

1 These are just a few examples to give you a
2 sense of our values and how we approach the issue of
3 education and training of CAM practitioners.

4 The National Breast Cancer Coalition believes
5 that both the medical community and patients should
6 approach CAM with an open but critical mind, exactly as
7 they should approach conventional care. The same
8 questions apply: What are the risks? What are the
9 benefits? How strong is the evidence that answers these
10 questions?

11 The two categories of CAM versus conventional
12 medicine are really not helpful to patients. The
13 categories themselves encourage the misperceptions; that
14 conventional medicine is all based on evidence, it is
15 not; and that CAM therapies are natural and therefore
16 harmless, obviously untrue.

17 Many conventional providers are justifiably
18 angry and worried that patients are being tricked into
19 wasting precious resources on dangerous and ineffective
20 CAM treatments, but many have yet to learn about
21 effective CAM treatments. For example, an oncologist may
22 have no idea that acupuncture can alleviate nausea

1 associated with certain cancer treatments. This "Us-
2 Them" mentality about CAM has serious consequences
3 because many conventional health care providers know so
4 little about CAM therapies they fail to discuss it with
5 their patients. Patients respond by lying or withholding
6 information and then end up weighing the potential risks
7 and benefits of CAM therapies on their own.

8 The medical community needs to stop thinking in
9 two categories and, instead, focus on developing better
10 systems for creating and weighing evidence that can tell
11 us what we really need to know, what does and does not
12 work. Allow me to use the Quality Care Values to
13 describe in more detail our vision of CAM education.

14 Information. Patients need accurate and
15 complete information in order to make good decisions.
16 They need a clear and complete presentation of all
17 conventional medical options, along with what is and is
18 not known about how well they work and what harm they can
19 do. The patients need the exact same evidence-based
20 information for CAM, and they need it at the same time
21 and place that they receive information about
22 conventional treatment options.

1 Choice. Guided by accurate information,
2 patients should be able to chose among therapies that
3 offer some benefit. Patients should also be told about
4 all clinical trials that are relevant to them. CAM that
5 has some evidence of efficacy must be part of the range
6 of choices presented to patients. Relevant CAM clinical
7 trials need to be presented to all patients as a
8 reasonable health care option.

9 Respect. Providers need to treat the patient
10 as a whole person rather than a disease or a body part.
11 For example, discomfort and anxiety need to be taken
12 seriously. They are a real and powerful part of breast
13 cancer and many other health care experiences. They can
14 also often be alleviated. All care providers should have
15 a basic knowledge of CAM and provide an overview to
16 patients. They should also respectfully encourage
17 patients to be honest about their interest in or use of
18 CAM.

19 Accountability. Patients need competent
20 providers with credentials that mean something to
21 patients. The system should be easy to understand and
22 transparent so that everyone can easily learn what a

1 credential or license means, but credentials by
2 themselves do not create accountability.

3 It is a clear and accessible appeals process
4 that protects patients. Any licensing or credentialing
5 process must include a convenient and effective way for
6 patients to appeal or complain, and there must be
7 meaningful consequences. This is true for both CAM and
8 conventional practitioners.

9 Access. Breast cancer patients should have
10 access to interventions that have been shown to help.
11 All providers should either provide or refer patients to
12 CAM therapies that have been shown to have some efficacy.
13 Health insurers and plans should have an evidence-based
14 approach to coverage and educate patients about CAM.

15 Improvement. We want a health care system that
16 is continually learning from patient care. We need more
17 and better evidence about both conventional breast cancer
18 care and CAM. NBCC believes that CAM research has been
19 extremely underfunded. A large investment in this kind
20 of research can not only bring great health benefits to
21 patients, but in the long run could provide savings in
22 health care costs. Right now, breast cancer trials

1 consist mostly of drug companies exploring slightly
2 different ways of using their patented drugs or slightly
3 different combinations of existing drugs. We need a
4 different focus, and CAM research is fertile ground for
5 innovative questions about breast cancer.

6 We also need to expand our notion of health
7 services research. We need to be measuring what matters,
8 not just morbidity or mortality and not just a handful of
9 quality of life measures. CAM research often requires
10 innovative design which may help expand what we measure
11 and how.

12 The federal government needs to fund not only
13 CAM research, but also CAM education for all the players:
14 patients, health care providers, employees and third-
15 party players. There is so much misinformation and
16 mistrust around this issue a major educational effort by
17 the federal government could go a long way in dispelling
18 myths and getting effective treatments to patients. NBCC
19 strongly supports increased funding for more and better
20 research to find out what CAM therapies are effective.
21 We also strongly support a federal educational initiative
22 on CAM and evidence-based medicine.

1 CAM practitioners certainly need consistent and
2 educational standards and accountability within the
3 licensing and credentialing process, but this by itself
4 would do little to help women get the care they need. We
5 believe that patients will be better able to chose the
6 right provider, CAM or otherwise, when there are national
7 standards for health care, standards that are
8 comprehensive, evidence-based, updated regularly and
9 accessible to everyone.

10 These guidelines should not be broken into
11 conventional versus CAM, but rather include the entire
12 range of care options. Guidelines can't tell anyone what
13 their treatment should be, but they can provide an
14 invaluable overview of what we have learned from medical
15 research so far. Patients will and should continue to
16 make very different choices about health care, but one
17 national trustworthy source for evidence-based health
18 care information would provide a powerful tool for
19 patients and their loved ones who are trying to get
20 quality care. It would also highlight what research
21 questions remain.

22 From patient perspective, it is not either

1 conventional or CAM but what actually helps that matters.
2 Health care policy needs to reflect this view. CAM
3 should be completely incorporated into all aspects of
4 health care policy.

5 Thank you for this opportunity. We believe
6 that breast cancer advocates and patient advocates have
7 an important role to play in the development of CAM
8 policy, and we look forward to working with you in the
9 future.

10 DR. GORDON: Thank you very much and thank you
11 for the recommendations, as well.

12 Questions. Joe.

13 Panel Discussion

14 DR. PIZZORNO: This is directed to Mr. Sampson.
15 As Dr. Orzack stated I think so eloquently earlier this
16 morning, for a profession to become distinct it needs to
17 establish educational and practice standards, and those
18 educational and practice standards must evolve over time.

19 At what point does the profession come under
20 the purview of your organization and, once it does come
21 under your purview, what impact can you have on those
22 emerging professions?

1 MR. SAMPSON: Generally, the way they are
2 recognized is, first, almost all of them have to be
3 accredited. That means the Department of Education is
4 the first area that gets approached for accreditation,
5 the accrediting body which has to be separate from the
6 professional body. They have to then show that they have
7 a series of information, science, et cetera, in order to
8 get accredited.

9 So that then sets up the base. The next piece
10 is then specific legislation which allows that emerging
11 profession to be included in the coverage of the Acts, so
12 they then have to get specifically mentioned. That is
13 really the only way that they are done.

14 The second part of the question is the degree
15 of involvement. Most of the involvement we have would
16 not be so much in the emerging profession, it is to
17 assist them. It depends on how the law is structured,
18 what Congress says that we are willing to use monies for
19 to do this. Most typically, they are the kinds of things
20 that were developed or mentioned here. Once these are
21 accredited and licensed and standardized, then the issue
22 would be curriculum development, faculty development and

1 to some degree student support. Those would be the kinds
2 of issues.

3 DR. GORDON: Effie.

4 DR. CHOW: Thank you very much for your
5 presentations. I am glad to see a nurse on board here
6 because being that there are so many nurses that have
7 been underrepresented. So I am very happy to see that.

8 Many of you mentioned about evidence based. In
9 fact, for the last panel, very strongly so, and this
10 panel. Then, you also talked about culturally sensitive
11 and looking at cultures. Then, the next comment is that
12 it should be evidence based before practiced. What does
13 that mean in terms of looking at practices that has been
14 successful within the culture, but because there has been
15 no money and it is new to this Western civilization that
16 it isn't "evidence-based" from the way we research
17 biomedical?

