industry.

One of your duties is to make recommendations in regard to health policy. You have a unique opportunity. You can take advantage of it or shrink from it. The public is turning more and more to alternative medicine. I plead with you to have the courage to recommend passage of The Access to Medical Treatment Act.

This would make it possible for these non-toxic treatments to be tried under strictly controlled circumstances. You should also recommend that any medical treatment that has been in use in a foreign country where there is no evidence of it posing a danger to the patient be permitted to be administered here in the United States. It is a crime that our people do not have access to the non-toxic treatments we are finding in Europe.

People all across the land are turning in increasing numbers to alternative medicine. You are in a unique position. You can have the courage to make a statement that will be heard, or you can shrink from this opportunity and come forth with a meaningless statement that ruffles no feathers.

In the meantime, people in our country will continue to die because we are unwilling to open up the system to treatments that are being administered in other countries.

[Applause.]

DR. GORDON: Thank you, Berkley. Thank you as always for your leadership and inspiration and for reminding us of which way our noses are pointed. I appreciate it.

Paul Kurtz.

DR. KURTZ: Delighted to be here. I was intrigued by the sessions all day. I suppose I am the token skeptic, having been invited about a week ago. In any case I represent perhaps the leading critic of alternative medicine, The Committee for the Scientific Investigation of Claims of the Paranormal, publisher of the Skeptical Inquirer, and the Scientific Review of Alternative Medicine, a new journal published by the Council for Scientific Medicine. Perhaps we represent the so-called "Establishment" in medicine today.

I have just returned from Australia where we had a World Skeptics Congress on Alternative Medicine,

and we brought people from China, India, and other parts of Asia. They were critical of Qigong. I didn't hear any of that today. They prefer Western medicine, but pursued Qigong because of the cost, and similar for the kind of healings in India.

In any case, we are committed to scientific medicine because we submit, in deference to Mr. Bedell, that this has been the most effective way of curing disease and leading to human health.

What we want is coherent theories that are falsifiable, randomized, double-blind clinical tests, and tests of effectiveness. What I have heard today largely were testimonials from patient and practitioners.

Now, I think much of what I heard or some of what I heard I would agree with, but I would not call it alternative medicine. I think that term is a misnomer. You have packed everything into it.

For example, lifestyle management in cardiology, I had a bypass, I do that. I don't know that that is alternative medicine, nutritional therapy, and many other things. There are plural methods of therapy. The main thing is are they effective, and the only way to

judge that -- and you, as commissioners on this Presidential Commission, have an obligation to see that these methods are carefully judged by double-blind tests, that they are coherent theories, that you can find mechanisms if they work and why they work.

Now, I applaud the call for evidence-based clinical tests that I have heard during the day. Let me tell you why the skeptics are skeptical about alternative medicine.

First, if you are going to have double-blind tests, they cannot be done simply by proponents. Now, we have heard about the tests of acupuncture or homeopathy. You need neutral observers, you need skeptics involved in this, not people trying to get funding and trying to sell a cause, and also there are a good deal of negative tests. I haven't heard any testimony about the negative tests. There is a good deal of literature where people are unable to replicate these claims.

One problem that we find is the failure of replication, and a further problem is experimental bias. Experimental bias enters into many fields, and particularly into protofields where people are trying to

establish a new profession, and naturally, they want the results. So, the tests must be done by neutral observers who are objective and impartial, neither strong negative skeptics, nor strong proponents, but people who are committed to scientific research.

One problem that we found continually in the field of pseudoscience, and we have examined so many from astrology to parapsychology, so many fields that claim to be sciences, and one problem that we find is the protocol. The protocol has to be very rigorous and very tight, and there cannot be any sensory leakage.

Now, this commission is going to make recommendations to the new administration, whoever it is. Do we know who it is at this moment? I haven't heard. Okay. It is vital that there be objective and impartial tests, not special pleadings for funds for the government for research or for insurance coverage. I mean what is at stake really is the health and the welfare of the American public, and you have an obligation to see that that is safeguarded.

Now, it may be that many of these pluralistic alternatives that you have work. Okay. Let's have an

open and fair, impartial hearing. Let's not be biased pro or con, and let scientific testing do the work.

It has been very effective in the last century in extending the life of people and getting rid of infectious diseases, many of the wonders of surgery. These powerful methods ought to be extended, and not limited or reduced.

I submit that this commission should open its panel to your critics, and that there be fairness, and that you should invite those who disagree and can bring the negative results and the contrary criticisms, so you can hear that.

You need a balanced position. I didn't find it today. But, in any case, thanks for inviting me.

DR. GORDON: Thank you very much for coming. I just want to say before we move into questions, we would invite you to help us put together balanced panels of researchers who would question in a honest, fair, and open way some of the modalities that we are discussing.

DR. KURTZ: I think that is the best service you can do to the public in investigating what is effective and what is not.

DR. GORDON: We look forward to working with you, and Steve Groft, our executive secretary, is very happy to collaborate with you in putting together those panels. So, thank you very much.

David, Tom, and Effie, to begin with.

Panel Discussion

DR. BERNIER: Well, as someone who has done double-blind and triple-blind studies in the university setting for a long time, I can tell you I wish it were that simple. We have a document called the Physician's Desk Reference. It contains some 10,000 medications that are very commonly used by American physicians.

Do you know how many medications in that document have ever been scientifically proven to be more effective than placebo? Less than 10 percent scientifically. Does that mean that those medications are not efficacious? Not necessarily. It is just that the placebo effect is so strong that it compares with many of the medications that are used in the PDR.

We use those medications in the PDR. The language that they use is very interesting. It says, "Possibly effective in the treatment of --" which means

it has never been shown scientifically to be more effective than placebo.

Do you feel that the double-blind test is an absolute acid standard for what should be utilized, what we should write policy for, for access?

DR. KURTZ: Let me say first that we are critics of medicine. Much of contemporary medicine falls short of evidence-based medicine, so we would bring a similar indictment against some of the traditional fields, and surely in the area of medicine, there are constant revisions and changes, which indicates that medicine is not fallible.

But I do think a double-blind test at least is a first stage. The thing that intrigues us about acupuncture -- and I know of many critics in China -- claims that it works, is whether it is a placebo effect and whether it has been tested by proponents or by neutral observers, but, of course, the same thing applies to traditional medicine.

The other thing is do you have a coherent theory and can you explain what is happening and why.

DR. BERNIER: Wait. Let me stay with this

point for just one second, if we could. In 1972, at UCLA, we did a triple-blind study in acupuncture in which the people sticking the needles in didn't know whether they were sticking real or placebo points. The people receiving who were receiving the treatment didn't know whether they were being treated with real or placebo points, and the people evaluating the data didn't know whether they were real or placebo points.

The experimental team was kind of mixed about it. Several of them were very skeptical, several were open, but it didn't matter what their opinion was, because this was a very tight scientific design, as tight as you could determine.

When we analyzed the data after the study had been conducted, we found quite reliably and repeatably and predictably that when we would stimulate acupuncture points we would get a reliable result, not so with the placebo. It didn't matter what our biases were when we did that kind of study.

DR. KURTZ: Well, I hope that your account is correct. The only way that you are going to persuade the scientific-based medicine is if there could be

independent replications by totally neutral researchers without any commitment either way.

I think that is true of science in general. You have to replicate in any laboratory worldwide.

DR. BERNIER: But are you saying then that 90 percent of the medicines in the PDR, we should not have access to those, those shouldn't be utilized because they have never had that done?

DR. KURTZ: I am saying that medicine itself is open to revision and reform. This is not a defense of the medical establishment. As it is, it is a defense of a method of inquiry, and that is the most effective method and I think people who argue for alternative therapies should appreciate this method and trying to use it. I reject the claim here that we should abandon those methods. They have been, by and large, effective where they are used.

DR. BERNIER: Just one other point as a scientist. If we want to talk scientific method, the first thing that we are taught as scientists is you can't prove the null hypothesis, you can only reject it. Negative studies don't prove anything, and I would take

exception with your comment that nobody is reporting negative studies. Because you can't find the phenomenon, it doesn't mean it doesn't exist.

