and consistency is related to safety.

I think that the recommendation that we might want to make is not something that the federal government can do, but we can urge that professional organizations, the disparate organizations within each of the disciplines, to come together and to develop national standards.

We had disagreements that we witnessed in front of the Commission, people refusing to talk to each other, and I think that if those entities want to be eligible for reimbursement, they have to develop national standards, and we can't make that happen, but I think we can say that it is something that will promote safety and conceivably lead to reimbursement.

People who want to stay outside of the reimbursement stream, people in the various communities that Tieraona alluded to, they don't need to access those dollars.

DR. GORDON: Let me just ask the question again. Is there any other information that we need, that we should be gathering about this subject? We have a lot already, as both Tieraona and Joe are pointing out.

DR. LOW DOG: Also, Jim, just checking because of the comment that nobody reimburses for their services isn't actually accurate. The VA hospital reimburses or pays and covers for sweat lodges in South Dakota and in New Mexico. There are groups that do cover non-licensed practitioners for certain mental health and social around Native American groups, and so it is not that nobody

does.

In looking at some of their liability or looking at why they have included that might be interesting if we are looking at licensure.

DR. GORDON: I think that is a very good idea, and generally looking at issues of licensure as related to reimbursement, which is kind of the charge.

Charlotte.

SISTER KERR: The only other input I would want is the international piece that we are going to get, but I want to hear how that is done and what are the values underlying the process and procedures.

DR. GORDON: Great. Thank you.

Joe.

DR. FINS: It sort of segues into the afternoon, but I mean the question of licensure and outcomes and safety is a research question that can be studied, and probably should be studied, before anyone makes a recommendation concretely about it.

DR. GORDON: And in line with that, one of the things that we would need to do is to find out if it has been studied either here or in other countries.

I just wanted to ask one other question related to access. Did this panel have some recommendations for access for low-income people or for Medicaid?

MR. DeVRIES: We talked about demonstration projects in terms of cost effectiveness related to Medicaid on the state basis, feeling that if those were effective, there would be the potential for coverage down the road. That was the limit of our discussion there.

DR. GORDON: One of the things that we are planning to do, and we will have some kind of meeting with Medicaid officials, and hopefully, at least, if not before the July meeting, certainly before the October meeting, we will be able to present some information.

If it seems appropriate, we may bring someone in from Medicaid, as well, to address some of these issues.

Wayne, did you want to say something?

DR. JONAS: I just wanted to make a comment on demonstration projects, it hasn't arisen yet. There are some difficulties with demonstration projects. They are basically observational studies.

There is a lot of limitations to those,

selecting which kinds of systems would be evaluated, in which areas would be difficult. Kind of ferreting out what aspects of those systems was valuable or not valuable would be very difficult.

Nonetheless, I think it is worthwhile having some demonstration projects for particular populations including underserved populations would be very useful, and I think that we have heard also in past panels, a number of federal organizations that would be interested and willing to run demonstration projects, that have the capacity to do that.

It is one thing to say you want to do it, and it is another thing to be able to do it, and I think those would probably require some support, specific support to actually run those because they can be quite expensive.

However, we heard over the last couple days that there are a number of groups that could probably be catalyzed to run their own or at least contribute significantly and partnership some of the health insurance plans, the employers, and this type of thing, if there were some way to facilitate this process.

It wouldn't cost a whole lot in terms of the government's input, but would probably need the government to facilitate the process in some way.

DR. GORDON: Thank you. One of the things that we are going to be exploring is with some of those potential partners for administering or running or implementing demonstration projects, and that is something we will be doing.

Again, one thing we would like, we will be asking some of you who have specific connections or interests perhaps in helping us work with those partners.

It is time for us to go to lunch. It is an early lunch, but we need to be back at 12:30. So, I want to thank the chairs of the subcommittees and everyone, and I want to thank particularly for this portion, the whole staff, but especially Maureen Miller, who really has done such a great job of bringing people in, in this last day and a half.

[Applause.]

DR. GORDON: Maureen, thank you so much.

We will be coming back at 12:30, and with David Eisenberg giving an overview of research issues.

So, we will adjourn for lunch.

[Lunch recess taken at 12:05 p.m.]

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A F T E R N O O N S E S S I O N

[12:35 p.m.]

Meeting Topic II

Complementary and Alternative Medicine:

Research Challenges

DR. GORDON: One minute to introduce Dr. David Eisenberg, who is going to be presenting an overview of the issues related to research, as well as recommendations. If everyone could take a seat, please.

Panel Session I: Overview of CAM Research Challenges

DR. GORDON: This presentation is going to be a little bit different, in that, we are going to have slides. David is going to spend 25 minutes going over the area of research in CAM and making his recommendations, and then we will have 20 minutes to have a dialogue with him about the recommendations.

David.

Presenter: David Eisenberg, M.D.

DR. EISENBERG: Jim, thank you.

I am honored to be here, and delighted to see many dear friends, and to meet several other people whom I have looked forward to meeting for some time. So it is

a pleasure to be here with you.

I am particularly grateful to the staff and to the Commission for giving me some time to present. I thought it would be useful before you read the recommendations, which are written somewhat succinctly. There are 15 of them. I have given you a summary of them in the form of an executive summary, and I have asked for copies of these to be distributed, the extra ones that we brought.

The presentation is really to give you the background behind the specific recommendations. I have also handed out to the Commissioners a bit of reference material that describes every study I will be referring to so you can go back to the original source.

If I could have the lights down just a bit.

[Slide presentation.]

DR. EISENBERG: I don't want to spend so much time on terminology as I do some of the language that is evolving to look at this very complex and provocative field. I am then going to discuss for about five or 10 minutes, trends that I think set the stage for research and research recommendations for the Commission.

I will then talk about some of the relevant research to give you a sense of the state of the science at this moment in time.

To give you a little preview, I want to give you the sense of how the research is relatively new. There has been precious little that has been satisfactory to the more conservative stakeholders of biomedicine, and in particular, we don't have as much in the way of basic science or health service research as I think we need to make proper recommendations.

I am going to give you some suggestions, and then you have my written recommendations.

You are all familiar with the fact that before the nineties, the pejorative language of unorthodox, unconventional, unproven was predominant in the literature, and that switched in the late eighties, early nineties to complementary and then alternative as a result of congressional direction and legislative -- I hate to use the word "fiat," but prerogative. They called the office the Office of Alternative Medicine, and that has stayed with us since 1992.

Now, I will use CAM as a shorthand in my

presentation, but I want to point out that most academic institutions these days are really wrestling with the term of "integrative care" or "integrative medicine."

Integrative medicine, at least conceptually, as discussed by a variety of deans and research directors, combines the best of both conventional and evidence-based CAM therapies, emphasizes patient participation, exercise, diet, stress management, and maximizing health, emphasizes the primacy of the patient-provider relationship, and the importance of shared decisionmaking, and emphasizes the contribution of the therapeutic encounter itself and the science to be gleaned from looking at encounter expectation, conditioning, and those sorts of so-called nonspecific effects.

Now, put in context, I want to share with the Commissioners that they should be sensitive to the debate going on at most of the universities as to whether we should continue with the language of alternative or complementary, or wrestle with this concept of integration.

One could argue that it as filled with optimism

as unconventional or unorthodox or pejorative, but this is the debate going.

I want to especially bring your attention to the language used by Richard Smith in the British Medical Journal that was devoted entirely to integrated or integrative medicine in January of this year.

"Integrative Medicine," in the editorial, he said, "focuses on health and healing rather than disease and treatment. The patient is seen as a whole, complete with dreams, disappointments, stories, loved one and enemies, not just a biochemical puzzle to be solved. It mightn't be too pretentious (although it might)" -- is that British -- "to say that such a growth of integrated medicine might restore the soul to medicine, the soul being that part of us that is the most important, but the least easy to delineate."

I think Ralph Snyderman said it best. He is the Dean at Duke and CEO of Duke Medical Center. He said, "We are really wrestling with the issue, not so much of integrative medicine, but re-integrative medicine, after we come back to the basic tenets that we all went into health delivery for and which aspects of

CAM can be applied judiciously in an evidence-based fashion."