18 Are you talking about absolute controlled
19 studies and squeezing it into a box, et cetera? Could
20 you make comments on that. And should there be practice
21 if it has been proven that it is used in the cultures
22 successfully?

1 DR. FISHMAN: Can I take a crack at that?

2 DR. GORDON: Sure.

3 DR. FISHMAN: One of the big problems I think
4 that we face is that, when we talk about CAM, we are
5 talking about such a span of activities that some are
6 potentially threatening. For example, acupuncture and
7 asthma, I have had some experience with that. You have
8 to take it into account. You have to be very good at
9 what you are doing.

10 On the other hand, there is music therapy and
11 there are other therapies where if you listen to a radio
12 while studying that is music therapy in a way.

13 So, therefore, we have not been circumspect in
14 breaking it down modality by modality. There is a big
15 difference, also, in what I as a practitioner in my
16 office can do and what I as a professor of medicine put
17 in the book to teach medical students. For example, I
18 can have you come in, make believe you are a patient, and
19 you say, "I have been taking this medication. It is
20 good." I say, fine, that is great. Evidence is there.

21 On the other hand, if you come in to me and you
22 say, "Should I take this?" I will say, well, you better

1 be careful now because you are taking phytoestrogens, you
2 are taking this, you are taking that. Or, I can go
3 further and say, uh-uh, you really can't do that.

4 So one of the big problems that we have faced
5 in dealing with your question is do we break down CAM
6 into modality-by-modality and treat it that way? And the
7 second is, what do you want the money for? Do you want
8 the money to investigate whether a cultural activity such
9 as acupuncture -- the way we do it is not in the context
10 of the framework that everybody does who really knows
11 acupuncture in China. For example, I visited China, it
12 is a whole scheme of things. Over here, it is like one
13 thing. Or, we will do tai chi, and it becomes a part of
14 physical therapy.

15 So the question is, how do we sort out CAM? A
16 very critical point. What do we want? What warrants
17 research? What warrants money?

18 On the other hand, why don't we just take the
19 evidence that, look, this thing works, it is harmless.
20 We will keep looking, but if we can prove it, yes, use
21 it.

22 MS. COLLINA: If I could add that this issue of

1 squeezing it in a box is interesting to me because we
2 have struggled with this.

3 Obviously, as a breast cancer organization,
4 there is a lot of unanswered questions. It seems to me
5 that we need answers and we want answers and we want some
6 way, a design of some sort of trials and some way of
7 systematically exploring what works and what doesn't.

8 To the extent that the box is a problem, we
9 need to change the shape. We need to look at that. We
10 need to rethink what we mean by a clinical trial, what we
11 mean by evidence. It doesn't mean that we give up the
12 basic core aspects of evidence-based medicine, but I
13 think there are more creative ways of looking at it.

14 I don't know if I am following up here or not,
15 but I would say that that is exactly where the funding
16 should be focused until we answer that question. Too
17 often in conventional medicine, things have come into the
18 system because we don't really know but people are
19 interested in having it, and then we learn later that it
20 doesn't work.

21 So I think that is a perfect example that that
22 is where the focus should be, and the focus should be in

1 looking for new and creative ways of measuring.

2 DR. BEDNASH: Just another piece of this, I
3 think there is a difference between developing a bond and
4 a partnership with the person in that therapeutic
5 relationship, so that you have a sensitivity to their own
6 cultural beliefs and views about what is helpful and what
7 gets them through the experience that they are having.

8 I can tell you that when my father had his
9 bypass surgery and ended up developing shingles
10 afterwards and said he would rather have another bypass
11 and have his chest split open again than to have to go
12 through the shingles experience, it was so terrible.
13 None of the traditional therapies and medications he was
14 given helped.

15 His brother-in-law, who is from Mexico, drove
16 in and picked him up, and took him to a provider in
17 Mexico who gave him an injection. I think, as far as I
18 can tell, it was a Vitamin B injection. My father came
19 home and was cured.

20 Now, I think we don't understand the placebo
21 effect, you are absolutely correct, but we also don't
22 understand the power of the cultural beliefs. We are

1 Latinos. What my father believed was going to be helpful
2 to him was helpful to him.

3 So there is this partnership. It may not be
4 that I, as a more traditionally oriented provider, would
5 suggest that he go and get this, but I need to understand
6 how it does relate to him or someone else in their
7 seeking some kind of relief or some kind of ability to
8 control this health care experience.

9 So it is a partnership. Above all, I think we
10 need to be concerned about not creating harm or
11 intervening when there is the potential for harm.
12 Sometimes, the only way we can do that is through some
13 base of knowledge that comes from the more traditional
14 evidence-based protocols to give us that comfort level.

15 MS. CHOW: Thank you very much. I do want to
16 know, how many are practicing alternative medicine?

17 [Laughter.]

18 DR. GORDON: Wayne, and then Charlotte.

19 DR. JONAS: I can't decide between
20 communication and evidence, so I am going to defer to
21 Charlotte for her question.

22 SISTER KERR: Assuming we can define food,

1 would you say that real food for real people is a
2 complementary alternative medicine? Specifically, I was
3 thinking to start with Sara.

4 MS. COLLINA: I think that is a perfect example
5 of what is wrong with the category. I mean, that
6 category means nothing to me. I couldn't even tell you
7 right now as a patient which things that I am doing you
8 would consider to be complementary or alternative.
9 Because there is very little profit in food research and
10 nutrition research, it has been underresearched. And so,
11 in that way, it is like many complementary interventions.
12 At the same time, there is clear biological -- I mean,
13 there is very little controversy in the medical community
14 that it impacts health. So I think that is the perfect
15 example of what is wrong with the category.

16 SISTER KERR: And when you answer, if anyone
17 else does, is there something we need to say about that
18 in policy?

19 MS. COLLINA: Well, I guess I will just jump in
20 here and say this is why I think that, to the extent that
21 we can give up the label -- and I realize that that
22 perhaps feels like a big task, but from where I sit that

1 doesn't feel like a big task. People don't look for
2 complementary and alternative medicines. They look for
3 things that will help them. That is the only question
4 people are asking.

5 So, like I said, I think the categories
6 themselves are very limiting, and not only does it create
7 stigmas and confusion about CAM, but it creates a lot of
8 dangerous myths about what conventional medicine is and
9 is not.

10 DR. BEDNASH: I would like to also come in
11 here, too, because I think I agree with you in what you
12 are saying, Sara.

13 I am very concerned about the power of language
14 and what language conveys and more concerned -- not to be
15 offensive to my colleagues in other fields but to be
16 concerned about the use of the term "medicine" as the
17 baseline here. Because medicine is medical practice and
18 medical practice does not represent the full range of
19 health care and health care professionals today.

20 I worry about medicine and a focus on that as a
21 baseline against which all others are measured, rather
22 than the notion, as all of us are aware, that health care

1 is provided by a variety of individuals, a variety of
2 professionals, who have a scientific base for their
3 practice, and some of what are considered complementary
4 providers have a scientific base and they are not
5 alternatives to medicine they are in fact team members
6 and partners in the process.

7 I would strongly encourage us to think about
8 complementary and alternative health care practices,
9 although sometimes it is hard to figure out what is
10 alternative and what is not depending on where you sit in
11 your life, in your culture, in your beliefs. So I think
12 language is very important and it is very harmful in its
13 process. Anything that can be done to change that would
14 be very useful.

15 SISTER KERR: I noticed when you presented you
16 said "complementary and alternative medicine and
17 therapies." It really hit me right between the eyes
18 there. Thank you.

19 DR. BEDNASH: I thought about dropping
20 "medicine," but you are the Commission on Complementary
21 and Alternative Medicine, and I think it is complementary
22 and alternative health care practices and policies for

1 those. It is not medicine only.

2 I am very concerned that there is a strong
3 emphasis in today's conversations about medicine and
4 medical practice and medical education and medical
5 certification and examination. There is a National
6 Council of State Boards of Nursing. I am sure there are
7 councils for the licensure of a whole range of
8 professionals that ought to be in this dialogue because
9 you want to influence them as much as they want to
10 influence you.