DR. KURTZ: But if you can't replicate it, why should you accept it? You say negative studies. How many studies have been done, have you reported in our literature where an effort to replicate it turned out to be negative completely? I mean you need that.

DR. BERNIER: It doesn't prove anything. You cannot prove the null hypothesis, you can only reject it with positive findings.

I am sorry, I will stop here.

DR. GORDON: I think the important thing here is not so much to debate as to elicit what the ideas are of the people who are presenting information to us.

DR. BERNIER: Okay.

MR. CHAPPELL: Mr. Miles, thank you for your very thorough submission, and I want to expand on a couple of questions that you ask here - should CAM be integrated with conventional medicine.

You suggest that we actually should frame a different question, and that is, should government policy

promote the appropriate availability of complementary and alternative practices. Then, you talk about ways that we can do that with better educational programs, legislative relief, and benefit program redesign.

This is very helpful to my thinking because I continue to, as a businessman, look to the consumer to ultimately define choices, so I am in a different context here with scientists, and I often have trouble making the transference of what works in the marketplace with what the world of "shoulds" are.

But I do want to just ask you to talk a little bit more about whether you see CAM as a coexistence, a parallel, or is it integration what we are looking for, is our role to help promote and give sort of equal opportunity, equal research, equal access, or is integration truly a valuable goal in your opinion?

MR. MILES: The way I would approach that is that our current system is based on competition, the different practices are seen as competitive with one another. The groups that I have worked with where they become collaborative is where they get the best outcomes, in other words, how can these practitioners work

together, not as competitors with one another.

So, I think that is a shift of model, and I think that what you might call the corporatization of medicine in the last 10 or 15 years is a move in the wrong direction, because it tends to put practitioners into kind of a time and motion study approach to doing the work, and I think being with rather than doing to is a huge factor.

One of the drivers of that is the reimbursement system.

MR. CHAPPELL: Right. I mean health insurance is not even the right name for reimbursement for promotion of wellness. Health assurance is the right product.

MR. MILES: Well, we have lumped insurance together with prepaid care, and prepaid care is not insurance. So, I would try to figure out some kind of way.

The movement toward the medical savings account is kind of a step in that direction, of separating routine care from insurance, because people, when we introduced health insurance back in the forties and

fifties, we didn't introduce it as insurance, we introduced it as benefits. That is a totally different concept. You buy insurance on your house or your car, you don't think of ways to collect benefits.

So, somehow, from my point of view, we have created a public expectation that they can live their life any way they would like to live it, and this insurance system is going to rescue them, and somebody else is going to pay for it.

I think until we deal with that straight out, I think we are going to have a hard time integrating CAM, integrating anything else, because the public expectation is that they are a victim, and somebody will rescue them.

MR. CHAPPELL: That is what you call benefit program redesign.

MR. MILES: Right, and if we don't deal with that kind of basic belief system in the culture, I think we are kind of plowing ourselves uphill.

MR. CHAPPELL: Thanks.

DR. GORDON: Effie, George, and then Joe.

DR. CHOW: Thank you very much. I have a couple of questions, and, Berkley, I appreciate your

whole animation towards this and your pursuit of this in your own personal dollars and time and everything.

You mention about accepting that which has been practiced in other countries. Can you elaborate a little bit, because we are seeking scientific evidence of this, and what you are saying is that the existence of it, and the value of it in the country is where it is, it has shown value. It is enough that at least we can begin to use it. Can you elaborate on that?

MR. BEDELL: I sure can. First of all, I think that Mr. Kurtz' criticism is wrong. My God, how could you invite anybody except him that would be more definitive in objecting to alternative medicine? You are doing that. It seems to me that you have done so.

But we come from a completely different concept. Forgive me. I care about the patients and the people and those that are suffering from disease, and I believe, maybe you don't, I believe we don't have very good treatments for most degenerative diseases. I don't believe we have got very good treatments for cancer or Alzheimer's or Lou Gehrig's disease, and right on down the list.

Under those circumstances, I think that if there is a non-toxic treatment where it has been beneficial to others, I believe that we are worrying about "scientific-based medicine" where we say that the scientists, but we are not really talking about the scientists, we are talking about the pharmaceutical industry, the NIH, the FDA, the AMA, the whole group, including my friend here or new friend, Mr. Kurtz, who are all trying to say that you can't do anything different until we spend years and millions of dollars and go through a whole lot of tests to find out that it satisfies the scientists. They don't worry about -- it is not the people that have to be satisfied, it's the scientists that have to be satisfied.

I would argue that we are a country here to help the people, and I would argue that you were put on this committee to be of help to the people, and I would hope that you would recommend policies that made it possible at least for those treatments to be tried.

That's all we need to do. We need to open up the system, so that it can be tried. If we had a perfect system of health care here, where everybody was doing

well, that would be fine, but I think you know we spend twice as much as any other country in regard to our health care. In many areas, we are right at the bottom of the list, if you really look at measurements of life expectancy, all these sorts of things.

Under those circumstances, surely it makes sense to remove the monopolistic system we have today and try to make it possible for these things to be treated, and that is my whole plea to you folks.

You know, you can do as you want to, and you can say we ought to have this barrier and this barrier and this barrier because the scientists want us to satisfy them. I think you are here to satisfy the people.

DR. CHOW: Thank you. Just to clarify, I know you are not against scientific research, what it is, is that you just want faster action because you are seeing people dying and that you want what has been used, to be used while we do science.

MR. BEDELL: That's right. Why should we only let the people that have the money go to Europe to get these treatments, and why shouldn't we at least, we are

trying, as I said, we are sending doctors in to check their records to find out whether the things work or not. They have got to submit those records to oncologists here to have them review it.

We are trying to find out, but you can be damn sure I am not going to do some double-blind studies that take seven years to find out. If you were my age, you wouldn't want to do that either, Effie.

[Laughter.]

DR. CHOW: Well, at my age I would like to see things expedited, but, of course, there is caution and there is quality, and I know you are interested in that.

We would like to get what studies you have already, Berkley, you know, that you find would be helpful.

MR. BEDELL: They are on the Internet, but we will be glad to.

DR. KURTZ: May I respond to that?

DR. CHOW: May I make a statement, first of all.

DR. KURTZ: Oh, please.

DR. CHOW: Mr. Kurtz or Dr. Kurtz?

DR. KURTZ: Either way.

DR. CHOW: Dr. Kurtz --

DR. KURTZ: I am not an M.D., I am a professor.

DR. CHOW: Dr. Kurtz, yes. I really appreciate your point of view because when I get skeptics, I like open skeptics, and that is what I feel you are is an open skeptic, and I like your comment saying that you should have not strong negative skeptics and not strong proponents judging, and I think that is a very balanced view, so I appreciate that.

Now, I put in one thought, though. In CAM, and I think maybe a lot of people don't understand that of CAM, that it is not just another therapy, but we are talking about that we treat individuals very individually and that all the components that combine together doesn't add up to -- one doesn't make two, it makes 10.

When you talk about double-blind studies, that is what we are struggling with is a research that would be suitable for this, and so how would you -- and maybe you can't answer it here -- but do you think there needs to be new research or revised research protocols that would be acceptable to you as a research methodology?

DR. KURTZ: Well, first, I think the patient comes first. Obviously, we are not concerned with pleasing scientists per se, but helping patients, and what is the best way of doing that?

We argue that the most effective way -- I mean, for example, take laetrile, now, would you permit that in this country verbatim, anyone can do it at any time, or are there difficulties, shouldn't that be pointed out, and there have been nostrums that have been used, that have been injurious. I think the FDA being taken off herbal and supplementary food in 1994, that was very unfortunate that that act was repealed. I hope this commission will argue that there ought to be some monitoring of herbal and food supplements.

But in any case, what is a protocol used, you need tight protocol. You can't delude yourself that you have the results. You want to see if they are effective. Now, maybe five to seven years is too long, so perhaps if there is some way of being fair to the science, I think that would be useful, by all means. So, I think it has to be rigorous protocol and replication.

DR. GORDON: Can we move along a little.

DR. CHOW: Thank you very much.

DR. GORDON: George, and then Joe, then Wayne, and then Veronica.