So, I would like that discussion to have a place in the Commission's report, because it is valuable and I think it takes away some of the provocation us-them dichotomization.

I will very quickly, for five minutes, summarize what I call a brief journey in time, since 1992, to set the stage for the research agenda now. You know all this, and I speaking to the choir here.

The Senate hearings in '92, The New England Journal survey in '93, the Office of Alternative Medicine in '93; '95, the 10 CAM centers, initial centers were funded. By '98, the OAM was established as a National Center.

'98 was a pivotal year. There was an important editorial in The New England Journal of Medicine, Jerry Kassirer and Marcia Angell speaking for many in the biomedical community said it is time to stop giving alternative medicine a free ride.

I think their point was that there was precious little science, and that there was a danger of promoting

this field in the absence of science lest it be viewed entirely as pure advocacy.

A month later, JAMA and the AMA journals published a total of 80 articles, 18 randomized trials, some positive, some negative, and their editorial, George Lundberg and Phil Fontanarosa said, "There is no alternative medicine." I read their editorial to mean there is simply medicine, good medicine, and our collective job was to distinguish useful from useless, safe from unsafe.

By 1999, the NIH had funded additional centers. They were beginning to fund Phase III clinical trials, definitive trials, each of which will cost or has cost millions of dollars.

I want to bring your attention to the fact that it is only two years ago that the big pharmaceutical corporations began to sell products in the urban supplement domain.

Here is an example, a partial list of representative household name labels - Bayer, One-A-Day, American Home Products, Warner-Lambert, Johnson & Johnson. You can't go into a drugstore in this country

without being a bit confused as to where the OTC drug ends and the herb, vitamin, or supplement begins.

This past year, your commission was founded. I think that was an important political act. The Macy Foundation, arguably one of the most important foundations interested in medical educational reform, devoted one of its conferences to this topic this past year, and I recommend their summary to you. It is referenced in the handout.

There has been a new group that has formed, the U.S. Consortium of Academic Health Centers for Integrative Medicine. Now, this is composed of executive deans and principal investigators currently from 11 universities, medical schools. I see Audi, who is here, and Jim Gordon has been to one of these meetings, and there may be others here who have attended.

This has been a discussion group that has met twice to discuss what is the role of the academic health center, and by "academic health center," I am speaking about university, university hospital, university affiliates, in terms of research, education, and training, and responsible delivery of care.

I want to put this in your heads as the overture to the symphony here, that these academic affiliates, universities, hospitals, medical schools are part of the engine that must guide the recommendations of this commission, and I think this consortium has a very important role to play.

It now consists of 11 medical schools. I think the goal for the next year is to bring it to 25. At that point, we will have 25 out of 125 medical schools represented, and we could begin to discuss this at a very different level vis-a-vis the larger medical community.

Just a few points. Since the beginning of this year, most of you are aware that the NIH had a joint conference with the Royal College of Physicians in London to discuss issues and research challenges involved in complementary and integrative medicine.

The British Medical Journal that I referred to earlier devoted its entire issue to this topic. Many of you may not be aware that the Federation of State Medical Boards, which is in charge of licensure of all M.D. licenses, has put together a committee to discuss practice guidelines in the area of CAM.

Specifically, they and I have served as a consultant to this group. They are looking not only at physicians who deliver CAM services, but, in my view, importantly, physicians who are co-managing patients who are simultaneously being seen with licensed or unlicensed CAM providers. In my view, that is the much bigger challenge.

I also want to bring your attention to another theme - that safety will forever trump efficacy, and in the last year we have become increasingly aware of that which we all predicted, clinically significant adverse drug-herb effects.

Now, there have been a series of articles mainly in the Lancet. This is one from Adrian Fugh-Berman, et al., looking at case reports. These are individual patients who had clinically significant adverse events that are attributed to -- I don't want to say we are absolutely certain -- but attributed to interactions between herbs like ginkgo or dong quai with Coumadin, warfarin, a blood thinner, St. John's wort with an antidepressant Yohimbe, which is an herbal aphrodisiac with antihypertensives.

I think the granddaddy in this set -- and they are all referenced in your handout -- is this study, because this is not a case report, this is a prospective clinical trial. Did Steve Strauss mention this to the Commission, are you all familiar with this? Well, if you are not, it is important.

This is a study that was done by Piscitelli and his group who took college age volunteers, gave them indinivir, which is part of the AIDS cocktail. It is a viral inhibitor that is part of the very potent drug therapy used to keep people with HIV alive and well, and in this instance, they were watched, they were observed while they reached a steady state of their indinivir level, and then they were given over-the-counter St. John's wort, and their indinivir level decreased significantly and, in many instances, below the therapeutic window that would safeguard somebody with HIV, or to put it bluntly, people with an HIV infection who were taking indinivir, who then exposed themselves to St. John's wort may not be in danger of a recurrence of the HIV virus because of the interaction of the herb with the drug, making the drug more easily to metabolize or

metabolize more quickly I should say, and therefore, less available.

Two other smoking guns. Patients with heart transplants who had been clinically stable reported in the Lancet, I believe, who then took St. John's wort, they were on cyclosporin to help keep their hearts from experiencing a rejection immunologically, once they started St. John's wort, they rejected their hearts, and the time course was close enough that the authors thought this was a causal relationship.

Now, both of these patients lived because this was picked up in time, but I don't think we need a long list of smoking guns like this to convince us that safety, drug-herb interaction, quality assurance of herbal products to the American consumer must be a very high priority.

As you all know, the business of herbs and supplements is enormous. These are marketing data estimating the worldwide sale of herbs and vitamins at $46 billion. We are the biggest single consumer at 11 billion, followed by about 10 billion for Europe, and then Asia makes up most of the remainder.

Now, this is a study that just came out last month, Robert Linden of Harvard School of Public Health, and now the Kennedy School of Government. He and his group did a series of surveys that looked at Americans' views of herbs. I thought this was a very important paper, and I brought a copy if you want me to make it available to the Commission.

These were three random surveys, each with more than 1,000 respondents, between '96 and '99, that found that among average Americans, 48 percent had used at least one dietary supplement regularly, 44 percent users believe that their medical doctor knew little or not much at all about these products.

These were the statistics that really surprised me - 72 percent would continue to use their herb or supplement even if a government study was negative. I want you to think about that. I don't have the answer to that. I don't know if it means they don't believe research or they believe that these are safe and effective, and they won't believe a study to tell them otherwise, or if this is just aberrant sort of, the way people who believe in any therapy will persist in spite

of the evidence.

On the other side, the majority were not aware of DSHEA and the current environment with which regulation occurs or does not occur for herbs, vitamins, and supplements, but in the abstract -- and this is just a hypothetical question -- they were asked, and 81 percent would require evidence of efficacy, safety, and FDA approval prior to allowing for the sale of an herbal supplement.

So, to suggest that there is not political will to go back and talk about a higher degree of quality assurance and safety of herbs is not founded by the data. Congress may think that, but these surveys argue, I think very potently, in the other direction.

Now, all of you are familiar with the JAMA article, so maybe I will just skip over the summary slides. You know that CAM use increased dramatically from '90 to '97, to 82 million adults, 42 percent. Number of visits increased to nearly 629 million we estimate. That was more than 200 million more visits to CAM providers than to primary care medical doctors.

Expenditures for CAM services increased by 45

percent to $21 billion. These are all in the handout, and you probably all know this article. Out-of-pocket expenditures exceeded $27 billion, disclosure still I think unacceptably low with fewer than 40 percent of CAM therapies discussed with physicians.

This was the predictor of some of these bad apples I have talked about, that we estimated conservatively that 15 million adults or 1 in 5 prescription drug takers was simultaneously taking herbs or high-dose vitamin supplements, therefore setting the stage for these clinically significant drug-herb interactions.

Lest you think this is just a baby-boomer phenomenon, among the elderly roughly a third used CAM regularly to treat their most severe illness, and 1 in 5 see a CAM provider per year. This is from the Journal of the American Geriatric Society.

Interestingly, the top two CAM therapies used by adults over 65 are chiropractic and herbs, and particularly for herbs, I am concerned about adverse events of too weak kidneys and livers.