11 DR. GORDON: I would like to make one point.
12 We agree that there has been more of a focus on medicine.
13 In the solicitation of recommendations and
14 considerations, we consulted all the professions,
15 including a number of different nursing organizations.
16 Your point is well taken. We used medicine as one
17 example, just as a little bit later on we are going to
18 use acupuncture and Chinese medicine as an example of a
19 so-called CAM approach.

20 I had a question for Mr. Sampson. I really
21 appreciated your remarks and I am wondering what you
22 would have us do, what you would like us to do to support

1 you in helping to encourage training both in this more
2 holistic approach and in specific CAM modalities, and
3 also for CAM practitioners? You indicated an interest in
4 encouraging this to happen.

5 What can we do as a Commission? What kind of
6 recommendations would you like to see from us?

7 MR. SAMPSON: You have broken down -- I mean,
8 in terms of health professions, there are two parts. One
9 part is conventional, the conventional practitioners and
10 their need for information on complementary and
11 alternative therapy and how they can be used and which
12 ones are effective, just some information on what is
13 occurring in various cultures and populations. That is
14 essential because you can't treat an individual without
15 knowing basically the whole person, and you need to know
16 what can help and also what they are doing so that you
17 can work as a part of that.

18 So that has to do with faculty development for
19 all of the professions. It has to do with, again,
20 curriculum reform and the integration of research
21 findings when we do find information out into practice.
22 We do have some programs that do that. Their primary job

1 is to take the findings from such places as ARC or NIH or
2 FDA or others and try to put them into practice as to how
3 they would. Because, remember, any individual that comes
4 out of a health professions program today has what a 30-,
5 40-year career ahead of them. So you want to influence
6 the next three or four decades, that is where most of the
7 practitioners are.

8 So that is one set of issues, make sure that we
9 can provide information to current practitioners, to get
10 faculty development and faculty mentors going and that
11 kind of activity for the existing health professions.

12 The other side is for those practitioners, we
13 can refer to CAM practitioners, there is a different
14 problem. That one is, as we sort of describe the issue:
15 One, there has to be an acceptance by the public. I
16 mean, that is really where all these are going to start
17 occurring and where they are going to grow. Then, the
18 profession itself has to come together, has to get a core
19 set of knowledge, has to start standardizing its approach
20 to treatment, has to deal with the 50 state -- or 56
21 depending on how many you want to call -- the state
22 licensing procedures, the accrediting requirements, and

1 the universities and colleges and the whole educational
2 and academic infrastructure that is going to support
3 them, et cetera. So that all has to occur.

4 Then, there has to be an issue where there is
5 specific legislation that says these kinds of
6 practitioners -- and names them -- will be available for
7 these range of things, which for the profession itself
8 would include curriculum, faculty support, perhaps the
9 support for students and a whole host of issues that are
10 similar for the kinds of programs that support medicine,
11 nursing, dentistry, et cetera, et cetera.

12 DR. GORDON: I am wondering if also one of the
13 issues that we have heard about many times is many
14 practitioners, both conventional and CAM -- or CAT, I
15 suppose might be a better term, I kind of like that --
16 CAT practitioners, want continuing education. I am
17 wondering if the Bureau, as a possibility, might be
18 interested in supporting some of the efforts at
19 continuing education for this whole spectrum of
20 practitioners.

21 MR. SAMPSON: When I started out, I said
22 primarily taking information and putting it into

1 practitioners, you know, those community-based programs
2 working with the local professional groups at perhaps the
3 nursing associations, state medical societies, local
4 medical societies, the CE.

5 Yes, we do a number of those activities. What
6 is occurring today in practice for a lot of us is that we
7 still have individual practitioners, but more and more
8 people are coming together in teams and working in
9 groups. They are finding that that is really the best
10 way to deal with the patient population. That is one of
11 the critical bases for understanding not only the
12 therapies but who the practitioners are. If you don't
13 work with them, you don't understand what they can offer,
14 how they can provide.

15 If one doesn't work with a social worker as a
16 case manager for a very complex geriatric case, then the
17 nurse or the physician or others don't understand how
18 valuable that social worker is in making sure that the
19 treatment plan, the therapeutic plan, can actually occur.
20 You know, if you just send a very complex elderly patient
21 home without knowing what is going to occur and what the
22 home setting is, the likelihood of that individual really

1 being able to benefit is limited.

2 That is where these kinds of activities -- we
3 have found that in a number of different ways. So, an
4 appreciation of the other practitioners is important, a
5 kind of inter-disciplinary training. Continuing
6 education is also where it can work, but sometimes that
7 is difficult to do. The kind of continuing education we
8 have today we are not quite sure, frankly, it is very
9 effective.

10 So, while it is a wonderful idea, we haven't
11 really found the necessarily best mechanism to assure
12 that lifelong learning, which is really what CE is
13 supposed to be, is actually occurring as opposed to, you
14 know, a nice cruise where we go and do a little course
15 work in the morning and then we can spend the rest of the
16 day playing golf or something.

17 DR. GORDON: Would you be interested in some
18 recommendations about effective continuing education from
19 us?

20 MR. SAMPSON: That is exactly what we would be
21 interested in. That, and as I said what we need also is
22 then the authority to act. We are somewhat restricted.

1 Certainly, one way to start is in the interdisciplinary
2 part. That is not easily done in most of the academic
3 institutions. Academic institutions, if they are
4 training particular health professionals, they stick to
5 their own. Pharmacy school, it is tough for them to
6 break out.

7 We are trying to look at ways that -- you know,
8 we think anatomy is the same for a physician or really a
9 nurse or a pharmacist or another practitioner. You know,
10 the body doesn't change that much. But that doesn't
11 occur. And, yet, if people work together, there is an
12 opportunity to do that.

13 So we would suggest that one of the things that
14 you might want to consider is how interdisciplinary
15 education would be very valuable.

16 DR. GORDON: Great. Thank you.

17 Do you have a quick question, Wayne? We are
18 just about out of time.

19 DR. JONAS: Very briefly, I just wanted to
20 know, Ms. Collina, has the National Breast Cancer
21 Coalition kind of taken the next step, it seems to me the
22 next obvious step, and that is how to really integrate

1 patient perspective into the development of this better
2 system of evidence-based medicine that you have described
3 which I think is a broader system than what we currently
4 have in terms of better research?

5 Because these are value issues, and it is not
6 simple just to have a panel of lay people or patients who
7 then sit on a few advisory boards. Have you thought
8 about actual mechanisms as to how patient values can be
9 injected into the research system and into the evidence-
10 based decisions that are made?

11 MS. COLLINA: That is a good question. Well, I
12 will tell one story. We have been integral in founding a
13 very innovative research program as part of the
14 Department of Defense. We were looking to dramatically
15 increase breast cancer research funding, and we were told
16 that there was a firewall, that there was absolutely
17 nothing we could do about the fact that this money was on
18 this side and this money was civilian.

19 So we just jumped over the wall and said, all
20 right, then let's have a war against breast cancer. We
21 would like to have this amount of money spent on
22 innovative ways of thinking about breast cancer. And we

1 have, through that -- I wish I had the numbers here
2 because it would be very interesting. We, the taxpayers,
3 all of us, have funded a dramatically impressive new --
4 many, many new different kinds of ways of thinking about
5 breast cancer research and some of them have included
6 some CAM.

7 Although, what I would be interested in hearing
8 from you all is ways that we could even expand that. For
9 example, though, there are a number of ways in which
10 breast cancer advocate involvement is integral to that.
11 Every single panel, including the scientific peer review
12 process, includes a trained advocate. So I think that is
13 a model.

14 DR. JONAS: Do you have a training program
15 then?

16 MS. COLLINA: Yes, we do. We have a science
17 course for breast cancer activists.

18 DR. JONAS: So that they know how to
19 communicate and interact in those various groups?

20 MS. COLLINA: We have. I know all about this.
21 Yes. We now have over 1,000 breast cancer activists who
22 have graduated from Project Lead, our science course for

1 breast cancer activists. It is a very intense course.
2 It starts about 7:00 in the morning, ends about 10:00 at
3 night. It is five days.