MR. DeVRIES: Actually, I think Effie touched on what I was going to ask, but Berkley, you and I have had discussions about the foundation and your organization.

Maybe you can describe some of the steps you are taking and some of the outside, sort of third-party organizations you are working with to help substantiate the validity of the results that you are finding from the various treatments in centers in Europe.

MR. BEDELL: We have visited 50-some clinics in 14 different countries, and there is always a medical doctor, an M.D. on the team that goes in, and the main thing we are looking for is to go through their patient records to see what we can find.

We are using something that was used at the NIH called Best Case Series. What we are really looking for are a number of phenomenal cases that can be documented, and what we are doing now, in fact, I just approved it today, that we are now going to -- we have had those from

two clinics now translated into English, and we are now in the process of having those submitted to oncologists here in the United States.

We want to find out whether or not these things work. We are not trying to sell laetrile or anything like that, we are trying to find out. Where we have the difference is that in my opinion, that if you have something that is clearly non-toxic, and where there is evidence that it is beneficial, that it should be more up to the patients than it should be a bureaucrat at the FDA to decide whether that patient can avail himself of that treatment.

We just plain disagree in that I believe we have got such tremendous controls. When I was in Congress, I was the chairman of a subcommittee, the Agriculture Committee, and we had the same problem there, that it took more money and more time to prove that crabgrass was effective than it did -- to prove that a treatment for crabgrass was effective than it did to satisfy that it was safe.

I said, "My God, you shouldn't worry about that." I said, "If it doesn't work, people are going to

quit buying it anyway."

Now, it is a little bit different in medicine because you might hurt people, but my argument on medicine is that since it doesn't work very well for the crabgrass, we maybe ought to be a little more open to letting them try something if it doesn't hurt anybody or anything. That is where we have got our big difference.

I don't know how well I answered your question, George. I get too emotional about all this, but, you know, people are dying, they are going to continue to die, and I tell you I wouldn't be very happy for me to find out that a friend had Alzheimer's -- which I just did -- or to find out somebody has got pancreatic cancer, or this sort of thing, and I think under these circumstances, it is time for us to quit being so darned careful, careful, careful, careful, let's do something about it, and I believe we had better do something about it pretty quickly, and I believe you folks have a tremendous opportunity here to recommend that the system somehow be opened up with adequate safeguards, that these things are not frozen out of our system.

DR. GORDON: Thank you, Berkley.

Joe, Wayne, Veronica.

DR. FINS: Congressman, I thank you for your enthusiasm and your comments. I just want to ask you, and maybe Dr. Kurtz can also comment on this, but it seems like there is really not a fundamental disagreement, it is just a matter of getting it done a little quicker, and I wanted to ask you, Congressman, about the issue of what happens when you have things that are maybe toxic, and maybe have an element of risk, but also have benefit, what kind of mechanisms can the government engage in - if you find something in Germany in the clinic that has some associated toxicity, it would seem to me that based on what you have said and your prudential method, that you would want that to be validated and have adequate safeguards, but from what your testimony said, there was not adequate access at the NIH and other federal agencies to conduct that in a responsible way. Is that what you were --

MR. BEDELL: Well, I think that you have got a completely different situation if you have a toxic medication, assuming it is significantly toxic, you know, I guess aspirin is toxic, but if you had any significant

toxicity, I think you have a completely different situation, I think you have to be much more careful about what you do. Fortunately, those that we have seen have had almost little or not toxicity to the treatments we have seen.

DR. FINS: So, for more toxic therapies, you would endorse going through the convention Phase I, II, and III trials and the FDA process?

MR. BEDELL: Well, I wouldn't endorse anything the FDA does probably, but the Access to Medical Treatment Act that I talked to you about, that was one of the requirements, that there be no evidence of toxicity, which I support.

I would not recommend that you people recommend that toxic treatments can be used without further tests. I believe it is a completely different situation when you have something that is --

DR. FINS: Professor Kurtz, if I could just follow up, using sort of the ethical doctrine of proportionality, balancing risks versus benefits, how does that limited recommendation of the congressman sound to you, where is no toxicity and there may be benefit?

DR. KURTZ: How do you know there is no toxicity? That is the real question, unless you submit it to some kind of test. Take ephedrine -- I am not a pharmacologist -- which apparently is very dangerous, can cause strokes and heart attacks, how do you decide that it is toxic or not? Who is to decide that? You listen to what the Germans say, is that what you do, you have a German Commission, or do you allow the FDA -- I think that act was a great mistake. I don't think the free market is sufficient -- and I think the gentleman here suggested it was -- for determining which herbs or dietary supplements should be available.

MR. BEDELL: Could I reply to that?

DR. FINS: I would like you to if the chairman would allow it. I would like the rebuttal, if it is possible.

DR. GORDON: Sure.

DR. FINS: Thank you.

MR. BEDELL: I think you determine toxicity if you have got enough patients that have been treated, and there has been no toxicity. I don't know how else you would do it any differently than that. It seems to me

that is the best way to prove it.

DR. FINS: Let me ask you, just to get concrete for just a moment here. Would you both be in favor of some recommendation from the Commission to set up a mechanism within some federal agency to do the peer review in an expeditious manner for things that had some evidence of benefit and what we would classify as minimal or non-existent toxicity just to expedite the process? Would both of you gentlemen agree to that?

MR. BEDELL: No, I would not.

DR. KURTZ: I would.

MR. BEDELL: I don't trust the Federal Government. I think that FDA is too tied to the pharmaceutical industry.

DR. KURTZ: Well, do you trust the pharmaceutical industry?

MR. BEDELL: No.

DR. KURTZ: Okay. Then, who is going to decide? They manufacture the drugs.

MR. BEDELL: Wait a minute. I have been a businessman. Business is motivated by profits and money. Does anybody think that is different for God's sakes?

Does anybody here think the pharmaceutical industry is mostly concerned about helping people rather than making money, if there is some way they could help people and lose money, that that is what they would do?

Do you think that they don't want to continue to sell their products no matter what? That's just the reality. That's not something radical, you know. I am a businessman -- I was a businessman most of my life. We tried to sell fishing tackles.

DR. FINS: So, we are not going to solve it this afternoon, but I thank you both for your exchange. Thank you so much.

[Applause.]

DR. GORDON: Wayne.

DR. JONAS: Well, now, I am very confused.

MR. BEDELL: It is not the first time I have confused you, is it?

[Laughter.]

DR. JONAS: I appreciate both your passion. It is tremendous actually in finally, I think, getting at the heart of a number of issues, literally at the heart.

Berkley, what I am confused about is are you a

Republican or a Democrat?

[Laughter.]

MR. BEDELL: You know what I am, Wayne.

DR. JONAS: Well, you seem to be shifting a little bit, so I am thinking if we don't end up with a president, maybe as a neutral party, you could step in and assist here.

In many ways you have answered a number of the questions. I really do think good, rigorous science has to be done. That is why I am involved in research. In many ways, conventional medicine, for all the tips of the iceberg of success it has, which are very good, there is a huge carcass of failures, because they have not used good scientific medicine and research, and actually they have only recently figured out or begun to figure out how to do it, and they still don't know all the ways to do it, and that is why we are looking at a variety of methods.

Controlled trials, randomized, controlled trials, never mind properly double-blinded ones, have only been around about 50 years, so we are still trying to figure out what they do and what they don't do.

I think the important thing is that we apply proper rigorous methods to get the kind of information that we need. We don't do laboratory research on new psychotherapies in mice, for example, you know, nor can we double-blind invasive surgical procedures, and so you have to do the most rigorous methods you can for the particular goals.

So, I think clearly differentiating those goals and applying good research methods are important, and it seems to me that often what happens is that there are different audiences that prefer different types of information even if they are all rigorously done.

What I am confused at, not from that, but from the issue of what should the role of the government be in this area, because on one hand, if we need a neutral party, if we truly can't trust those with vested interests and biases, then, I see no other place except the government that can at least begin to do that kind of balance, but on the other hand, I agree with Berkley that I am not sure if they can, even that.

So, that is what I am in a dilemma about, do you feel like the government should, in fact, have a role

at this, and if so, how should those priorities be set, should we go after the controversial things, should we go after the biggest killers in the society, should we go after the things that are the most popular, or should we just leave the government out of it and let the free market determine it and pull off the government regulations?