Again, just as backdrop, I think it is

important to say we lack definitive information about minority patterns of use of CAM therapies. We need to have oversampling of our Spanish-speaking population, African-Americans, Asian-Americans.

The NIH recently has put together a committee that I have worked with to give NHIS, National Health Inventory Survey, to perform a survey of random households in 2002, but these questions will only scratch the surface, and I think you should vociferously interest the Surgeon General, the NIH, and the Centers that are appropriate, CDC and elsewhere, to look at detailed patterns of use by the minority populations.

Their herbs and supplements, all the products taken by mouth are probably different, their patterns of access are different, their reimbursement profiles are different. I think we need those data.

This is from an abstract, but it shows that among quartiles of income, interestingly, even those in the lowest quartile, this is from the same national survey, those making under $20,000, while income is a barrier to CAM use, 43 percent of the lowest income quartile has spent, approximately $250 annually, which in

terms of expendable income, is still considerable.

I think I am speaking to the choir here, but it would be a shame if, as CAM therapies are introduced by third-party payers, those without insurance and those with less expendable income are excluded.

Let me go more quickly to get to the research side. You know that current use underrepresents utilization, not if but when insurance increases, and now we come to the research.

I have given in your handout examples of I think the best examples we have to date, most of them from the last five years, where the evidence suggests that there is some efficacy of CAM therapies for particular conditions, and I have culled the literature and given you about 20 to look at that come from major journals, and they are either well-designed and peer-reviewed clinical trials, or they are consensus conferences from the NIH or other federal agencies.

I think some of these you are familiar with, but there is at least to some degree, some evidence that chiropractic is useful for acute low back pain, mind-body for pain and insomnia, acupuncture for nausea, dental

pain, moxibustion, just one study in the treatment of foot first or breech presentation, psychosocial support for cancer.

Two studies, meta-analyses suggesting homeopathy as distinct from placebo, St. John's wort for depression, ginkgo for Alzheimer's, Chinese herbs for irritably bowel, saw palmetto for benign prostatic hypertrophy. You are aware of these. These are sort of the examples of good research suggesting positive effectiveness. This last slide is just five more from this year alone.

I would be remiss if I didn't mention that there is, not an equally large, but I think almost as large group of studies suggesting lack of evidence in these same journals. Some of them get the same amount of press as the positive ones, and this is my point - that all this research, which is really five or six years old, is now in the medicine literature.

The scientific community is engaged, positive and negative studies are being reported, so this means there is now traction, and I think this is a good sign that the field is beginning to mature as a research field

that is worthy of our collective attention.

Many of you know that I leave from here this afternoon to go to San Francisco for the First International Conference on CAM Integrative Medicine Research. That meeting cosponsored by Harvard and UCSF is a research meeting only, only original research will be presented.

We received 327 abstracts, we didn't know if we would get 50. We accepted 223, 23 of them are being presented orally, the other 200 by poster, and the meeting is sold out with 400 registrants and standing room only.

So, I think this means that the national and international community want to come to a research meeting to discuss basic science, clinical research, research methodology, and policy-related science.

So, that is what is coming about over the next few days. Again, I think this ushers in another chapter within the discussion of CAM and its appropriate insertion into the health care system.

So, this is really I think the new slide of my presentation. In thinking about the evidence we have so

far, if you think about the way the trajectory of conventional orthodox medical and biomedical research versus complementary and integrative medicine, much of, not all, but much of conventional orthodox medicine proceeds from basic science to in vitro animal model, to clinical trials, Phases I, II, and III, cost effectiveness, health service research, policy, reimbursement, politics issues come up later, after the science is done, and then there is a change in the delivery.

But if we reflect honestly about the field of CAM, it was a series of epidemiologic surveys, mine included, that got the attention of a whole group of stakeholders. It was epidemiology and popular demand that launched the OAM, that fed NCCAM, that informs much of the Commission's work and mission.

Political support is already engaged, I need not tell you that, you think about it all the time as commissioners, but there have been few clinical trials, most of them Phase II, and now a few in Phase III, osteoarthritis of the knee, chondroitin sulfate, St. John's wart for depression. You know these.

There are very few, I don't know of any Phase I trial of a CAM entity, a safety trial, as there is in drug studies. There is precious little -- these are in italics and yellow, but you can't see -- precious little in the way of cost effectiveness and health service research, and that is where I want to spend the last five or six minutes of my time. Can I still go for another five or six, Jim?

DR. GORDON: Yes.

DR. EISENBERG: And even less in the basic sciences. One of the themes that I have put front and center in the list of written recommendations is that research in this area has to have basic science, clinical research, and health service cost effectiveness research, and all have to be fully resourced.

The medical community will not accept the field changing its behavior in the absence of basic science, mechanistic, plausible mechanistic and rational explanatory models.

The health care delivery side, policymakers and third-party payers will not, from a fiduciary standpoint, pay for this in the absence of health care, health

service research that shows clinical benefits at reduced cost or cost neutral.

White and R. Ernst reviewed all the literature to look for economic analyses of this field, and he basically summarized it as follows - there is a paucity of rigorous studies that could provide conclusive evidence of differences in cost and outcomes between complementary therapies and orthodox medicine.

Following up on some of the themes I heard George DeVries pick up on this morning, in spite of the fact that there is precious little in the way of health services research, these CAM programs are being offered by managed care organizations throughout the United States.

This is an ad that you can't quite see from the New York Times just a few months ago. It is an HMO, it doesn't matter what the name is, and in addition to orthopedics, neurosurgery, dermatology, and all the other conventional allopathic orthodox specialties, I have highlighted where it says this HMO also provides acupuncture, massage, chiropractic, naturopathy.

To the average American, this is now insinuated

within our health delivery system. They don't understand the provocative nature of this debate of how much evidence is there and should it be paid for and who licenses, et cetera.

So, most of you know, and I am sure George has briefed you, that most of the CAM delivery services are really reduced fee-for-service at this point in time. Networks of providers are described by HMOs or insurance carriers. These are efficient, convenient, carved-out services, but they are not yet, in my view, fully integrated.

We can't track the clinical and cost offsets, and that is really I think part of the Holy Grail.

So, I was asked for examples of models that are ongoing to look at how you track this, and I think the critical question is in any condition, if you randomize patients -- and I am a believer here, in this instance, of randomized trials being useful -- if you randomize a population to integrative or CAM therapy options versus usual care, what does it do to your clinical outcome costs and satisfaction?

I will showcase two examples. We could talk

more about them in the discussion if you would like. This is a study funded by NCCAM, one of the few health service research projects I am aware of funded by the NIH. It was originally sent to the Agency for Health Care Policy and Research. They did not have the funds to do it, NCCAM picked it up.

The point of this slide is that this is a trial with people in an HMO, Harvard Pilgrim, Harvard Vanguard, with acute back pain, who show up at their doctor's office, and they are invited to participate in a randomized trial.

One in three get usual care, and two in three get a choice of expanded benefits. This is fairly heretical design in the eyes of NIH. We are really looking a monotherapy and fairly causal relationships.

The only thing this study can tell us is if the group that gets expanded benefits, their choice of chiro, acupuncture, massage, or usual care fares better in terms of clinical outcome, cost, satisfaction, that sort of thing.

The hypothesis in the study is that people have access to these benefits and they are paid for as part of

this NIH study, will have greater symptom relief, greater improvement and function, greater satisfaction, and decreased utilization of conventional services, visits to the orthopedist, follow-up x-rays, PT, et cetera.

The medical community I think can argue on very solid grounds that there is not much evidence to suggest that this will happen. They say balderdash, these people are not going to get better faster, 85 percent are going to get better in six weeks no matter what.

The CAM community says you give them to us quickly, we turn them around more quickly, we reduce the rate of occurrence, we change the degree of dysfunction over time, but particularly in the acute setting, let us prove our worth.

So, this is when I think a controlled trial is useful. That is what this study is about. I am showing it to you as a model, but embedded in this model are a few things that are key to your discussion.

We drew a circle around our clinical site, our first pilot site, West Roxbury, a suburb of Boston, a working class suburb. There were 347 licensed chiropractors, acupuncturists, massage therapists,

basically in walking distance from that medical site.

Which ones do you bring into this research project? Which ones do you, as an HMO medical director, bring into your HMO? Which ones do you, as a physician, refer your patient or your brother-in-law to?