4 Anybody who is interested, any breast cancer
5 survivors out there who would like to have the tools of
6 science to be able to dialogue effectively with the
7 scientific and medical community and also just become a
8 better advocate, has gone through this process. It is a
9 free program. We do it four times a year across the
10 country. We will be doing it in Europe next year. It
11 has provided us an opportunity to become educated.

12 DR. JONAS: Can we get information about it?

13 MS. COLLINA: Absolutely.

14 Are we done? Because I want to try to answer a
15 question that came up before which is this issue of -- it
16 seemed like it was laid out as a very difficult question,
17 the issue of should practitioners incorporate CAM into
18 their practice or should they refer others. Was that the
19 question or was there some question about whether that
20 was a sort of a tricky thing, whether people should be
21 doing the acupuncture or referring the acupuncture.

22 If I heard that question right, that doesn't

1 seem, from where I sit at least, to be a very complicated
2 question. I mean, from a patient's perspective, the
3 issue is that the care is coordinated and that it is
4 convenient and that it is respectful. So I don't care if
5 I go to my -- I mean, certainly with breast cancer we are
6 used to having a team. I don't need my surgeon to be
7 able to do acupuncture. I just need my surgeon to
8 understand that they are a part of a team, and this issue
9 of interdisciplinary rises right to the surface here.

10 What I need is for a team of people to
11 understand how they all relate to each other, to
12 communicate. And I need one person, not me, to be able
13 to coordinate all aspects of my care. I guess it doesn't
14 matter to me, from where I sit, whether one person -- I
15 don't need one person to do it all.

16 DR. GORDON: Great. Thank you. Thank you all.

17 We are going to take a 15 minute break, then we
18 will resume.

19 [Recess.]

20 MS. CHANG: If the following speakers would
21 please come up to desk: Dr. Joseph Helms, Dr. Lixing
22 Lao, Mark Blumenthal, please.

1 Plenary Session II: Continuing CAM Education
2 and Training

3 DR. GORDON: We are going to begin the next
4 panel now, and the first speaker will be Dr. Joseph
5 Helms.

6 Welcome.

7 DR. HELMS: Mr. Chairman, members of the
8 Commission, I have been involved in physician acupuncture
9 education since 1977. During this quarter century, the
10 discipline of medical acupuncture has emerged and defined
11 itself, creating its training guidelines, establishing
12 its practice standards and regulating its credentialing
13 requirements. I am pleased to review its history and its
14 current status for the Commissioners and for the public.

15 It is necessary to clarify that I address only
16 the discipline of medical acupuncture. That is,
17 acupuncture as taught to and practiced by physicians who
18 are licensed in conventional, allopathic and osteopathic
19 medicine. I do not address other disciplines of
20 acupuncture that are taught or practiced by credentialed
21 non-physicians in this country.

22 M.D. and D.O. physicians come to acupuncture

1 already fully qualified in Western biomedical science and
2 practice. Having spent over 4,000 hours in their formal
3 training programs, they are experienced as health care
4 providers and are embracing it as an additional
5 discipline to integrate into their practices. Most
6 physicians limit their acupuncture practice to 25 percent
7 or less of their professional activity.

8 In 1980, the first comprehensive medical
9 acupuncture training program in the United States was
10 sponsored by the American Holistic Medical Association,
11 as one of its core training modules. It was accredited
12 for 200 hours of continuing medical education and was the
13 forerunner of the Medical Acupuncture For Physicians
14 Program which has been sponsored since 1983 by the Office
15 of Continuing Medical Education of the UCLA School of
16 Medicine.

17 From its beginning, the Medical Acupuncture
18 Program has been enthusiastically received by physicians
19 and spread quickly by word of mouth and favorable
20 coverage in conventional medical newspapers and meetings.
21 Because medical acupuncture is an unusual discipline in
22 medicine, one that requires the student to think and

1 perceive in non-conventional ways, the teaching of the
2 discipline must be clear and rigorous.

3 The content and organization of the curriculum
4 and the standards of the knowledge base and clinical
5 skills required of the didactic and clinical teachers in
6 the UCLA program have surpassed all criteria expected for
7 compliance with the Association of Teachers of Family
8 Medicine and the Accreditation Council for Continuing
9 Medical Education.

10 The early professional challenges faced by
11 graduates of Medical Acupuncture Programs involved
12 recognition by conventional medical bodies such as third-
13 party payers, liability insurance providers, hospital
14 staff privileges, academic status and state medical
15 boards.

16 To address these and other challenges, in 1987,
17 graduates of the AHMA and UCLA programs created the
18 American Academy of Medical Acupuncture to represent the
19 professional interests of well-trained physician
20 acupuncturists. Entry membership requirements were
21 established as 200 hours of formal training. Full
22 membership requires an additional 20 hours of training.

1 The formal training of 220 hours was adopted in
2 1987 by the World Federation of Acupuncture and
3 Moxibustion Societies which is a World Health
4 Organization-sponsored entity, as a requirement for
5 physicians training in its member societies, consistent
6 with the full membership requirements in the American
7 Academy of Medical Acupuncture.

8 In this country, as individual states created
9 training guidelines for physicians, 200 hours was the
10 amount of formal training uniformly adopted as necessary
11 to develop safe and effective practice skills. The UCLA
12 program and that of the New York University College of
13 Medicine and Dentistry, which are the two major resources
14 for physicians acupuncture education in the United
15 States, maintained their training programs to conform
16 with these standards.

17 The 200-hour criteria is considered to be the
18 minimum formal didactic and clinical training to prepare
19 a physician to safely and effectively practice medical
20 acupuncture. It is the equivalent of completing training
21 through the first year of medical residency. Like
22 practicing all medical specialties, practicing medical

1 acupuncture is a lifelong open book examination.
2 Physicians are encouraged to work with study groups,
3 regional chapters of the AAMA, and the national symposia
4 of the AAMA, to broaden and deepen their knowledge base
5 and clinical skills.

6 The AAMA requires an additional 20 hours of CME
7 in acupuncture for full membership and 50 hours every
8 three years for membership renewal. The American Board
9 of Medical Acupuncture requires 300 hours of formal
10 training for qualification.

11 Since 1984, there have been numerous meetings
12 of physicians from Western countries to discuss the
13 standards of physician training and practice of
14 acupuncture. These have been sponsored by national
15 medical acupuncture societies in the United States,
16 Canada, Australia, Sweden, Germany, Belgium and France,
17 and have served as the forum for cross-fertilization and
18 standardization.

19 Several enduring international societies, the
20 Pan Pacific Forum on Medical Acupuncture for the Pacific
21 Rim Countries and the International Council of Medical
22 Acupuncture and Related Therapies for European countries,

1 have developed from these meetings and continue to serve
2 educational needs and international exchange of the
3 member countries. The common denominator in the national
4 and international societies is integrating Western
5 biomedical training with traditional theory and practice
6 of acupuncture.

7 In 1996, the World Health Organization's
8 Division of Traditional Medicine convened an
9 international assembly that voted on training guidelines
10 for different levels of acupuncture practitioners. This
11 document was approved by the World Health Assembly and
12 has been distributed to member nations.

13 Qualified physician graduates from schools of
14 Western biomedicine who wish to include acupuncture as a
15 technique in their clinical work are recommended to have
16 not less than 200 hours of formal training. This
17 training should include the history and cultural context
18 of acupuncture, the basic theory of acupuncture and
19 Chinese medicine, knowledge of the acupuncture points,
20 traditional methods of diagnosis and the principles and
21 techniques of acupuncture treatment.

22 The document acknowledges that qualified

1 Western physicians already know medical theory,
2 diagnosis, safe practice techniques and practice
3 management, and that their use of acupuncture will
4 address problems they commonly treat in their medical
5 specialties. The WHO training guidelines embodied that
6 which has been recommended and practiced in Western
7 countries for 10 to 15 years. The regulations have been
8 well established in all European and Pacific Rim
9 countries and are time tested in the United States. They
10 provide a matrix in which each training program can
11 provide its physician students with an education in
12 acupuncture that results in substantial theoretical
13 understanding of the discipline and a responsible and
14 effective technique for its execution in clinical
15 practice.