I guess we could make recommendations from this panel another way, couldn't we.

DR. GORDON: Response, Berk?

DR. JONAS: Perhaps Dr. Miles, maybe you would like to address this.

MR. BEDELL: No, I think the government has to be involved. I have been part of the government, I think they have to be involved. I think the question is how should they be involved, and my argument be that the government is there to represent the people.

I think the people need access to non-toxic treatments that may be better than what they are now getting, and I think the government should be there to try to help the people rather than to prevent them from getting what might be best for them, particularly because

of the fact that in our capitalistic system, the system operates in such a manner that the motivation for corporations is to make money, and the motivation for corporations is to get the government to do what they want them to do in order that they can make more money.

I have been there. That is what it is. I think you folks have, I would hope, should have a different perspective of what you are here for. I don't think you are here to make money, I think you are here to help the people, and that is why I feel the way I do.

DR. JONAS: So, you do think the government should be involved in trying to forward our understanding and information in these areas.

MR. BEDELL: That's right, but mostly I think the government ought to remove the roadblocks that they are now placing in the way of having an opportunity to find out whether there is a better way to treat disease than what we are now doing.

DR. GORDON: Thank you very much for a very clear answer on that.

MR. MILES: One of the factors in that is that since most of these medical practices are regulated at

the state level, not at the federal level, there are a lot of regulations at the state level that prohibit or limit the ways that practitioners can work together, and they are thought of in the terms that the only reason that practitioners would work together is because they were going to split fees or they were going to do something like that to increase their revenue potential, but a lot of practitioners are trying to work together now in collaborative ways, and they are running into these kinds of legislative barriers.

So, the recommendations around that kind of thing can be --

DR. KURTZ: I wonder if I could add that I think the general welfare of the people is one of the purposes of the Constitution of this country, and we cannot abandon that. Obviously, this is a free market economy, but regulation is important and necessary. It has to be prudential, so that we disagree on how much regulation, but I would also -- I would not abandon the medical professions.

I have seen a strong indictment of medical professions. People in the health care industry are

concerned about the public good, and have devoted their lives to it and do the best they can, and we simply should not say they are opposed to any further changes.

DR. GORDON: Veronica.

DR. GUTIERREZ: To change the pace here a little bit, my question is for Richard Miles.

I noticed twice in your memo that you made reference to the difference between routine health care and catastrophic insurance, and what I am asking is that we are having a meeting on this very subject in May 2001, and you must have given quite a bit of thought to concepts of how to separate the two, and I would like to have that information.

MR. MILES: Okay. I definitely can put some thought to that, because I think if we don't separate the two, we will perpetuate the public concept of benefits, which means that I am going to get all these services and somebody else is going to pay for them.

That is a major responsibility shift. Most of the self-care lore in this culture has been lost in the last 40 years. We used to have all kinds of ways of taking care of things with Aunt Maisy's remedies or

whatever, that worked to a certain extent.

A lot of that has been lost because the public attitude is that I can go to a high-tech expensive professional and somebody else will pay for it. That is a huge attitude shift.

Another factor that I would add to the discussion is most of the research that we are talking about is research to validate technologies. That is not necessarily research to improve someone's health.

If we could shift our research paradigm and say, okay, what can we do to improve people's health, because most of the technology validation research that we do is product oriented, which feeds into the market economy that we are talking about.

So, if you want to do something that is really valuable for people and helps them improve their health, and it doesn't develop a product, or doesn't develop something you can market, there is a tremendous tendency not to pay much attention to it.

One of the things that I mention in my document there, that I didn't get a chance to talk about, is the whole concept of a health advocate coordinator kind of

person that knew about CAM practices and knew about conventional medicine.

I think a person like that out in the world would change the system dramatically, simply people would have somebody to go to talk to who could explain some of these things and indicate the options, because I think that public options and people having the decisions to make, having the option to make the decisions about the kind of care they want, would revolutionize the system. It doesn't work now because the question is not will this help me, the question is, is it covered.

DR. GORDON: Tieraona, did you want to ask a question? I couldn't tell. I know Bill does, and then we really need to end because we are running overtime again.

DR. LOW DOG: I guess I just want to clarify that with DuShea, in 1994, it actually did increase access or guaranteed access for dietary supplements and botanicals to assure the American population that they would have access to many, many substances.

Now, there were some problems obviously with the FDA, because they have to prove harm, so it is sort

of things are already out in public, then, we have to come back, which was some of things about ephedra.

But I guess the notion of non-toxic is always something very interesting to me as somebody who deals with botanicals and their pharmacology, is the notion of something being non-toxic, I think it was [Paracelsus] who said, "The dose determines the poison."

Toxicology is not real simple, and, you know, women consumed alcohol during pregnancy for hundreds and hundreds of years, and it took until 1972 to be able to understand the fetal alcohol syndrome was caused by consumption of alcohol during pregnancy.

That was a toxicity, a teratogenicity that was never noted for more than a thousand years, so I think we have to be diligent with new products and new substances that we bring in. I think people need to have the access.

I think that is what the purpose of DuShea was, but I think that we need to be careful when we talk about toxicity, because was it in somebody who is pregnant, is that in a 3-year-old, is that somebody with liver failure.

I think when we are talking about something going out to the American public where you just go buy it off a shelf, it is not going to be under the auspices of a health care professional in Germany that is administering it, I think that we do have some obligation to be diligent with our admissibility of those products. Would you agree?

MR. MILES: Me?

DR. LOW DOG: Yes.

MR. MILES: Yes.

DR. LOW DOG: Good.

DR. GORDON: Bill.

DR. FAIR: I would again like to congratulate Dr. Kurtz. I think that was a very open presentation and I enjoyed it.

My problem -- and I don't know exactly how to phrase this question -- but my experience of working for 16 years at a major cancer center was that we can always do something. When Berk was impassioned there about people are dying, we have to do something, I saw that all the time from radiation therapists, from chemotherapists, you can always take another bottle off the shelf.

Fortunately, surgery is getting a little bit more restrictive because it was the oldest specialty, and we have gone through all that nonsense about removing half the body, and so forth, but the other cancer therapies are still to that point, and that is what led us to things like autologous bone marrow transplantation in women with breast cancer.

Insurance companies were sued, PPOs were sued, you have to pay for this. Physicians testified this was the only chance, one that we now have four studies, and we showed that it doesn't have any effect at all.

So, my question is that this same kind of passion that Berk evidenced there, given the fact that it is not limited to complementary medicine, and that it is not just avarice that is driving this, it is not the pharmaceutical firms or the physician that is saying if I give more chemotherapy, I am going to make more money, it is truly an effort to try to do good.

But what kind of legislation would you recommend that would cover those kind of unnecessary use in CAM therapies, and yet we could extend it to conventional therapies and protect the public in that

way, because these are toxic therapies, they are not benign therapies.

DR. KURTZ: Yes. I think public education. I agree that preventative medicine is central, and there has to be full public education from the earliest grade schools on, so I would put health education in grammar school, high school, throughout the colleges.

It is the informed citizenry in one sense. It has to know whether or not he or she wants this treatment, so it depends on informed consent at the same time. This is changing. The state of the art is changing. I think people do not recognize the fact that medicine itself is fallible. There are great achievements and successes, but we need always to be willing to revise the therapies at any one moment.

Incidently, the hospice movement that was discussed earlier, I don't know, is that alternative medicine? I think we all support the hospice movement.

DR. GORDON: If you two would be very brief, we are 10 minutes behind, so we will lapse a few more minutes, if that is okay with everybody. Yes? Okay. Then, George.

DR. BERNIER: I have a question for Dr. Kurtz.

In your letter to us, you said that -- you sort of held things back, I guess -- the question was should CAM be integrated with conventional medicine, and why or why not, you said, "I do not think it should be integrated. I deplore the effort to do so."

DR. KURTZ: Yes.

DR. BERNIER: I guess my question is, if, in a validation process, we found that a third of modalities in fact survived a good scientific test, and recognizing that there are a variety of skills that are involved in the practitioners, would you then feel that CAM medications are not to be part of the mainstream?