This goes way beyond licensure. This is levels of credentialing, and by whose criteria? Now, we have worked with the chiropractors, acupuncturists, and massage therapists for four or five years. They co-funded the pilot of this. They built the scope of practice that we embedded in our criteria to pick the researchers.

We could spend a lot of time on this, but how do you decide who is the best practitioner among the licensed practitioners? Licensure and name is not sufficient. What about malpractice history? What about a written application, who writes it? What are the criteria for scoring it? Can it be reproducible, so somebody doesn't say you are just picking your friends? What about site visits and medical records? What about billing practices?

What if this person does something that is out

of keeping with 9 out of 10 of his colleagues in the community?

These are the credentialing issues that I have also put as front and center as recommendations from the Commission. Above and beyond licensure, we need to have credentialing.

The last model I want to give you as an example of health service research was recently published, just two weeks ago, in the Archives of Internal Medicine. This is a more fastidious randomization of chronic low back pain patients from Group Health in Seattle randomized to these three arms.

This article published by Dan Gherkin [ph] and others really compares two CAM interventions with sort of standard educational intervention. You can't see the slide very well, but the outcomes are what the health service research community looks for, disability scores, and in this instance, among the three groups, massage, acupuncture, and education, massage fared better in terms of disability. In terms of weeks, in terms of medication, number of pills, and cost of drug, massage fared better.

In terms of dollars spent, there was a trend to suggest that massage was the most cost effective.

Now, these conclusions of just one study give you an example of how you can look at CAM therapies, look at clinical outcome, and cost, and the conclusions were that massage appeared to be safe, acupuncture is safe but had little effect, self-care promising, but I think the new news here was that in this one study, provocative as it may be, that massage may, in fact, be a cost effective modality, and this warrants further research.

The only other theme I want to mention -- and I know my time is out, so I will just flag it for you -- we are seeing now integrative care teams crop up in major hospitals and medical groups throughout the country, some private, some public, some in major academic health centers. These are examples of major, high-visibility hospitals that have rolled out integrative care clinics.

I repeat my challenge. We must test whether these integrative care units, when given patients with a chronic or life-threatening illness, provide better clinical outcomes and at what cost.

These are testable hypotheses. These

integrative care units at the major universities should be encouraged to develop randomized trials to see if they do better with the patients with cancer or low back pain or intractable headache.

I don't have a chance to go into the model that we are working on in Boston, but you get the gist.

So, my final slide is the stakeholders and some of my recommendations that are written out for you. I encourage you to think about the universities, medical schools, hospitals, and these integrative care centers affiliated with them as part of the driving force.

To date, the managed care and the insurance industry have allowed us to look at some of their outcomes, but they are not investing in research in this area. Similarly, the private sector, although making a lot of money, pharmaceutical companies in particular, they have not invested in research in this area. They need to be engaged. Either they should pay for the research, or perhaps they could be incentivized to match federal dollars to invest in basic science, clinical research, and health service research.

Similarly, don't forget about the Fortune 1000

employers and employer groups whose employees want these therapies, and I think would pay good money to have randomized trials to see if this is cost effective for their employees - will it get the back to work, will they be more efficient and effective employees, will they be more satisfied.

Philanthropy has jump-started almost all of these university programs, Harvard included. The consumers are the ones you know the most about. Let's not forget the NIH to date has been the largest repository of funding, but I encourage you to explore ways in which CDC and the Agency for Healthcare Research and Quality can be engaged.

This is the group that has the most expertise, by the way, in best practices and cost effectiveness research. For some reason, they have not been a major player, and I think they need to be.

You are aware of Congress. I encourage you also to think about the Federation of State Medical Boards, and of course, the FDA.

I will close with a quote. Well, I don't have a chance to summarize this, but I think you get the gist.

Let me make one point.

Clinical research in the absence of basic science is insufficient. Health service research doesn't exist. Education, you are going to talk about, but let me also plant the seed that faculty across our universities arguably know perhaps the least about this, and while you are talking about training the trainees, think about faculty development.

When you think about delivery systems, I encourage you to fund research collaboratively between the private and the public sector, that looks not only at the efficacy of individual CAM providers, but do these CAM networks, as George has spoken about, deliver cost value, and do these integrative teams deliver improved clinical outcomes and at what cost, yes or no.

Credentialing is a bugaboo. Quality assurance and safety, I have highlighted. From my view, you cannot create judicious policy informed by research in the absence of getting these things right.

So, I will close there with a quote. "Doing everything for everyone is neither tenable nor desirable. What is done should ideally be inspired by compassion and

guided by science, and not merely reflect what the market will bear."

Thank you very much. I am open to your questions.

[Applause.]

DR. GORDON: Thank you, David.

Could we have the lights on and questions from the Commissioners.

DR. EISENBERG: I have synthesized these, by the way, in a list of specific recommendations in your handout.

Panel Discussion

DR. GORDON: David, do you have a copy of that most recent study, as well?

DR. EISENBERG: Which one?

DR. GORDON: The one on massage.

DR. EISENBERG: Yes.

DR. GORDON: One question I want to ask while people are collecting their thoughts is when you think of health services research, which is clearly one of the areas that is important to you, what are your suggestions to us about recommendations that we should be making in

terms of funding health services research?

Do you want to come down here with us and sit at the table? That way, we won't have to keep looking up.

DR. EISENBERG: Sure.

General thoughts about health service?

DR. GORDON: Well, thoughts about it, where, any particular priorities that you would seek?

DR. EISENBERG: As I mentioned, I think, first, we need to engage the experts in health service research. The Agency for Healthcare Research and Quality has been doing health service research for years.

Each of the major universities, that is a player in this Consortium of Academic Health Centers looking at integrative care, has armies of health service researchers, but most of them know that you start with the premise that you don't know the answer, that you have to keep the variables consistent, so if you have uneven credentialing, you don't have a consistent intervention.

If you have herbs and supplements that can't be extracted in a uniform way, you don't have a testable intervention at all. Health service research looks at

clinical and financial outcomes, so if you don't have a consistent way of tracking the financial outcomes, not just the amount of cost to the insurer, but the number of visits to the health care provider, the number of hours spent on the phone, all the lab tests, et cetera, then, you know, we don't have health care research that will dictate policy.

So, I think the short answer is play to your strength, go to those agencies that know how to do this well, and in fairness to NIH, they were not established to do health services research, and yet my view of this commission is it is charged to make recommendations that fall squarely in the domain of areas informed by health service research. So, I think we have a big gap.

DR. GORDON: Have you formulated or has anyone formulated some of the conditions that you are describing for making sure that the providers are equivalent or for measuring cost?

DR. EISENBERG: Well, you know, we have submitted manuscripts that are currently in peer review to look at standard approaches to credentialing of practitioners.

We have -- and you will hear from Bridget Duffy at Medtronic -- suggested across interested university programs that we create a unified data tracking system. There is no point in these integrated units at Columbia or Harvard or Maryland or UCSF or Stanford looking at clinical outcomes, DRGs, or financial utilization units in ways that can't be compared and contrasted, or to put it differently, if there was a unified data tracking system for clinical outcomes and costs, then, all the parties that were looking at CAM therapies for individual conditions could be contrasted and compared, or one could imagine, in a somewhat grandiose way, the beginning of a national data warehouse.

Now, the insurance companies desperately need this to make fiduciary decisions on where to set the premium. I am sure George DeVries can speak about this from the business side, but that is actually the missing piece of the puzzle, how do all of these individual practitioners, networks of practitioners, and integrative units compile data that is comparable across institutions.

I don't think you can do it without setting

standards for credentialing the intervention itself and the data captured, financial and clinical.

DR. GORDON: How far along are you in the process of formulating those guidelines?

DR. EISENBERG: I think we should be modest. I am as far as these studies can take me, and I am comparing and contrasting them with studies being performed by other universities that are also doing clinical health service research, and we are comparing notes to see if we can create a unified data tracking system.

But, you know, Woody at Maryland and New York, and we in Boston, and some of the other integrative care units are meeting to say why don't we, for goodness sake, use the same electronic medical record, why do we capture the same information, because again, without that, you know, there is strength in numbers, and when you capture information on 2,000 back pain patients as opposed to 20 in a small study, you have a different level of authority.