16 Public safety is well protected by the current
17 standards of training and regulation. In the United
18 States, the American Academy of Medical Acupuncture
19 recommends that individual state medical boards require
20 the 200-hour minimum formal training for physicians to
21 register as medical acupuncturists. Currently, all
22 states except three that require physician registration

1 follow the 200-hour standard. Most state medical boards,
2 however, are disinclined to regulate or certify
3 physicians in medical acupuncture. They argue that the
4 discipline is included in the scope of practice of
5 medicine and does not need additional registration.

6 In the practice of medicine, it is the hospital
7 staff privilege and liability insurance guidelines that
8 document quality of training. AAMA membership
9 eligibility is the gold standard in every state for
10 practice privileges and insurance coverage. The AAMA
11 serves the profession and the public by establishing
12 minimum training and practice standards for membership,
13 offering continuing education in medical acupuncture,
14 recommending practice privileges and liability insurance
15 qualifications, encouraging regulation by state medical
16 boards and by disseminating reliable information about
17 the discipline to the public.

18 The American Board of Medical Acupuncture, a
19 sister society to the AAMA, offers a certification
20 process in medical acupuncture that requires
21 documentation of acupuncture practice and results and
22 passing an examination. Because the majority of

1 physicians practicing acupuncture in the United States
2 are graduates of the UCLA Medical Acupuncture for
3 Physicians program, the majority of physicians in the
4 AAMA are UCLA graduates. Membership is not limited to
5 UCLA graduates, rather members come from all schools and
6 disciplines of acupuncture taught in the country.

7 Given the wide public acceptance of acupuncture
8 and the broad appeal of the discipline to physicians, it
9 seems reasonable to organize exposure programs for
10 physicians in training as well as physicians in practice.
11 There is certainly a strong interest among medical
12 students, residents and fellows in acupuncture and other
13 CAM disciplines. Exposure programs are being tested in
14 medical schools around the country and some specialty
15 programs such as anesthesiology, pain medicine and
16 osteopathic manipulative medicine require exposure to
17 acupuncture.

18 Programs for medical students of as little as
19 one or two hours provide useful information and
20 orientation to the phenomenon of medical acupuncture.
21 Half-day or full-day programs for residents and fellows
22 can give an experience of the technique and an

1 understanding of its role when integrated into practice.

2 In conclusion, with respect to the training and
3 education, credentialing and licensing of physicians
4 practicing medical acupuncture, I contend that the
5 discipline has defined and regulated itself and a
6 standard in a fashion that is acceptable by national and
7 international standards.

8 Furthermore, the medical acupuncture training
9 and credentialing infrastructure has shown, through 25
10 years, to be reliable for these physicians, and safe for
11 their patients. I consider medical acupuncture to be a
12 mature and effective discipline with a responsible
13 training, credentialing and accountability system, and
14 recommend that it be endorsed by the Commission in its
15 current form.

16 I strongly recommend that exposure programs for
17 medical students, residents, fellows and practicing
18 physicians be encouraged in all specialties of medicine.
19 Such an education exposure will inform them of the value
20 of medical acupuncture, how to refer appropriate patients
21 for treatment and the recommended format and content-
22 responsible training. Thorough basic training and

1 follow-through programs also should be made more readily
2 accessible through conventional CME vehicles.

3 Thank you very much for inviting me to offer
4 this presentation to the Commission.

5 DR. GORDON: Thank you.

6 Lixing Lao.

7 DR. LAO: Good morning, and thank you for the
8 opportunity to speak here today. My name is Dr. Lixing
9 Lao. I studied traditional Chinese medicine, known as
10 TCM, and acupuncture at the Shanghai University of
11 Traditional Chinese Medicine, and have practiced
12 acupuncture and TCM for more than 18 years.

13 Many of you may know me as a researcher because
14 of my work at the University of Maryland where I conduct
15 clinical trials on the efficacy of acupuncture. I was
16 the principle investigator on acupuncture research for
17 postoperative pain after dental surgery which was one of
18 two uses of acupuncture which received the full
19 endorsement by NIH at their 1997 consensus conference.

20 I come to you today, however, to talk about
21 education, training, licensure and certification of
22 acupuncturists in this country. Ten years ago, along

1 with some very dedicated and esteemed colleagues, I
2 founded the Maryland Institute of Traditional Chinese
3 Medicine, a school that is accredited by Accreditation
4 Commission for Acupuncture and Oriental Medicine, known
5 as ACAOM, and is a representative of acupuncture schools
6 that prepare students to become certified by the National
7 Certification Commission for Acupuncture and Oriental
8 Medicine.

9 I currently teach and serve a board member and
10 clinical director of the school, and the comments I am
11 about to make reflect my experience in this capacity, as
12 well as from my experience as a former board member of
13 the Maryland State Board of Acupuncture which regulates
14 acupuncture licensing for the State of Maryland, and as a
15 site visitor for ACAOM which is the nationally recognized
16 accrediting agency in the United States for the quality
17 of education and training in the field.

18 First, I would like to talk about the training
19 of professional acupuncturists. Accredited schools
20 provide a minimum of three years of acupuncture training
21 program, more than 2,000 hours, with at least 500 hours
22 of clinical training and 360 hours of training in Western

1 medicine, and a full year of acupuncture and oriental
2 medicine training program. The Western medical component
3 focuses mostly on training acupuncturists to recognize
4 signs and symptoms indicating that the patient should be
5 referred to another practitioner, such as a physician,
6 and also trains students on how to effectively
7 communicate and interact with the conventional medical
8 system.

9 This is similar to other health care
10 professional, such as chiropractors, psychologists, and
11 even physicians who are trained to work with the medical
12 system and refer patients when necessary to another type
13 of provider. This is emphasized throughout acupuncture
14 training, even though it is more common for a patient to
15 come to us after they have already pursued treatment by a
16 conventional health care provider.

17 This typical three- to four-year training
18 program is comparable with the number of training hours
19 that are required by other health professions, and is
20 considered to be a minimal amount of time required for
21 understanding the richness and complexity of a medical
22 system that has been under development for at least three

1 thousand years.

2 Acupuncture and TCM is a medical system not
3 just a collection of points on the body and, like modern
4 Western medicine, it takes years of study and practice to
5 achieve competency and lifetime of learning to achieve
6 mastery. Acupuncture schools provide extensive training
7 meridian theory, diagnostic methods, tongue diagnosis,
8 pulse diagnosis, differentiation of Chinese medicine,
9 accurate acupuncture point locations, various acupuncture
10 needling techniques, principle about treatment, dynamics
11 of acupuncture formulas for point combinations and
12 dynamics of Chinese herbal formulas which is not unlike
13 the combination of different drugs that, when taken
14 together, have an effect far different from the
15 individual components.

16 Perhaps the most important part of the
17 training, however, is extensive clinical training that
18 the students receive. Like a doctor fresh out of medical
19 school, it is not until one gets some clinical experience
20 that all the information and theory starts to come
21 together in a practical way. In our school, following
22 ACAOM's high standards, the student begins by spending

1 150 hours doing clinical observation, and then 500 hours
2 where they must provide at least 250 treatments to at
3 least 30 patients before they can graduate. Each case is
4 discussed with a clinical supervisor, most of whom have
5 been trained in China and have many years of practical
6 experience.

7 Traditional Chinese medicine is a completely
8 different way of looking at health and illness, as
9 compared to Western medicine. While the bodily organs
10 such as liver, spleen, heart, lung and kidney are the
11 same, their function in the Chinese medicine is very
12 different than their function in Western medicine.
13 Therefore, someone presenting with asthma may be
14 diagnosed with a kidney yin deficiency, and someone with
15 irregular menstrual cycles may have liver qi stagnation.
16 Obviously, training in Western medicine diagnosis has
17 very little overlap with Chinese medicine. Traditional
18 Chinese medicine in acupuncture often provide fundamental
19 health care for the patient rather than just symptom
20 relief.