DR. KURTZ: Well, I said that merely using CAM as a generic term, alternative medicine is a generic term, does a great disservice because there are so many things under that rubric.

I mean you have therapeutic touch, you have psychic healing, so many things. Now, some of these alternative therapies may very well work. Those that work should be integrated, but those that do not -- and I think you have a lot of enemies out there of alternative

medicine because they are afraid that if put this in, what seems to perhaps have some evidence, that you have to put everything else in.

That is why I am against the term CAM to include everything on this list, and I think it is a great disservice to do that.

DR. BERNIER: I would urge you to look at it as if a great many may well get to be validated.

DR. KURTZ: Well, if they are validated, yes, integrate it. That is part of scientific medicine.

DR. GORDON: Thank you. Tom.

MR. CHAPPELL: Mr. Miles, in this paradigm that you are envisioning in your report, would you make room for patents and exclusive marketing on discoveries?

MR. MILES: Well, that is a huge question.

MR. CHAPPELL: As you know, a natural substance cannot be patented.

MR. MILES: Right.

MR. CHAPPELL: But I can add camomile to echinacea and have a discovery that is patentable.

MR. MILES: The whole question of patenting and the whole idea that is coming up in bioengineering and

that kind of stuff, just gets to the edge of, from my point of view, a very dangerous place.

MR. CHAPPELL: Could you help the Commission on this?

MR. MILES: Because I think we ought to be getting closer to nature rather than further away from it, and the idea of taking things and manipulating them a little bit, and then calling that a product that I can patent -- well, perhaps the most dramatic example I am aware of right now is a farm in Ontario where Monsanto has put this genetically engineered corn in next to this guy's farm, and the pollen is blowing over into his farm, and Monsanto has sued him for stealing their patent.

He has sued them back for polluting his farm. Well, that is the level that this thing is going to get to. Again, as I said earlier, this thing of managing living systems, we have this kind of hubris that we are going to be able to manage life, and I think we have carried that about as far as we can carry it, and we are up against some really major barriers around that.

If you look at most of the major social environmental problems that we have in this culture, it

is the result of that hubris. In other words, the air quality is going down, the water quality is going down, the farms are becoming contaminated, because we think we can take science and technology and fix nature.

Well, we are not being very successful with that, and my point, the same thing in the field of medicine, is -- well, I mention in my report that I see kind of a spectrum. At one end of the spectrum is immediate, traumatic, crisis-type care. The other end of the spectrum is chronic degenerative issues.

As you move across that spectrum, you move away from the effectiveness of conventional medicine and toward its ineffectiveness, because chronic degenerative disorders are systemic problems, they are not diseases. They are not something that can be fixed.

So, when you get over to that end of the spectrum, rehabilitating the system or rejuvenating the system, or whatever you want to call it, can be a very effective way to deal with some of those chronic disorders, but you don't fix the disorder. You revitalize the person, so to speak.

DR. GORDON: Thank you. Thank you all three.

I think these are wonderful examples, each one of which illuminates a certain area that we need to grapple with as a commission. So I really appreciate your coming and sharing and talking with us.

DR. KURTZ: Thank you for having me.

DR. GORDON: We will take a five-minute break, and then we will have the final panel come out.

[Recess.]

DR. GORDON: This is the second part of the panel. With the first part of the panel, I hope you were able to see that what we are trying to reach for and look at are broader views, not necessarily views that agree with another, or even views that complement one another, necessarily, but differing views of how CAM can be integrated into service delivery systems, really views that have to do with world view and ideology even more than they have to do with practical considerations.

So that is why we have asked these two groups of panelists to come and to kind of expand our vision and help us take a broader look, and raise some of the issues that got all the discussion going.

So in that spirit, I would like to ask Donald

Kendall to be the first speaker.

DR. KENDALL: Thank you. I would just like to clarify that I am a member of the National Guild of Acupuncture and Oriental Medicine, which was set up under the auspices of the Office and Professional and International Union of the AFL-CIO. This is a professional guild for licensed practitioners of Oriental medicine and acupuncture.

We are a new organization and what we are trying to do is to get everything organized on a national level, not to compete with our professional organizations, because you have to be a member of one of those organizations to be on the Guild. So the Guild thanks you for inviting us. I would like to share some of our thoughts on integrating complementary and alternative medicine into conventional care.

Now, of course, we are promoting health and well being through the utilization of acupuncture Oriental medicine, but one of our goals is to recognize the real-world -- I am going to use the words -- "coherent theory" of physiology on the physiological basis of acupuncture and Oriental medicine that has been

confused over the years because of one interpretation of what the ancient Chinese said, which was fundamentally flawed, and more recent, and some older, interpretations that are more in line with modern understanding of physiology.

Now, we submitted answers to five questions, and after a little introductory march here, I am going to answer those, but not in the same order. I want to answer Question 4 first, because it is the most important item of those five questions.

Oriental medicine is a physiologically based primary health care approach that historically, maybe 3,000 years or more, has always been part of world medicine, a major base of world medicine. There is a very rich diversity in this field, I mean, a wide range of modalities.

This is why there is sometimes some confusion on who does what and different techniques or different approaches. It involves herbal medicine, nutrition, heating therapy. It involves manipulation, articulation of joints, specialized massage and pressure techniques. It involves other physical things like cupping and

scraping, lifestyle counseling, exercise therapy, rehabilitation, movement and breathing exercises, movements like tai chi and gao lin exercises, and breathing exercises like qigong, preventative care, and then a very sophisticated needling therapy that is called acupuncture in the West. This is totally a Western name.

Acupuncture is obviously used to treat ailments in our system by stimulating certain critical locations on the body in order to control and regulate many physiological things, including the circulation of blood and vital substances, regulating autonomic systems, and endogenal mechanisms to restore physiological balance. This includes restoring somatic, visceral, immune function and homeostasis, as well promoting pain relief and tissue healing.

So one of our primary goals is to try to put our profession on a solid foundation that uses the same recognized world body of physiology. There is only one human physiology we know of. Now, the difference in Chinese medicine, or in Oriental medicine, we have a different view of it. We are looking at the organization of the body in terms of visceral-somatic relationships,

in terms of somatic-somatic relationships, in terms of visceral-somatic relationships, to explain how this works, and also how the treat diseases, to restore function of the body.

Fortunately, acupuncture research and neurophysiologic research over the past two decades have provided us sufficient insight, enough information now that we have been able to explain how the logical insertion of needles can bring about a medically significant reaction in the body, a restorative process in the body.

[Alarm.]

DR. GORDON: It's time, yes.

DR. KENDALL: Okay.

DR. GORDON: We will come back. We want to find out how you are integrating this into your work with the unions.

DR. KENDALL: Sure. No problem. Thank you.

DR. GORDON: Thank you.

Candace Campbell.

MS. CAMPBELL: The American Preventive Medical Association was founded specifically to lobby at the

federal level for health care freedom. We work to increase the flow of information about CAM therapies to consumers and practitioners, as well as increase access to those therapies.

We do not promote one type of practitioner over another or one therapy over another. Our goal instead is to increase patients' awareness and access to the full range of health care options. We led the effort, for instance, to pass the legislation that created the National Center for Complementary and Alternative Medicine at NIH. We did that for two reasons, first, because it was ineffective as an office, and second, because we believe there is a crying need for more and better research into CAM.

Part of that legislation created this White House Commission, as you know. We were also painfully aware of the fact that there was not coordinated, concerted effort to achieve an integrated health care system. In fact, we discovered that not only was the federal government not doing everything it could to ensure that consumers have access to a full range of treatment options, it was also getting in the way of

access and education regarding CAM.

People often call our office looking for help. They want help finding a practitioner who uses natural therapies, who knows about nutrition, who offers alternatives. Typically, these people have already been through the conventional system and they feel either abused or disappointed. Often, they are angry because their regular doctor didn't tell them they had other options.

Sometimes they share stories that break my heart. A mother who is facing the loss of custody of her children because she feeds them a vegan diet and doesn't want to vaccinate them; a father whose daughter was killed by radiation therapy for a brain tumor, even though the hospital's Tumor Board was well aware of a safe, effective, but experimental therapy undergoing clinical trials, and knew that radiation had never worked in these types of cases; or an elderly man faced with driving hundreds of miles for a life-saving, off-label therapy that his own physician is now afraid to offer because his colleagues in that state have lost their licenses for doing so.