DR. GORDON: Great. So, we can sort of tap into that through you and through Woody and through some

of the other people.

DR. EISENBERG: Certainly, to be aware of where they are, and Bridget Duffy and the Consortium of Universities that Medtronic has funded, we will be meeting once or twice a year to discuss that as a high priority issue.

DR. GORDON: Thank you.

DR. EISENBERG: Again, for the greater purpose of delivering evidence as to whether these things are useful or not, cost beneficial or cost additive.

DR. GORDON: Thank you.

Other questions, Commissioners? Wayne.

DR. JONAS: Thank you, David. Good to see you. Thanks for that very nice overview and highlighting the significant challenges in research in these areas.

I want to question, and I would like your opinion about this, the current strategy that you put up there about how this is being approached, because I know this is the strategy of NCCAM explicitly, like Steve Strauss and others, and many folks are going in this direction.

You put up on one side kind of a standard way

in which in conventional medicine, biomedical research is normally done through the basic science research to pilot trials, to clinical trials, et cetera.

I think there is a reason for that, there are some very good reasons for that. I question whether it is wise not to use that sequence, because if we jump -- and you have just illustrated it yourself here -- if we jump directly into demonstration projects, health research, et cetera, in which we don't have the underlying background of, well, what is the standardized herb and how do you produce it, and what is the mechanism of vitamin C I.V. before you do a clinical trial of it, or what practices are you going to uniformize or standardize for us to be able to explore what you do in a pilot trial, what is the wisdom of jumping around, though, or is this perhaps foolhardy especially since many of those studies are quite expensive, are we not in some sense shooting in the dark here and should we maybe rethink this strategy in some way despite the public's continuing venture into this area.

DR. EISENBERG: Wayne, I completely agree and I put up this slide to really humbly reflect on how the

trajectory has gotten rather cockeyed, that in the absence of a robust basic science program, certainly the scientists in the medical community will continue to be irritated. In the absence of health service research, the people in the business sector will not have the information they need to set appropriate policy. So, I am agreeing with you.

I would say it a little differently, though. I think my suggestion in a positive, in a way to give a friendly amendment to what has happened, I think it has happened because it has happened. I mean, you know, if the first study was a basic science study of the mechanism of homeopathy, we would have a very different trajectory, but that didn't happen.

I think if we can all commit ourselves as a larger community interested in this area, to say we need the resources to develop all three - basic science, clinical research, and health service research, and I didn't show the slide, the penultimate slide, but I think your university partners are still arguably the trusted, honest brokers if you will, that industry can relate to, that insurance companies can relate to, that

pharmaceutical companies can relate to, and I think you should utilize them and help them create a critical mass of university programs that can do this in an honest and often skeptical way.

My own philosophy at Harvard has been to engage some of the more senior skeptical scientists before I even begin a pilot study, to ask them what would be the most rigorous way of addressing this question, what would be the best methodology to use, and to invite them to be either consultants or co-authors.

So, in a way, Wayne, I am agreeing with everything you are saying. I think it wasn't broken, we don't need to fix it, that research trajectory is very sound, and somehow CAM and policy recommendations are occurring on somewhat shaky ground in the absence of a lot of the science that needs to be built.

DR. GORDON: We are going to have to move, though, Wayne, because we are very pressed for time this afternoon.

Effie, Tieraona, and Joe. Sorry.

DR. CHOW: David, thank you very much for the nice encapsulated background. I have a couple of

questions.

Can we get a copy of what you presented?

DR. EISENBERG: I will try to generate as many of the slides as are now on PowerPoint.

DR. CHOW: The other is that in your definition of integrative medicine, what seems to be a new or old integrated is the bioenergy concept, and do you want to make some comment about that? Also, I would like to know how are you going to go about the minority study, you know, that you are undertaking.

DR. EISENBERG: Let me try to be brief. The integrative medicine slide is not mine, but rather a reflection of discussions ongoing of the Consortium, and it was meant to make you aware of the rhetorical debate and an attempt on the part of many people within the academic sector to depolarize this, to make it less inflammatory, to talk about improving conventional care based on the best evidence available.

To my knowledge, there is no part of the definition that speaks directly to energy, so I just say that to you.

You then asked me about minority issues. I

have been a broken record at NIH, Wayne knows this, people in CDC know this, I have been pounding the table saying it is immoral in my view not to replicate the national survey by including at least our large minority populations, and I stand by that. I think it is unacceptable.

So, this is, I think, a compromise to get it on this National Health Inventory Survey to 43,000 families, but I don't think it will address the issues we need, which are detailed patterns of use by our minority citizens.

DR. GORDON: Tieraona, and then Joe.

DR. LOW DOG: Thank you for the presentation.

The issue of botanicals is a big one right now with a lot of the sort of negative media that has been coming out, and the statistic was kind of interesting about 81 percent of people would like it to be safe, efficacious, and FDA-approved before it was released, which doesn't happen at a current DSHEA.

I guess my question would be, since many of us are tackling with this issue, what would your recommendation be, one, as far as how to address this

since DSHEA has already been passed, and, two, do you think there would any role for basically funding the top 20 to 25 herbs that are sold in the United States to be funded and paid for to have safety data? Not necessarily efficacy, but safety data done that would provide information on genotoxicity, teratogenicity, safety dose limits, et cetera, if we don't -- yes, and drug interactions involving p450 systems and that -- if it is going to take time to do DSHEA, do you think this might be a temporary measure that might be useful?

DR. EISENBERG: I think when I speak before groups of physicians -- and I used to practice primary care for a long time -- I think physicians are in an impossible situation right now, and I think they are speaking to this.

We don't know whether what is said to be on the label is in the bottle. We can't be assured of the quality of the product even if they say it is tested to this percent. There is no regulation to ensure it. We don't know its interactions with prescription drugs or with one or another herbs or supplements.

I am saying the same thing. I am not

comfortable with the current atmosphere vis-a-vis herbs, vitamins, and supplements. At a minimum, I would agree with those 80 percent who said safety has to be a prerequisite to sale of these items.

Now, you will see in my recommendations, short of demanding safety and changing DSHEA right now, at a minimum, we could push for a postmarket surveillance program and share the burden of that with the manufacturers and distributors of these products. We do that with pharmaceuticals.

Furthermore, this is another perfect area where the pharmaceutical industry should be constructively engaged. Don't you think the manufacturers of cyclosporin or serotonin re-uptake inhibitors want to know precisely which herb interact with their drugs and on what receptor sites?

It is a two-edged sword. On the one hand, they protect themselves from future liability, and on the other hand, there is drug development and drug discovery to be made, either metabolism of drug or receptor sites. I think you get my gist.

This is where we should take what I think is a

disastrous situation and use it to our collective benefit to engage those stakeholders and say only up to the bar, create a consortium for research to look at adverse events. You say they don't happen. Let's constructively and prospectively monitor that with your products. We do that with the pharmaceutical industry.

Personally, I would like to see efficacy also as a prerequisite, but I am a clinician here, I am not speaking as a regulator, so you see where I stand.

DR. FINS: Thank you for your comments. Your fourth recommendation addressed potential ethical issues associated with CAM therapies, co-management, and presumably with research.

Based on your experience with IRBs and designing these studies, could you say more about that?

DR. EISENBERG: When you say "ethical," I think I point to malpractice.

DR. FINS: You said issues of malpractice, liability, and ethical practice associated with CAM therapies, but if you could expand that to talk also about the ethical dimensions of the research endeavor that you propose.

DR. EISENBERG: Well, I think all of the research that I am aware of and support is cleared by IRBs and looked at very strenuously for ethical issues, conflicts for patients, but there are also legal constraints.

I think you have met Michael Cohn [ph], who works on our staff, and is really trying again in the peer-reviewed literature to lay out some of the malpractice issues, and Karen Adams from the University of Washington and others have written on the ethical issues. These are all in peer review now.

I think suffice it to say apropos Wayne's point, there is not a new approach here. It is the same, if not a higher standard of excellence that we need to aim for. Something that is unethical, immoral, or is not sanctioned by the law cannot proceed as a university-affiliated project. End of story, finished, complete.