21 Why I make these points to illustrate the
22 contrast between the 2000 hours high standard acupuncture

1 training as compared to fewer hours of training in some
2 other health professions? I believe that it is a very
3 positive phenomenon that more and more physicians are
4 learning about acupuncture and chose to use it as part of
5 the treatment options they have in their profession.
6 When they incorporate this modality into their practice,
7 it can significantly benefit and improve patient care,
8 especially for temporary relief of some symptoms and
9 simple illnesses.

10 However, just like a family physician would
11 recognize the limitations by referring patients with a
12 cardiovascular disorder to a cardiologist, a health care
13 professional with minimum training should recognize
14 limits when treating patients with a complicated, chronic
15 condition that requires comprehensive treatment by a
16 professional acupuncturist.

17 I must take issue that in some states even a
18 fully trained professional acupuncturists is required to
19 practice under the supervision of some other types of
20 health care providers. It is incomprehensible to me how
21 a physician, for example, with little or no training in
22 acupuncture can be legally authorized to supervise a

1 licensed acupuncturist. This is like requiring an
2 electrician to supervisor a plumber. Knowledge of one
3 field does not automatically confer knowledge of the
4 other field, and it does nothing to assure the competency
5 of the practitioner.

6 This is a public safety issue. I urge the
7 Commission to consider this issue and be fully aware of
8 the different levels of training and scope of practice
9 among health professionals. People seeking acupuncture
10 are unlikely to understand the difference in training
11 among different types of practitioners.

12 In addition to accreditation standards,
13 national certification is one of the few ways that the
14 public can determine the level of training of a
15 practitioner. Just like every medical doctor is required
16 to take a board examination, most states require
17 acupuncture practitioner to pass the national examination
18 offered by the National Certification Commission for
19 Acupuncture and Oriental Medicine in order to be eligible
20 for an acupuncture license. The passage of a national
21 examination ensures that the practitioner has the basic
22 knowledge of acupuncture and TCM required for an entry

1 level acupuncture practitioner.

2 Another reason that is very important for the
3 Commission to look at the education, training, licensure
4 and certification is for reimbursement. More and more
5 insurance companies are beginning to cover acupuncture,
6 although with many limitations and restrictions. I
7 sincerely hope that in the near future all government
8 health care programs, such as Medicare, Medicaid and the
9 military, include acupuncture in their health care
10 program. Some of these programs do not even offer
11 acupuncture or only offer it if performed by a physician.

12 To assure high quality of practitioners, I hope
13 that the Commission will recommend that licensed
14 acupuncturists be part of the health care team to help to
15 facilitate that to happen.

16 As acupuncture and TCM become more and more
17 incorporated into mainstream medical systems, it is
18 important that acupuncture practitioners and medical
19 doctors work together rather than competing with each
20 other to deliver the best health care for the patients.
21 In the University of Maryland medical system where I
22 work, physicians, medical acupuncturists, professional

1 acupuncturists work together as a team referring patients
2 to each other as appropriate. Our patients are very
3 satisfied with the health care we have been delivering in
4 this system. I truly believe that this should be an
5 ideal model for the health care system in this country.

6 In summary, I would like to ask this Commission
7 to recognize that acupuncture is a comprehensive medical
8 system that requires extensive training to be fully and
9 correctly practiced. The national standards for
10 accreditation of acupuncture schools assure high quality
11 and comprehensive training program and a national exam,
12 such as NCCAOM examination, for certification of
13 acupuncturists assures that the practitioners have a
14 basic level of knowledge necessary for high quality care.
15 These are gold standards for all health professionals and
16 are important tools to protect the public from untrained
17 and unqualified providers.

18 Other health professionals should have a basic
19 understanding of acupuncture as a different approach to
20 healing that can complement conventional treatment and be
21 encouraged to include acupuncture as part of health care
22 options for their patients.

1 Health care reimbursement should be made
2 available to patients receiving treatment of acupuncture
3 and Oriental medicine.

4 Finally, I would like to mention that the
5 American Association of Oriental Medicine and the
6 National Acupuncture and Oriental Medicine Alliance have
7 read these remarks and fully concur with these
8 recommendations.

9 Thank you very much, and I will be happy to
10 answer any questions. Thank you.

11 DR. GORDON: Thank you, Dr. Lao. One of the
12 things that I want to mention, just for you as well as
13 for other speakers, is we very much appreciate efforts of
14 organizations to come together to make recommendations
15 together. In a sense, one part of our effort is to
16 encourage that in the fields. So, thank you for that.

17 Mark Blumenthal.

18 MR. BLUMENTHAL: Thank you.

19 I am from Austin Texas. Thank you for inviting
20 me back to speak. I am grateful for the invitation. I
21 hope it doesn't reflect poorly on the collective wisdom
22 of the Commissioners that I am back here again.

1 I am going to be speaking about herbs only, not
2 CAM in general, because our specialty is herbal medicine
3 at the American Botanical Council. Basically, I have
4 been teaching, for the last four years now, a course in
5 the pharmacy school at the University of Texas on herbs
6 and phytomedicines in today's pharmacy, and I have had a
7 little bit of experience in dealing with at least those
8 students who are in their fifth year tract for the
9 Pharm.D. degree on how much they know or don't know about
10 botanical medicine and alternative medicine and nutrition
11 in general.

12 It is surprising and disappointing and, of
13 course, even a one semester course in herbal medicine for
14 these pharmacists, in my opinion, is inadequate to
15 adequately train them for what they are going to have to
16 deal with when they get out there in the open market
17 either as retail pharmacists and/or as health system
18 pharmacists.

19 I will stray a little bit from the printed
20 remarks that I have given you for the record. Because
21 you have them, there is no reason to be verbatim about
22 it. I would like to share just a few things about our

1 organization.

2 We are a non-profit organization that is
3 committed to disseminating accurate, responsible science-
4 based information on herbs and medicinal plants, at the
5 same time honoring the various traditions and indigenous
6 cultures from which those information come.

7 We were probably the first organization in the
8 country to develop a home-study course for CE for
9 pharmacists on herbal medicines, introduced with the help
10 of the Texas Pharmacy Foundation back in 1994. Also with
11 the Texas Pharmacy Foundation, we started a series of
12 ethnobotany on-site herbal tours to the Amazon Rain
13 Forest, which have now been extended to Belize, Costa
14 Rica, and Africa twice, for pharmacists and physicians
15 for CME credit.

16 So we actually take pharmacists and other
17 health care professionals on-site into the Amazon and
18 other places where they can see plants that modern
19 pharmaceutical drugs are derived from, as well as how
20 local cultures, indigenous cultures, utilize these plants
21 in a very different but in some cases very sophisticated
22 ways, within the context of their culture, as medicines,

1 as well as as foods in some cases.

2 I would like to point out that as far as CME
3 courses are concerned for physicians, right now, for
4 botanical medicine, the only one I know of that is really
5 adequate -- and even then, it is only five days which is
6 inadequate -- is the Columbia University course developed
7 by Dr. Freddie Kronenberg, of which several people here
8 are on the faculty.

9 I usually lead that off with a course in
10 botanical history. That is the history of herbs in
11 medicine and pharmacy which I think is an important
12 aspect of any CME. People need to understand the
13 relationship that plants and plant drugs have had in the
14 entire evolution of medicine and pharmacy. I think that
15 was alluded to earlier.

16 This is a five-day course. It was originally
17 designed for physicians. It has also opened up to other
18 health care professionals, and it is taught by,
19 primarily, M.D.s like Dr. Low Dog, who is here, but also
20 Ph.D. pharmacognosists and ethnobotanists. Some
21 herbalists and acupuncturists also participate in the
22 teaching here.

1 I would like to tell you a little bit about a
2 project we are doing at ABC in the area of CE for health
3 care professionals. We are developing a book of
4 monographs of 30 of the most popular herbs in the U.S.
5 market, focusing on their therapeutics, and this book
6 will also serve as a reference book as well as a CME and
7 CE course accredited now by the Texas Medical
8 Association.