Physicians call us frequently, too. They call us when their medicine board starts harassing them for using alternative therapies or unconventional diagnostic tests. They are harassed for getting kids off Ridalin, or for daring to treat cancer patients with something other than chemo and radiation.

Medicine doctors in this country who are using CAM are running scared. It is pathetic. Instead of being praised for getting people well, they are being harassed, censured, and shut down. I am not talking about cases of malpractice or quackery. I am talking about good doctors doing everything they can to help patients, and their patients are happy and healthy, and enjoying an improved quality of life.

It is both embarrassing and frustrating to me that in a nation such as ours, built on the bedrock principle of individual freedom, built by founding fathers who risked their lives to get the government off their backs, that we are now beleaguered by a medicine dictatorship that is more interested in maintaining its own power base than in seeking out and incorporating the best the world has to offer patients.

In my naivete, I used to believe that doctors or researchers discovering and innovative therapy would be met by colleagues, or the FDA, or NIH, saying, Hey, you could be on to something here. Let's pursue it.

No. Instead, they hear, That is unapproved. That is not what I learned in medical school. That is not the way we do it here. Or, worse yet, if you keep doing that, we are going to through you in jail and take away your license.

A significant part of the problem we are facing today is due to the fact that we have created and are now propping up a tremendously wealthy, powerful, successful, and dare I say, monopolistic allopathic medical system that is doing everything it can to stifle the competition.

Let's not encourage by sicking the federal government on the competition. Let's not encourage that by making criminals out of the people and the companies who are doing their best to offer patients something better. Let's take the high road and force the system to put patients first by investigating and validating, and then incorporating a more thorough range of health care

options.

Let's make our anachronistic federal programs reflect advancements in science. If the existing system does not accommodate new products and therapies, let's change the system, not abandon the products.

My hope is that this commission will seize the great opportunity I believe you have. You can start by recommending passage of the Access to Medical Treatment Act that Berkley recommended. You can go further by recommending that the FDA and the Justice Department be prohibited from prosecuting practitioners or suppliers unless there is evidence that they or their products have been seriously harmful to patients.

Our health care system is confronting a huge challenge. You have a chance to shift the health care paradigm in ways that can ensure that Americans truly have access to the entire toolkit, not just the hammer, for health promotion and disease treatment, and I hope that you will not miss this window of opportunity.

DR. GORDON: Thank you very much, Candace.

Michele Forzley.

MS. FORZLEY: Good afternoon. Last but not

least, here I am, talking about the law and the business side of CAM this afternoon.

I chair the American Bar Association Commission on Complementary and Alternative Medicine. I really have just two points to share here this afternoon. The first one is that I want to bring to your attention that some international law and related materials restrict what policy recommendations can be made on access and delivery, or they can be aspirational, and at the very least, they can be extremely helpful reference material.

I have heard of a number of instances this afternoon in discussion that I know you can find answers to from other countries and systems of operation. An example is the International Convention on Economic, Social, and Cultural Rights, which is both aspirational and helpful, in that, an international standard of health is enunciated and access is defined.

The standard is that every human being is entitled to the highest attainable standard of health conducive to living a life in dignity. The United Nations Committee on Economic, Social, and Political Rights, which administers this treaty, is helpful by

defining the elements necessary to achieve the standard, one of which is access. The U.N. defines access to include non-discrimination, physical access, economic access, and information access.

Now, keep in mind that when the United States ratifies an international treaty, that treaty becomes domestic United States law. I have selected the area of intellectual property rights as an example of how international law can set an outside policy limit. I have done so because right now an ethical, legal, and public health debate rages with respect to access to drugs, most notably in the news on AIDS.

That same debate, part of which is based on intellectual property law, can arise with respect to botanicals, herbals, and indigenous medicinals. Of the many treaties that may have an impact, two that absolutely do are the Tripps Agreement and the U.N. Convention on Biodiversity. These define rules on plant variety and exclusions from patentability for diagnostic, therapeutic, and surgical methods of treatment.

I would urge the Commission, therefore, to forthwith make an international analysis an integral part

of your work, not only on access and delivery, but for all elements of the mandate of the Commission.

The second point I want to make is that access and delivery of CAM are impeded by the lack of basic business skills, governmental support services, and information on capital formation and funding sources. I base this statement on the results of the Business Model Pilot Study, which I did in Boston earlier this year, and my 24 years of experience in developing and teaching business courses.

I will explain in light of two study conclusions. The study began with a question of whether any CAM organization was making money, and, if so, under what model did they function. First, there is confusion over what people are delivering and the difference between and healing and a business model; are they delivering wellness or sickness treatment services, products or services, education or health care.

No entity can succeed financially unless it decides what it is delivering and who wants it, or basically who wants access to it. In business parlance this is called the five Ps of marketing, or Marketing

101.

Another study conclusion is in the area of credentialing and licensing. Access and delivery will not be fully implemented, if my study findings are correct, until harmonized national standards are established. I would add even that internationally harmonized standards should be established.

I know of no other industry that would tolerate such a hodge-podge of essential professional regulations as licensing and credentialing. I think it is telling that no respondent would share credentialing guidelines, claiming them as proprietary. This is like saying, well, we want employees, but we won't tell you what the job description is.

For this reason, I have invited JACO [ph] to address the Conference on CAM Law and Regulation at this summer's annual meeting of the American Bar Association. The resources to fill the lack of basic training and support services are already in place in the public and private infrastructure. They simply need to be redirected toward the CAM community. This was done in the 80s with the entrepreneur. It was done in the 90s

for companies going global, and now it is health care's turn.

Thank you for the opportunity to share my views.

DR. GORDON: Thank you very much.

Do we have questions from commissioners? Who would like to begin?

While you are collecting your thoughts, I want to ask Dr. Kendall, I would like you to address the way this particular CAM benefit or acupuncture, and perhaps Chinese medicine, is being integrated into programs for unions.

DR. KENDALL: For unions?

DR. GORDON: Yes. How is that happening? Can you tell us a little bit about it?

DR. KENDALL: The parent union, the Office and Professional International Employees Union has several guilds, one of them for medicine doctors, one of them for podiatrists, and one for, I think, some other health care workers, and of course the new people are practitioners of acupuncture and Oriental medicine.

The way they can help has to do with the fact

that they have a lot of experience in trying to integrate things into the system. The AFL-CIO union, for example, has a 13-and-a-half-million member base. If you include their family members, they represent about 45 million Americans. They are well trained in lobbying the federal government and state agencies as well.

So one of the problems they have had in this field of trying to get some kind of parody within the medical care system, is lack of some hard core focus on the part of our practitioners. A lot of different schools of acupuncture, Oriental medicine, from minimal training from 1,000 hours up to 4,000 hours. So we have had a wide range of standards, when we really should have some kind of uniform standard.

So the thought was, when the union approached us -- actually, not me; I am just a member, but approached Dr. Preevy [ph] and Dr. Wright who is the vice president -- it became obvious that this would be an opportunity to get some voice in this medical field because it has been difficult.

We have been doing this for 25 years, and are still really not into the system. Patients can't get

reimbursed for everything. Now some insurance companies are starting to cover it. The federal programs, basically, don't recognize it, don't cover it. All the research that is done --

DR. GORDON: I am wondering, though, if you have used the AFL-CIO, if the AFL-CIO has said, yes, we want this to be included in benefits for our members, or if you have negotiated with them about this.

DR. KENDALL: One of the things when they approached us was -- in fact, I think the main insurance carrier they have does include acupuncture. They have some other ideas on how to make this Oriental medicine available to their 45 million family members. Certainly this is one of the ideas.

DR. GORDON: Is there an active movement among union members to bring not only acupuncture, but other CAM benefits, health promotion, into insurance plans?

DR. KENDALL: Well, we would have to talk to the parent union, but I think the answer is there is definitely a growing trend, that people want to have the ability to go to alternative therapies, even though some of these may be offered by medical doctors, simply

because there is no single medicine system that can cure everything because people are just uniquely different.