That is why I think again these university-affiliated research centers and institutes are your honest brokers. The rules have been put in place, let's play by the rules. I think none of the studies that I have been a participant in, none has been rejected to the

point where we can't go back. I think some have been very difficult to convince the IRB on their merits, but none has been rejected out of hand.

DR. FINS: On that specific issue, do you think IRBs need education to supplement what they already know to address the challenge?

DR. EISENBERG: One of the interesting things to consider is whether IRBs should begin to have participants who are knowledgeable or members of the CAM community to help advise them on what the standard of care is.

If you talk about some therapies and some IRBs where nobody has heard of the therapy or realizes that these are licensed practitioners up the street, there is really a knowledge and information gap to inform the larger group.

So, again, I think use the IRBs, expand them, refine them, so we can have valuable discussions about these things.

DR. GORDON: We have two very eager, one quick follow up from Wayne, and one quick one from Dean, but we are already about 10 minutes overtime.

DR. JONAS: This is an easy question for you. What do you think about the current strategy to reduce the number of centers and center funding that is currently going on at the NIH?

DR. GORDON: What, Wayne? I couldn't hear you back here.

DR. JONAS: To reduce the current, at least projected strategy to reduce the number of centers, CAM-supported centers at the NIH.

DR. EISENBERG: I think, Wayne, you know from my own personal reflections that I disagree with that. Jim, you and I and Dean were at a meeting of foundations and principal investigators of universities not three weeks ago, where we talked about the wisdom, if you will, of creating greater resources for university centers, not just NIH funded, but university centers that could proceed with a research base and educational base and a clinical delivery infrastructure, and that these universities need to be supported.

Now, part of that will be the NIH research base, so I am a big champion of a critical mass of academic affiliated centers that can do this work, but

again, you can see that is totally self-serving because I live in an academic institution.

I still think they are your honest brokers. I think they are the only group that can engage all the stakeholders and the consumers and win the respect of everyone and say we did the studies that needed to be done to figure out what worked and what didn't, what is safe and what was not, and how to create policy that is ethical and within the law, so I hope that answers your question.

DR. GORDON: Dean.

DR. ORNISH: Just quickly. I again want to thank you for your wonderful presentation and also your leadership in the field, and particularly your commitment to getting good science.

A number of people who have testified before us have said things like, you know, there needs to be a different kind of experimental design for some integrative medicine, CAM therapies, that if you are comparing St. John's wort with Prozac, it lends itself to a double-blind design, but if you are looking at other CAM modalities, they don't really lend themselves, and

you have also given an example of a different kind of a design in the back pain study.

Can you briefly comment on how you feel about that or do you think that everything should be held to the same type of design?

DR. EISENBERG: I think I am on the side that says we don't need a new paradigm, that the tools we have are excellent for most, not all, of the questions we want to ask, certainly many of the basic questions we have sufficient tools.

I think what has happened is there has until recently been no engagement of the biomedical community, particularly the basic scientists, to see the beauty and the excitement of the puzzle.

I think some of these studies -- you know, you are shaking your head, Wayne is shaking his head -- all of us that do research for a living in this area know that it is very complicated to design a placebo-controlled study of acupuncture, but it becomes intellectually a beautiful, artistic project, a challenge, and when you get the best researchers at the university to say, well, let's look at this critically,

they come up with ways of refining study design.

I think that may be some of their contributions to the field down the line, but it is not a new science, it is not a new paradigm, it's an extension of existing approaches. You know, David Sackett said it best, "Can a therapy withstand attempts to prove its worthlessness?"

It takes great creativity to design studies that do that in a fair and honorable way, and I think we just haven't engaged the medicine community enough to do it, and when we do, I think we will get a lot of answers to this.

I also want to return the compliment to you, Dean, and I didn't mention this, but it is important. You will see in the written testimony, when I talk about university-affiliated programs, I think that is because they get the most traction as universities do, and they also have the greatest resources and infrastructure, but many of them must be informed by demonstration projects that have not grown up in the university, that are being done by the private sector and by entrepreneurs that can inform the universities.

So, I don't want to make this a monolithic

university or nothing, take it all, but I think the university has become the vehicle, the factory to build these new projects.

DR. GORDON: Thank you very much, David. Thank you for all your work. Good luck with the conference in California, and we may well be back in touch with you to find out how it went and any further thoughts you may have.

DR. EISENBERG: Thank you all very much for having me.

[Applause.]

Panel Session II: Foundation Support for CAM Research

MS. CHANG: We are going to go ahead and move on to the next session for this agenda. Dr. Bridget Duffy, Dr. Doriane Miller, Susan Braun, and I think we have a substitution for Ron Chez, Susan Samueli speaking for Ron Chez.

DR. GORDON: Welcome. We will begin with Bridget Duffy.

Presenter: M. Bridget Duffy, M.D.

DR. DUFFY: Thank you for inviting me. I enjoyed meeting some of you in Minnesota. Was it a month

ago when you were there for the Town Forum? It was great to get here today, because it is 99 degrees in Minnesota this morning.

Today, in Minnesota, the nurses vote whether to strike, and I bring this up because it is very pertinent to what I want to talk about today with you. Most believe that they will strike, and if they strike, they will walk on May 31st.

I was asked a few months ago to come and speak to the nurses at the largest hospital in Minnesota, on May 31st coincidentally, and they called me yesterday to confirm my title and to ask me what my objectives would be.

In lieu of this potential strike and walkout on the day that I am speaking to them, I changed my title. The original title was, "The Use of Complementary and Alternative Therapies in the Nursing Practice," and I changed my title to read, "Restoring Healing to Health Care: The Crucial Role of Nurses".

Now, I think what is at the core of the writ, of the issue that they have in health care today, and the reason they may strike, is not what the papers would have

you believe, just money, but it is about the loss of their profession as a healing profession. It is the loss of a relationship with themselves, with their patients, with the ability to provide the healing services and care that they know impacts their patients.

So, their issues form the basis of my comments and my recommendations to you today, and I believe that the interest and the use of complementary alternative therapies is a symptom of a much deeper issue in medicine, and through my work, through the Medtronic Foundation, and in my collaboration with other foundations and philanthropists, we are seeking to change this.

So, what I would like to do in the few minutes that I have with you is talk about four things. I would like to tell you what we are seeking to do to change medicine, how we will do it, what are the obstacles we have encountered, and what are our recommendations to you.

So, what are we seeking to do? We are seeking -- and as you asked me in the first question, which is included in your handout -- is our foundation funding

complementary alternative medicine research, and my answer was that we are not supporting the study of specific CAM modalities, rather, we are seeking to support research efforts that are identifying the best clinical care models to improve the lives of people with chronic disease.

Now, Medtronic, for those of you who don't know who the company is, is the world's largest device company, makes implants for the brain and for the heart. There are 22,000 employees worldwide, and we make devices for Parkinson's, for every aspect of heart disease.

So, the people that we serve are quite large. As you know, heart disease is the number one killer in the United States with neurologic conditions expected to surpass that in 10 years. So, our goal is to transform the way we care for people with chronic disease.

Medtronic believes and due to an enlightened founder and CEO that it is not enough to just crack a chest, put in a valve, and send a person home in four days, or to put a burr whole in the brain and put an implant in to stop the tremor and send him home in two days.

We believe that there is much more to healing and that we, as a device company, needs to play a role in shaping what that model looks like. So, how will we do it? Point No. 2.

We could wait for government and academia to redesign or overhaul the medicine, but we decided we would find those who we felt could just go build it. So, through philanthropy, we are seeking people that have vision and leadership in place to build these models of care, and that is because I am impatient and so is the founder of my company and the current CEO.

In fact, Earl Bakken, who invented the pacemaker 50 years ago, said to me, "Bridget, 25 years ago I wrote a paper called Vision 2010: The Hospital and Health Care of the Future," and it was about the incorporation of alternative therapies and creating a healing environment, and he said, "It took me 20 years to get them to even start listening to me."

I said to him, "Earl, I don't have 20 years, we are going to do this much more quickly." So, how we are seeking to do that is that Medtronic's main customers are heart patients and brain patients, so our customers are

neurosurgeons and heart surgeons that implant these devices.