9 To our knowledge, it is the first time a
10 medical organization has actually accredited CME
11 monographs on herbal medicines; also, simultaneously
12 accredited by the Texas Nursing Association, the
13 University of Texas College of Pharmacy at Austin, and
14 the American Dietetic Association. So these monographs,
15 which are extensively peer-reviewed, focusing on
16 therapeutics, will be marketed for all the four major
17 conventional health care professions.

18 It will be about 400 pages and will include not
19 only the focus on individual herbs and the information
20 available on them, extensively referenced, but also
21 inclusion of fairly classic herbal combinations from
22 Ayurveda, Chinese Medicine, some from Western Europe that

1 have been evaluated in published clinical trials.

2 So we are basically showing that physicians and
3 pharmacists should not just focus on herbals as
4 individual monopreparations, but as well they should be
5 aware of the fact that in many traditional cultures, in
6 fact, the rule is that herbs are used in combinations and
7 the exception is that they are used individually. We
8 will focus on some of those leading combinations that
9 have been the subject of published clinical trials in the
10 West.

11 Basically, we are also going to be focusing on
12 the branded names of those products used in published
13 clinical studies, at least acknowledging those brands in
14 tabular form in summary forms of tables, as well as
15 various charts, because one of the biggest questions we
16 get in CME and CE courses from physicians and pharmacists
17 are, "We know about ginko, we know about saw palmetto, we
18 saw all the wealth from that analysis of JAMA, but we
19 want to know which brand should we recommend, which brand
20 should we trust. We don't understand these products. We
21 don't understand this industry. We don't necessarily
22 trust it. What brands?"

1 Well, obviously, those that are subject of
2 published clinical trials are at least the first ones
3 that one should look at for possible evidence of their
4 safety and efficacy, and we will be outlining and
5 highlighting those; not to promote or support those
6 products, per se, but at least to acknowledge the fact
7 that they have been clinically studied, at least in one
8 or more clinical studies. And I believe, in reference to
9 my previous testimony back in October, this also helps
10 provide an incentive for private investment in botanical
11 research because people should get their name mentioned
12 when they do clinical research.

13 I would also like to point out that Dr. Victor
14 Sierpina, at the University of Texas Medical Branch in
15 Galveston, is a recipient of a CAM Curriculum Development
16 Award from NCAM. I am sure you are all aware of that. I
17 am involved with that program, and there will be, I
18 think, a great deal of herbal medicine material produced
19 in that recommendation for how to develop curriculum in
20 medical schools for CAM.

21 Ms. Axelrod asked me to deal with a couple of
22 recommendations and questions in my testimony, so I will

1 try to do this, briefly.

2 Who should be receiving continuing education?
3 I believe, frankly, all health care professionals should
4 get some form of herbal CE. Of course, it should be
5 tailored to the extent that herbs show up in their
6 particular practice, but particularly physicians of most
7 types, pharmacists, dieticians, clearly, who are
8 constantly helping people evaluate their dietary intake,
9 they should know about dietary supplements and their
10 risks and their benefits. Unfortunately, there always
11 seems to be too much emphasis on the risk and very little
12 acknowledgement or support for the benefits.

13 Nurses, as well, in various levels, depending
14 on their exposure to patients with respect to the use of
15 dietary supplements.

16 So, I think that very few medical or health
17 care modalities are basically immune from the proposal
18 that they should get some CE accreditation in alternative
19 medicine, especially botanical medicine. There may be
20 some exclusions, neurosurgeons or possibly orthopedists,
21 but even then more dietary supplements are being shown to
22 be useful in some kinds of classic orthopedic conditions,

1 neurosurgery as well. So I am not sure that anybody is
2 really immune from the need for being aware of the latest
3 scientific and clinical research on these products.

4 Who should be teaching these materials? Well,
5 this is a problem. I think there is a paucity of
6 adequately trained people to actually address the issue
7 of how to understand, from a scientific and clinical
8 perspective, the risks and benefits of herbal medicines.
9 I think that there are number of people that are fairly
10 well qualified. Many of them are herbalists and
11 naturopaths who may or may not have an extensive
12 knowledge of conventional biomedicine and, therefore,
13 might be marginalized or might not be well received by
14 some medical practitioners or conventionally-trained
15 practitioners. I hope that is not the case anymore. I
16 think, historically, that may have been the case.

17 But the fact is that there are a number of
18 people out there who have an extensive knowledge of herbs
19 who are not trained in the conventional medical modality
20 or domain and, yet, that should not preclude them from
21 being able to offer expert instruction in this area.

22 What should be taught? And how and by whom

1 should the content be determined? Well, clearly, I have
2 already said history. I think it is important for people
3 to know the history of their own profession, especially
4 as it relates to botanical medicines, and I teach this at
5 the Columbia course. I emphasize it in my pharmacy
6 class, as well. One of our elective texts in the
7 pharmacy class is a book called "Green Medicine," by
8 Barbara Griggs, a British author who chronicles the
9 development of herbal medicine in the West and how it
10 intertwines and has been marginalized and/or oppressed at
11 various times in the Western world over the last 2,000
12 years.

13 I also think some degree of information about
14 regulation of herbal medicines needs to be included. I
15 think there is too much misinformation or lack of
16 knowledge by conventional health care practitioners about
17 the regulations and/or underregulation, as the case might
18 be, or lack of enforcement by the agencies, as different
19 people might characterize it, on herbal medicines and the
20 distinction between the regulations on herbal medicines
21 and dietary supplements compared to conventional drugs.

22 Of course, therapeutics, and it is in here as

1 well, but I think the therapeutics should focus not only
2 on the risks, but also support the benefits.

3 The rest of my comments are in here, and I
4 would like to point out that I have also included some
5 recommended reference materials and texts, some basic
6 outline of my class in the pharmacy school, and the basic
7 outline of the monographs that we are publishing at ABC
8 for health care practitioners.

9 In conclusion, I would like to say that one of
10 the primary recommendations that I would recommend is
11 that any kind of CME or CE courses be adequately and
12 appropriately peer reviewed by people knowledgeable in
13 this area. It is very discouraging to see information
14 published in medical and/or pharmacy texts and journals
15 regarding herbal medicine that are often misleading or
16 grossly inadequate. I have cited a point here in the
17 written portion here.

18 There is a lack of adequate reviewers in this
19 area, possibly, or the lack of proper review. I think
20 this merits your attention because some of the material
21 being published from conventional publications is lacking
22 in accuracy on these herbal medicines, and this is

1 something that needs to be addressed if this is going to
2 be included in any kind of course.

3 I thank you for inviting me.

4 DR. GORDON: Thank you very much.

5 Questions. David.

6 **Panel Discussion**

7 DR. BRESLER: This is for Dr. Helms. First, I
8 want to congratulate you on your pioneering work in
9 developing your training program for physicians and how
10 you stood up to the early criticism that you must have
11 had in doing so.

12 If we look at your program as a model for other
13 training programs that will bring physicians up to speed
14 in CAM procedures, we also have some concerns about scope
15 of practice issues. We have heard a lot of testimony
16 from people who have concerns that patients will go seek
17 alternative practitioners and, therefore, not have access
18 to conventional care which has proven efficacy.

19 The question that I have is: When you compare
20 the scope of practice for people that have had 200 hours
21 of training versus those who have had 2,000 hours of
22 training, I have no doubt that physicians could treat

1 musculo-skeletal pain problems with that level of
2 training, but if you are dealing with complex issues like
3 endocrine disorder and so forth, looking at it from a TCM
4 point of view, do you feel that your practitioners have
5 adequate training to be able to handle that as well as
6 the non-medical practitioners? And, two, if you feel
7 that they don't, do they ever refer these complex cases
8 to the non-physician acupuncturists?

9 DR. HELMS: This is an important question that
10 always comes up in the discussions of comparing the
11 training expectations of physicians who are embracing
12 acupuncture as an additional discipline and those health
13 care providers who have traditional Chinese medicine as
14 their primary or exclusive health management offering.