DR. GORDON: I am wondering if there is somebody at the level of the parent union whom we also could be talking with to see what they are doing and the directions they are going in.

DR. KENDALL: Yes. We can do that. We can get you in contact with the -- in fact, I think the president of the union is right here in Washington.

DR. GORDON: I would hope so. That would be great.

DR. KENDALL: We know it is the lobbyist center.

DR. GORDON: That is exactly the kind of thing we would like to hear. We hear from your side what you are trying to achieve.

DR. KENDALL: We are trying to do something from the professional side, and then you are saying what about the delivery side and the interest of the consumers.

DR. GORDON: That would be great if you could help us with that.

DR. KENDALL: We will definitely give you some contacts on that.

DR. GORDON: Thank you.

DR. KENDALL: In fact, might even set up a meeting with you.

DR. GORDON: Joe.

DR. FINS: For Ms. Campbell, if I may. I was reading through your testimony, and you used the phrase about medical dictatorship.

DR. KENDALL: I didn't use that phrase, I think.

MS. CAMPBELL: I did.

DR. FINS: No, Ms. Campbell did.

DR. KENDALL: Oh, oh.

DR. FINS: You might have wished you used that phrase.

[Laughter.]

DR. FINS: But I want to ask you, just to get beyond the rhetoric and all, there is a lot in your testimony about self-regulation of CAM practitioners by CAM practitioners.

How can we create a neutral body so that there

is an honest broker who is neutral? What would you envision, sort of neutral regulation? Because I think, just to argue the other side, the skeptics out there, some of whom you have heard of from this afternoon, and other policymakers, say, look, we have to maintain the safety of the American public at the same time giving them access to CAM therapies.

So what kind of mechanism would you suggest us to think about that would balance these conflicting needs, access and regulation?

Obviously, you are not thrilled by the Federation of State Medical Boards. Is there anything that can be done with them? Are there alternatives?

MS. CAMPBELL: Well, I think there are two angles to answer this. First of all, there is a trickle-down effect from the federal government to the states. So whatever the FDA does, the state medical boards tend to abide by. So if you fix a problem at the federal level, you tend to fix it at the state level, even though the states have the constitutional right to regulate the practice of medicine. The FDA has inserted itself tremendously in that process.

I think if you do things like get the federal government, in this case specifically the FDA, out of the business of withholding information, vetting how much and when information can be shared, that would free things up tremendously at the state level, solve a lot of problems for practitioners.

You can look at ways that the federal government discriminates against different types of practitioners. For instance, there is a bill that I don't think has passed in this Congress yet that would allow for Medicare reimbursement for nutrition education for diabetics. It is probably a great idea. It will probably save billions of dollars, but the way the federal government has drafted that bill, the way that the sponsors have drafted that bill, is to restrict reimbursement only to registered dieticians.

I would argue that somebody with a PhD in nutrition, maybe a chiropractor with training in nutrition, should also be allowed to be reimbursed. So there are little ways through the federal insurance program where we could eliminate discrimination, which then would have a trickle-down effect at the state level,

with HMOs, with insurance companies.

DR. FINS: That is a good example to just kind of get more specific. Who would set the standard of whether or not -- a PhD gets accredited, gets reimbursed, but a masters degree wouldn't, or a bachelors degree wouldn't, or someone who has been practicing in a naturopathic way without any kind of degree for 25 years and is esteemed in their community.

What kind of body would set the standard that would allow us to say, that person gets reimbursed, that person is credentialed. What kind of mechanism would be neutral?

MS. CAMPBELL: Typically, that happens at the state level, and it should probably stay there. I think if it is legal in a state, if someone is authorized to offer health care services in a state, the federal government should honor that. If a state decides that unapproved therapies are accessible, then the FDA should honor that.

DR. FINS: So, would you be satisfied -- I mean, some people have suggested this at our other sessions -- that the Federation of State Medical Boards,

each state, have some representation of CAM practitioners to kind of balance? Or, do you think that would be inadequate to give access to the practitioners that you represent?

MS. CAMPBELL: Well, I think I share the concern of one of the acupuncturists who spoke earlier, who said that it is very uncomfortable for, say, an acupuncturist to be under the authority of a medical board, because whether it is true or not, there is a huge perception that they are not understood and they are second class citizens.

I understand that boards are normally a factor of payment. If you don't have enough acupuncture in a state to support a board, you have to be under the medical board. I don't think that is an insurmountable problem, but I would worry, I think, on the part of practitioners, that if they are stuck under the Federation of State Medical Boards, they are not going to get a fair hearing. So there would have to be a separate body.

I think emerging professions need to do more in terms of setting credentials for their own practitioners.

Again, it is not rocket science, it just hasn't been done yet. In the past, the federal government has done a tremendous amount to help this burgeoning allopathic medical community. Those resources have not been dedicated to these other types of practitioners. We wouldn't have the hospital system, the internships, that we do now without federal support.

So if the federal government treated them fairly equally and turned resources toward that, I think the system would develop just as the allopathic did.

DR. FINS: Just, historically, it has been a 70- or 80-year process.

MS. CAMPBELL: Right.

DR. FINS: With the evolution of the first medical boards, I think, in the 30s. So there is a lot of catching up to do here to get regulatory parity.

MS. CAMPBELL: It is not fair to expect the CAM community to do it all on their own, because the biomedical model was not developed with its own resources.

DR. FINS: Thank you very much.

MS. FORZLEY: I would like to talk about the

word "harmonization," which is something that is used in international law, and it is used within the European economic commission. It may provide a course of action. There could be a federal body, whether it is Congress or this commission, or some other entity, that establishes guidelines for what should be the requirements for licensing and credentialing at national level.

This is being done in Europe at this time. So that, a German acupuncturist can qualify under the French rules, under the Italian rules, and maybe the British rules. So the methodology, legally, is called "harmonization."

It is not making the laws the same from state to state, but it is harmonizing them. It also is very valuable when you get to the discussion on education and training on how to come up with a national system that doesn't remove states' control over who practices what within their borders but gives them higher level to work under. That is the way of an international treaty, by the way.

DR. GORDON: Thank you. Effie.

DR. CHOW: I just have a simple question of Dr.

Kendall:

DR. KENDALL: Yes.

DR. CHOW: In here, you elaborated on the organization is to promote health and well being.

DR. KENDALL: Yes.

DR. CHOW: And your definition of Oriental medicine focused on the treatment. Can you elaborate where is health promotion in there? Or, did I misread it?

DR. KENDALL: Oh, in the definition? Promotion wasn't in the definition. The only reason I provided a definition is, I know there may be some members on this board, not you of course, that haven't heard of the wide diversity of modalities that is included in Oriental medicine, with acupuncture just being one of those.

So that was just a strict definition of that.

DR. CHOW: But, do you feel that Oriental medicine, one of the primary function is health promotion?

DR. KENDALL: Oh, is, yes. Right.

DR. CHOW: I didn't see it in the definition. I just wanted to clarify.

DR. KENDALL: Well, all of these are used to promote health, all these modalities.

DR. CHOW: Thank you.

DR. GORDON: Wayne.

DR. JONAS: I had a couple questions. First, I want to thank Ms. Forzley for this nice summary. It looks like a very nice beginning, and I think it would be very useful to have a systematic comparison of what goes on in a variety of countries.

I assume this is an ongoing project and you are looking at other countries like Australia, and perhaps some of the Asian countries?

MS. FORZLEY: Yes. Actually, I didn't mention in the report I wrote for today the Interview Project, which has done some specific one-on-one interviewing with providers from other countries. I have talked to the aromatherapy industry in Australia, the physical therapists people in Germany, and a psychiatrist that practices CAM in South Korea.

I think a lot can be learned from that. Plus, the group of lawyers I put together to try to move the International Research Project forward have reported just

what happens in their own countries, just from their own experience. That was another source of information.

I think there is a lot to learn there. Also, because in many other countries, legal systems have had to learn to incorporate cultural traditions without infringing on them somehow, and so much CAM comes from cultural tradition. We really walk a very funny road when we try to regulate a tradition.