So, I decided to target these folks. We know that nurses and family docs and internists usually get this, they usually know what it takes to heal. We decided to go to this group of individuals to have them help us build the models.

Hierarchically and financially within the institutions, these people run the hospital. So, we realized that if we could get and identify some champions in these fields, that we could ask them to build these models, and we would have a ripple effect across the country.

So, we have identified some of the top academic centers and clinical centers across the country, and we are supporting several of them, and the number will be growing, as David Eisenberg alluded to.

Now, how do we identify them? We had institutional and programmatic criteria. I will tell you briefly some of the criteria, that we really wanted them to have a strong research infrastructure because we believe without the data, people will not adopt these

behaviors.

Secondly, they had to have the ability to implement and apply these therapies in a clinical setting. So, we targeted specific cardiac and neurologic diseases, so that some of the centers to date that we have funded are Duke, Harvard, Stanford, Scripps, Alina Health Care Systems, St. Barnabas, Beth Israel, New York, with several others that we are investigating.

The first year and a half we focused on cardiovascular disease. This year we are focusing on neurologic, and we specifically are looking at pain. So, as an example of the way we are using our dollars in philanthropy is at Beth Israel in New York, they have the top pain guru who sits within the Beth Israel campus and 20 blocks away they have the leader in integrative healing within the same health care system, and with our dollars we have asked them to work together and to build an integrative model of pain management.

My ultimate goal is across the country, through our support, we will build integrative centers of excellence around specific disease and device entities, so that you could look on the Internet or a patient could

find the integrative center of excellence for pain, the integrative center of excellence for coronary artery disease, et cetera.

So, through, as Dr. Eisenberg alluded to, I think the most important thing about our funding of these centers is that all of them have said to us we are not just interested in your dollars, we are interested in true collaboration among the centers, because there is nothing more frustrating to me than to see 10 different spirituality surveys or 30 different proposals on whether guided imagery works, and 10 different ways to measure pain and anxiety, and there is no ability to pool the data at these different centers.

So, they have agreed to do three things - to share a common database, to share common assessment tools, and to share in the dissemination of the findings, so that others might learn.

Lastly, and most importantly, they have agreed to collaborate in the training of future leaders on healing. By this, I don't mean setting a medical school curriculum on how you teach people which herb works, how it works, sort of like memorizing the Kreb's cycle or the

mechanism of action, but rather how do you teach people what the core principles and values are around healing and how you apply these therapies.

As an example, to demonstrate how we are hoping to disseminate these findings, this is not anything I am pushing, but this is the brochure that I will leave behind from the American College of Cardiology, the first conference ever on the integration of complementary medicine in a traditional cardiology practice.

One of the participants here said to me he never thought in his lifetime he would see the ACC sponsor a meeting on this subject. So, in this program, the CEO of Medtronic will be the keynoter and then I will have a panel where we profile the centers that we have funded to date, but I think that's miraculous. We have a long way to go, though.

Third, what are our obstacles? My greatest obstacle is not the absence of data, and personally and professionally, inside Medtronic, my greatest obstacle is the perception that I am about building alternative clinics. I believe that what I have found is the greatest obstacle as I talk around the country to people

who have built these models or are trying to build them, I ask them, what is your greatest obstacle, and they tell me it's, number one, the physicians -- and I am one -- and number two, the administrative leaders.

So, I could not agree more with what Dr. Eisenberg said about the need to have an institution or an entity that can train current faculty and future leaders and administrators of these health care systems that can help us get the adoption of these models into place.

So, what are our recommendations to you? I have five brief recommendations.

The first would be to broaden your mission and your focus to include study of the delivery mechanism or the context in which this care can be delivered. First is just the safety, efficacy, licensure. We are trying to do that through the centers that we are working with, and I will talk about further, we would like to figure out a way to collaborate with the work that you are doing.

Secondly, I would eliminate terminology that will exclude or delay the adoption of these healing

practices. I believe those words are alternative and complementary. When I work with these cardiologists, these neurosurgeons, and they hear that I am coming to a committee like this or hear these terms, they run for the hills.

So, I think that there is a need to establish something like an academy for health and healing, and under that are boards and panels that look at the safety and efficacy, licensure, et cetera.

Third, I would create a vehicle or a mechanism to keep informed of the work that philanthropy is supporting. There has got to be a way that we can communicate and relay the information of the best practices or the findings that we know about.

Fourth, I would establish an entity, a committee or academy, that then takes these findings and proactively works to shape policy and reimbursement.

Lastly, I would recommend that you seek and support educational initiatives that foster a new breed of leaders who can drive the adoption of these best practices, thereby allowing patients access to the best that medicine has to offer.

Thank you for your time and thank you for the invitation to be here.

DR. GORDON: Thank you. Thank you for your precision and concision.

Doriane Miller, welcome back.

Presenter: Doriane Miller, M.D.

DR. MILLER: Thank you, Dr. Gordon.

Yesterday, I had the opportunity to talk with you a little bit about minority and under- and uninsured issues regarding CAM, and today, I would like to put on a slightly different hat, and that is the role that I serve at the Robert Wood Johnson Foundation as Director of the Program Development and Grantmaking in the area of clinical care management.

For those of you who are unfamiliar with the Foundation, the Robert Wood Johnson Foundation was established as a national philanthropy in 1972, and is dedicated to the health and health care of people in the United States.

We fund programs in three major areas - increasing access to health care services, providing care and support for people with chronic health conditions,

and reducing the harm from substance use.

From an asset base of approximately $8 billion, we will fund about $400 million in grants this year only in the area of health and health care.

In preparation for my testimony today, I reviewed the Robert Wood Johnson Foundation's grantmaking in the area of CAM for the committee. You will find in your packets a summary of selection of those grants, which I think actually range pretty much across the board in terms of the area.

However, for the purposes of the discussion today, I think that it would be helpful for the Commission to hear a little bit about how our philanthropy and actually many other health philanthropies think about strategic decisionmaking when making decisions about what projects to fund.

In my opening comments, I mentioned many areas of Robert Wood Johnson Foundation, but within these broad goals, narrower focused areas help Foundation staff to direct their programmatic development and grantmaking, and also helps grant applicants to understand our strategic priorities.

Within these areas, staff link program development and grantmaking to measurable strategic objectives. We based our program development and funding decisions on a specific project's ability to contribute to achieving the strategic objectives.

The Foundation funds projects that use the tools of research and policy analysis, demonstration, education, and training, communications and evaluations to achieve those strategic objectives.

The area that I am responsible for is the clinical care management area at the Foundation, which is designed to narrow the gap between what is known and what is practiced in health delivery systems today for people with chronic medical conditions.

We attempt to effect change in three strategic areas - change in purchaser behavior to support the delivery of evidence-based medicine, improving delivery system capacity to provide evidence-based medicine, and also engaging people both as consumers and also as patients to become more involved in evidence-based medical care.

The projects that we funded are both cross-

cutting in terms of those strategic elements that I mentioned, but also disease specific.

Some examples of these projects include a project in Adina, Minnesota, that has developed a protocol for depression screening in an adult day center, a project in Lafayette, Colorado, that is working to improve community resources to support chronic illness self-management within a low-income, Spanish-speaking population, and a project at the Medical University of South Carolina that is testing the benefit of group visits for low-income people with Type 2 diabetes.

The focus that I want to make here is that we have not a basic science focus or even looking at best practices, but much more of a translational agenda, and that is looking at ways in which we can take evidence-based and translate it into implementation on a widespread basis.

How does this translational agenda affect our view of funding CAM research? If there were sufficient evidence that a particular CAM approach to treatment could positively affect the outcome of a treatment of a condition we are targeting, we would consider funding CAM

as a part of a total program or system of care.

CAM is not currently an area of strategic funding for the Robert Wood Johnson Foundation, nor are we considering making it a funding priority for the Foundation.

To the extent that current and future CAM research and implementation could help to make improvements in our strategic funding areas, however, we would consider funding CAM on a case-by-case basis.

The Robert Wood Johnson Foundation has tremendous experience in the area of convening, training, and demonstrations in the health field. We had the opportunity to collaborate with the Medtronic Foundation just this summer on a project that looked at issues around patient empowerment and consumer activation.