DR. JONAS: Right. I have a question, really, for any of the panel members, related to this. And that is, a lot of the attempts to regulate medicine, whether it be in states or in other countries, is based around the idea that unregulated medicine is harmful.

I am wondering if anyone has ever actually looked at this, using good research methodology, to see what the evidence is for harm in countries or in situations where there is very little regulation and perhaps extensive, should I say, free-for-all type of medical practice.

England comes to mind as a fairly unregulated situation compared to other more regulated situations, to actually see if harm actually occurs in those situations,

or, does the market and do the public do a fairly good job of regulating themselves.

Has anyone actually looked at that systematically?

MS. FORZLEY: Well, the most systematic review of this question I have taken so far is looking at the concept of consent to treatment, and I compared it internationally in other countries. Depending upon the type of legal system in which you find yourself, there will be a different analysis of consent to treatment. The Brits think very differently than the Australians on this. The French think even more differently.

The French think that we have a contractual relationship between a patient and a provider, as opposed to a consensual relationship. So you take everything out of tort. So we don't any longer have a question of harm in the negligence sense of the word. We have now a breach of contract, which is a very different approach.

So I believe that further analysis of that question would be very helpful, but it again, brings us back to how cultural traditions treat things, because law and health care, and some of the principles of it

literally come from our culture.

The other comment I can make is I think that we really ought not to do everything ourselves, that there should be some effort made to work in conjunction with our brothers in the EC, and in other regions of the world because I don't the United States grappling with CAM issues. Lots of work is being done on CAM in other countries from a regulatory perspective.

In some countries, different entities are regulated. Here, for example, if you take something like an herbal preparation, it is not subject to the FDA anymore, but you now have Federal Trade Commission regulations that impact it. So that is an approach we can take, and if I can ever get to the provider of it, I might have a claim against them.

What the French do, as an example, is they regulate the dealer, they regulate the store. So herbs can only be sold at herb stores. You can go to a pharmacy for patented drugs, and then you go to an herb store for an herbal product. The seller is regulated.

The Brits do things like, instead of regulating the acupuncturist, they allow the local level of

regulation to limit what can be done. The only way you can open up a shop to provide acupuncture is to go get a local license from the London authorities, which I have described in my paper, you have to demonstrate a national certifying board that regulates before you can then get a business permit.

So I think there are a lot of approaches we can take beyond what we now do. I don't think medical boards are the only body that can do it.

DR. JONAS: I think it would be very interesting, maybe, to take a limited number of conditions or patients and try to systematically examine, is there increase, decrease, alterations in harm specifically from of these regulatory approaches which are quite radically different.

Candace, along those lines, do you know what is going on in Minnesota? I don't.

MS. CAMPBELL: No, but Diane Miller does, and you can ask her.

DR. JONAS: Okay. We will hear about that tomorrow.

MS. FORZLEY: I don't know that they have had

enough of a track record yet with that.

DR. JONAS: No, I don't think so.

MS. FORZLEY: But I know a lot of states are watching.

DR. JONAS: I just wanted to get a clarification of what the law actually is, because I have heard very contradictory statements about it.

DR. KENDALL: With respect to your question on harm, in regards to acupuncture, it is a surgical procedure in the sense you are inserting a surgical device into the human body. There were cases early in Europe, early use of acupuncture where they had fatalities from inserting needles that got into the organs.

There was, a few years back, a fatal pneuma thorax in England. There have even been a few accidents in Japan, a couple in China. The incidence is very low, but there is always that probability if you don't understand the human physiology, as far as what is under the skin, and you are dealing with needles that are an inch long, two inches long, three inches long, four inches long, 14 inches long. There is possible risk.

Then there was one other incident that just happened last year, where in Belgium they did research where not using an herbal specialist included a toxic herb in a kidney test research, and the subject ended up with kidney damage.

DR. JONAS: It would be interesting, and that is a good example, to see, for example, in countries where they regulate the practitioner, compared to countries where they regulate the needle, compared to countries where they don't regulate it all, if it makes any difference in terms of harm.

DR. GORDON: Candace, thanks as always for your coming. I really appreciate hearing what you have to say, as well as your efforts on behalf of moving health care ahead. I had a specific question about what you were saying about intervention by the FDA or the Department of Justice.

Do you have a standard that you would want to share with us now, and maybe even elaborate on later, for the kind of freedom that you think should be given to practitioners, and when intervention is and is not necessary, so we can consider it.

MS. CAMPBELL: You mean intervention on the part of the FDA or the Justice Department?

DR. GORDON: The FDA or the Department of Justice, yes.

MS. CAMPBELL: Well, I think I would agree with Berkley and the broad picture that if we know that a substance is non-toxic, for instance it has a history of use, I think acupuncture is a perfect example. How many years did it take us to change the classification of acupuncture needles? I think they were in the same class as heart-lung devices. There is not a lot of common sense, and there is an awful lot of regulation.

I think it might be hard to change a huge bureaucratic system that functions on a very rigid model of testing. So what we might have to do is have a separate body, not the FDA. If you are talking about non-patentable substances that can't go through the drug approval process, there is just no economic incentive for anyone to do that.

At some point, there will have to be testing, there will have to be clinical trials. NIH can only do so much, but you can leapfrog way over that dilemma. If

something has been used for 30 years in Germany safely, why does that same company have to go through 10 years, $300 million to get FDA approval?

There ought to be something in between that can address access without all or nothing. Right now, we have all or nothing.

DR. GORDON: I guess what I am looking for is, not necessarily on the spur of the moment, but your guidance about what kinds of regulation. And again, raising the same question that Wayne and Michele Forzley were talking about, should it be regulation of the practice, or the practitioner?

Because the Access Act, in my mind, seems to focus on regulation or freedom for the practitioner and the patient, and does not focus so much on the modality or the practice that is being used.

MS. FORZLEY: The Access bill really leaves it to the practitioner to determine. The latest version of the bill has a lot more language about what level of proof there must be for a practitioner to safely offer an unapproved therapy, and I think that is a question worth answering. We can't just throw it wide open because

everyone will have a different level of what they feel safe using.

But I would be happy to give you some feedback on what we think would be a feasible solution to that.

DR. GORDON: I think that would be particularly useful, especially in the spring as we come to issues of licensure, focusing on education and licensure. Then again, coming around to reimbursement.

MS. FORZLEY: In terms of the Access bill, if I can add one thing quickly, there is already plenty of regulation of MDs doing alternative therapies. There is the threat of malpractice, there are the state medical boards. I am not really worried about what would happen to an MD who crosses the line. There is more than enough disincentive there for someone who would think of it. It would be unethical.

One of the things the Access bill does that is critical to this increasing flow of products is, get the FDA out of the business of stopping interstate shipment, because right now that is a huge barrier. Sure, they are not regulating the practice of medicine, but if you can't ship something across state lines, you have to live in

the right state. Interstate shipment may only be the label on the bottle that qualifies it as interstate. So that is a huge barrier right now, that is the FDA's.

DR. GORDON: Joe, did you have your hand up?

DR. FINS: I just wanted to talk about something Ms. Forzley said a few moments ago about the different countries having different cultures and the relationship of regulation to those national cultures.

Just again, to make a plea for us as a commission to probably ask some anthropologists to talk about the anthropology of CAM therapy in the United States and the regional differences across the country to make sense of what this phenomenon is.

Your legal analysis here has really demonstrated there is heterogeneity from different European countries, and I think we just need to be comprehensive to make some better sense of what motivates this and how we can be responsive to the people and do it safely.

It was reminder to remind us. So thank you for that comment.

DR. GORDON: Any other questions? We are going

to close in a couple minutes.

[No response.]

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

We will adjourn for today. We will begin again tomorrow morning at 8:00, and we look forward to seeing you then.

[Whereupon, at 6:10 p.m., the meeting was recessed to reconvene the following day, Tuesday, December 5, 2000, at 8:00 a.m.]

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CERTIFICATION

This is to certify that the attached proceedings

BEFORE: White House Commission on Complementary and Alternative Medicine

HELD: December 4-5, 2000

were held as herein appears and that this is the official transcript thereof for the file of the Department or Commission.

DEBORAH TALLMAN, Court Reporter