If we chose to become more active in the area of CAM, we would draw upon these experiences to help stimulate more activity and interest in CAM, and we would also welcome public and private funding partners in this endeavor.

Thank you for your time.

DR. GORDON: Thank you very much.

Susan Braun, nice to see you.

Presenter: Susan Braun

MS. BRAUN: Good morning. Thank you for inviting us to speak. I am Susan Braun. I am CEO of the Susan G. Komen Breast Cancer Foundation, which was started in 1982 by Nancy Brinker in honor of the memory of her sister who was Susan Komen, who died of breast cancer at the age of 36.

Since that time, we have grown from just a group of a few people who have an interest in what breast cancer does to men and women with the disease, into a network now of 115 affiliates in the United States, in 45 of our 50 states, and we have three international affiliates.

We have about 70,000 active volunteers, and to date we have raised more than $400 million towards our mission, which is to eradicate breast cancer through research, education, screening, and treatment.

I will talk a little bit about our own approaches to CAM and what we are looking towards in the future, but I also want to point out one way in which our foundation model is perhaps uniquely suited to address

some of the questions that we are needing to address here, and that is because our primary base, our primary group of constituents are the public.

For example, our Race for the Cure events, which are our major fundraiser, although by no means our sole fundraiser, will have more than a million participants this year, and our corporate sponsors are million dollar council members are Kelloggs and G.E. and Lee Jeans and American Airlines, Ford, a lot of large corporations like that, and yet we are the largest private funder of breast cancer research.

We fund a great deal of basic clinical and translational research, to date more than $68 million we have put into those programs, and pretty much following the model that Dr. Eisenberg put forth and which you all are familiar with within the academic institutions of the United States and around the world.

So, we really bridge that gap between who the public is, what the public wants, and then research that have followed those interests of the public, so much of our determination as to what we will be funding comes from the public interest, although it is driven certainly

in terms of which proposals are accepted by peer-reviewed processes and by the scientific community.

Our choices as to what we will fund are very, very much driven by the public, and they are driven by an interest in filling gaps, in doing what isn't being done by someone else out there and doing things that we are particularly well suited to do.

Another thing, too, about Komen is we really didn't get to where we are today by following the status quo. Although somehow we have become a real major player in grantmaking, it wasn't because that is what we sought to do, but it was really because we followed the emotions, the needs, and the demands of the public, and the public is not accepting that breast cancer doesn't have answers yet, just as they aren't accepting that cancer doesn't have answers yet, and that is what continues to fuel what we do.

So, we plan to continue to ask all of the difficult questions, both those inside and outside of the proverbial box.

We also are pretty aware of most of the statistics and surveys that have been done and

particularly one that looked at cancer patients, finding that 50 percent of those patients who were surveyed did combine complementary and alternative modes of care with their conventional care, but also that breast cancer patients are more likely than other cancer patients to use complementary and alternative medicines and/or therapies, and we find again and again and again without constituency base this interest and this need in continuing with these therapies, but also in understanding them better scientifically.

So, I believe that one of the things that we need to help do, and will do, is identify the dichotomy that was pointed out between people, the public wanting to have proven therapies, wanting to have data, but yet also interestingly a willingness to continue along with something that has not been proven, and I think we are in a good place to help identify and understand that dichotomy.

You had asked about our specific endeavors within the field of complementary and alternative medicine, and we do have now in last year's portfolio, which was $19.2 million in grants, and this is just

within our structured grant programs. We also have thousands and thousands of community programs that we fund that are educational and outreach programs.

We funded over a million dollars in complementary and alternative, within that part of the portfolio, and then also programs within the community, such as wellness and improvement in quality of life.

One of the things, for example, that I wanted to highlight within our portfolio is research that is being done on black cohosh. I think many of you are familiar with some of the recent reports that identify that this substance might have estrogenic properties.

Breast cancer survivors and those who are either at risk of breast cancer or who fear breast cancer, whether they are truly at higher risk than the average or not, are increasingly reluctant about taking estrogen replacement therapies although a definitive link to breast cancer is still debated.

So, we find, for example, not only in patients, but in well women who either fear or are at high risk for the disease are not going to take estrogen, so they will look to alternatives.

Well, we have also begun to recognize, for example, that with black cohosh, there is a concern about is it tumorigenic or does it cause the lining of the uterus, for example, to expand, and so we are funding a study that is being done by Vicky Davis at Cedars-Sinai Medical Center that will look at black cohosh, and that will look at its activity particularly in the breast and whether or not it does accelerate breast tumor development.

We are also, though, looking more and more, not only in our funding, but also in the programs that we are a part of or that we fund in the community, at areas such as spirituality and other forms of healing that are not necessarily invasive.

We have recently had Larry Daucy [ph] come and speak to a group of us in Dallas as a part of a lecture series that we helped to fund, and I think what is so fascinating -- and I sat in as he spoke to the medical staff at Baylor, and he spoke to our folks, so he spoke to a number of audiences -- and what is fascinating to me in this, and as I have spoken about his visit since then -- I do a lot of public speaking -- how it grabs the

attention of everyone there.

I spoke to a large group in Little Rock late last week, and when I began to talk about that and what Larry Daucy had done, the room was perfectly silent, and afterwards -- and I had talked about many things, I spoke for almost 45 minutes -- and that is what people came up to, wanted to share their stories and talk to me about.

So, there is this huge groundswell clearly of interest, and rather than go on too much further with all of this, because you have my remarks, a couple of recommendations that I would like to make specific to what we have been finding and to the public interest that we are seeing around us is working with patients, and it is something that we will be funding more to, talking to patients and talking to consumers who have a high health care interest, about that dichotomy that was pointed out earlier and what it is that we need to find out in that, not necessarily just how do we close that gap, but what is that telling us.

I think, too, especially as we talk to cancer doctors, I was at the American Society of Clinical Oncology meeting that is taking place this week in San

Francisco, 28,000 very mainstream cancer professionals, and one of the areas that they are most concerned with, of course, is medical interactions, what is going on with the things that patients ingest as they are having chemotherapy, radiotherapy, for example.

So, we would like to suggest a strong differentiation between those things that are ingested or at least that -- can I finish my sentence --

DR. GORDON: Go ahead.

MS. BRAUN: -- but that have a potential for a toxic effect compared to those that have a more complementary or a potential for a healing effect in a different way, so the differentiation.

Also, I think as I sit here with, in the world of not-for-profit funding, a funder's consortium, bringing together funders to say what are you doing compared to what are you doing, what are you doing, so that we are doing things in ways that work together as opposed to reinventing wheels.

Then, I think, very importantly, when we talk about what isn't there in basic science, there has been no question from our experience in the funding of breast

cancer research, both our own and then what has happened at the National Institutes of Health, the Department of Defense, and other funders, that the basic scientists really do, as they choose their career, look at where they are going to be able to be funded, so that they continue the science that they want so desperately to study.

Our Young Investigators program and our Fellowship programs have demonstrated that in spades, so I think it would be very important if we want to see more basic research, to fund young scientists who are interested in the field.

Thank you very much.

DR. GORDON: Thank you very much.

Susan Samueli. Welcome.

Presenter: Susan Samueli

MS. SAMUELI: Thank you very much, and I am very honored to be here today.

After spending 20 years of studying homeopathy and nutrition, I am very excited that the government is beginning to focus much more in this area. I would like to spend my time today before you to share with you the

vision and the history of the Samueli Foundation and the Samueli Institute for Information Biology.

The Samueli Foundation was created by my husband and myself as a way to express our philanthropic interest. My husband, Dr. Henry Samueli, while a Professor of Electrical Engineering at UCLA, was successful in creating broadband technology, which eventuated in his co-founding the company Broadcom, Inc.

The success of this company has brought us great wealth, and it is our privilege to return a good portion of this to our community in the forms of grants and gifts.

Through our foundation, we have funded various projects and programs in the areas of education, religion, social services, and fine arts, but because of my passion for the study of alternative and complementary medicine, we are committed to support scientific research that will affirm the credibility that this field so deserves.

Much of the public is utilizing various modalities and interventions that are placed under the complementary medicine umbrella. Current documentation