15 The physicians who come through the program are
16 all licensed, fully qualified by American and Canadian
17 standards which as we know are the highest qualifications
18 in the world for practicing responsible medicine, and
19 they bring that entire discipline to bear on every
20 decision they make, whether they are using chemotherapy
21 or acupuncture as their chosen treatment modality.

22 Clearly, 200 hours does not cover the full

1 spectrum of traditional Chinese medicine and it is not
2 designed to do so. It addresses acupuncture from a
3 neuro-anatomical, neuro-physiological basis, as well as
4 from the tradition of acupuncture, divorced from the
5 rigors of the herbal diagnostic system under the rubric
6 of traditional Chinese medicine.

7 So the acupuncture quality that a physician
8 trained in medical acupuncture walks out with from a
9 program is, I claim, equal or superior to the acupuncture
10 training that non-medical practitioners are given. The
11 difference has to do with embracing traditional Chinese
12 medicine as a separate discipline. That is where
13 physicians are not engaged.

14 The complexities, the application of
15 traditional Chinese medicine to complex chronic medical
16 problems, particularly internal medicine problems, are
17 often far more responsive to Chinese herbal input than
18 they are to acupuncture alone. That is made clear to the
19 physicians who are participating in the program. And,
20 when herbal evaluation and treatment is indicated,
21 physicians are instructed to have adequate training
22 himself to address that or to refer the complex patients

1 to work collaboratively with the licensed TCM
2 practitioners.

3 So we are not comparing acupuncture and
4 acupuncture with your question. Your question implies
5 the comparison of medical acupuncture which is embraced
6 by physicians for incorporation and integration into
7 their specialties versus the discipline of traditional
8 Chinese medicine as imported from Communist China.

9 They are different disciplines. They overlap
10 in some of the acupuncture perspectives, but the
11 versatility and flexibility of the acupuncture that is
12 taught to the physicians in a 200-hour program is
13 adequate to responsibly apply it not just to muscular-
14 skeletal problems, but to general medical as well as
15 specialty medical problems as well, as either a sole
16 intervention or as a complement the conventional medical
17 intervention.

18 When it is serving as a complement to other CAM
19 disciplines, then obviously the physician, as he would
20 with other specialties in medicine, would work
21 collaboratively with other CAM practitioners.

22 DR. BRESLER: Do your graduates, in fact, do

1 that? Do they work in collaboration?

2 DR. HELMS: Yes. Yes.

3 DR. GORDON: Effie.

4 DR. CHOW: I think there is value in both
5 aspects, but I wonder if Mr. Lixing Lao would expand on -
6 - because, Dr. Helm, you are saying that the traditional
7 acupuncturists have the same training. Could you
8 elaborate on, without the herbal training, how many hours
9 of training does the acupuncture version have.

10 The other thing is, are the organizations in
11 communication? Because there is lots of discussion that
12 we should all work together. Perhaps the medical doctors
13 who are trained in acupuncture have not had the exposure
14 to the extensiveness which acupuncture can work with the
15 individual in complex cases and that the exposure is
16 important. Because if you haven't had exposure, you
17 can't expect them to know.

18 Could you or both of you make comments on that.

19 DR. LAO: As I mentioned in my speech, I
20 already mentioned that there are two programs. One is
21 acupuncture purely program is about 2,000 hours, and the
22 other program acupuncture practitioner program, usually

1 about 3,000 hours, approximately.

2 DR. CHOW: So the acupuncture is 2,000 hours?

3 DR. LAO: Yes. Yes, approximately. I want to
4 emphasize that usually acupuncture treatment is not just
5 points and meridians. They are also based on the TCM
6 diagnosis. This part takes lots of hours, if I answer
7 the question.

8 The second question is mainly how to
9 collaboratively work with other physicians. I think this
10 is also, recent years, I think since the awareness of
11 usefulness of acupuncture brings up, more and more
12 physicians get more and more open minded and accept
13 acupuncture treatment. So, from my own experience, I can
14 tell I get lots of referrals from physicians. Also, the
15 medical acupuncturists, we work together very nicely.
16 The acupuncturists also refer patients to physicians when
17 they feel there is a need for the diagnosis for
18 medication from physician, they work together. I think
19 this is the direction.

20 DR. HELMS: I would like to address your
21 question of the comparison of the training. The 2,000
22 hours that are involved in training a student wishing to

1 embrace the health care discipline of traditional Chinese
2 medicine or the acupuncture division of traditional
3 Chinese medicine starts with basic exposure to medical
4 sciences, to the basic sciences, to physical examination
5 and necessary in that process is training a student how
6 to be a responsible and safe primary health care
7 provider.

8 2,000 hours are not spent exclusively training
9 that person in acupuncture. Physicians come to
10 acupuncture training as added specialties. They are
11 already fully trained as primary care providers, fully
12 licensed as practicing physicians, and they come to
13 acupuncture with the ability to embrace this additional
14 discipline to incorporate into their practices.

15 So the difference in hours is not the valid
16 comparison. The valid comparison is the content of the
17 program and the evaluations of the skills and knowledge
18 base that are accomplished in each of the programs. I
19 would contend that I would place my best student in equal
20 status with the best student coming from a TCM program
21 and my worst student with the worst student coming from a
22 TCM program, and I think that we have practice parity.

1 DR. CHOW: The part is that, do you see a
2 collaboration on a larger level? You are saying you are
3 collaborating. Is there a collaboration on a larger
4 level with the NCCAOM?

5 DR. HELMS: To my knowledge, there is not a
6 direct collaboration between the physician and the non-
7 physician professional societies. There is exchange of
8 the material of the disciplines in that physicians who
9 have gone through full TCM training are teaching in the
10 physician environment and are bringing the quality of the
11 full herbal model and the herbal diagnostics and the
12 application of TCM to complex medical problems either as
13 exposure or as in-depth courses for physician
14 acupuncturists.

15 DR. GORDON: Tom, and then Charlotte.

16 MR. CHAPPELL: Mr. Blumenthal, in your
17 presentation we get down to the what should be taught
18 question. This group is hearing a lot of different
19 recommendations about how we handle standards and safety
20 and efficacy issues concerning herbs. We have had
21 recommendations of creating standardization.

22 As I understand herbs and our knowledge of

1 herbs to date, we don't know what active elements in
2 certain herbs are doing the actual work. There is more
3 research needed before we could boast standardization.
4 At the moment, we are standardizing markers instead of
5 active ingredients.

6 Given still the lack of ability to land on a
7 single active ingredient the way we do in FDA sort of
8 orientation to drugs and to build a claim around a single
9 drug, how do you think we should approach the consumer's
10 concern, the physician's concern, for employing more
11 herbs in their well being and health care? What can we
12 do to improve the confusion or the quality?

13 You do address this in some respects, but the
14 language you use is that it bears clarification.

15 MR. BLUMENTHAL: Well, thank you, Tom. That is
16 a \$64 question you are asking there.

17 The issue of standardization deals with the
18 fact that herbs are, by nature, chemically complex, which
19 is part of the natural situation, and that different
20 herbs, even the same herb will have different chemical
21 profiles depending on where it is grown, how it is grown,
22 chemotypes, processing procedures, et cetera. This is

1 anathema to a chemist, pharmacologist, pharmacist who is
2 trying to focus on one single ingredient based on the
3 reductionist biomedical model. At the same time, we have
4 evidence that different kinds of non-standardizable
5 preparations can be clinically effective, as documented
6 in published clinical studies, as published by Dr.
7 Francis Brinker [ph] in "HerbalGram 46."

8 There are a number of studies on "non-
9 standardized preparations." The issue of standardization
10 goes well beyond chemistry, as well. There are
11 standardization issues that go from agricultural
12 production of these herbs as well, which is from the
13 ground up. I mean, that is another issue as well, but it
14 is part of quality control. The standardization is often
15 a chemical conversation in the popular domain, but it
16 really goes beyond that into quality control issues;
17 determining what seed you are going to use, how you are
18 going to process. Those are all part of standardization.

19 The issue I think that you were speaking about
20 is how do consumers and health care professionals
21 identify products that are reliable, safe, effective and
22 repeatedly reliable, and that is not always easy to deal

1 with. There is no published GMPs at this time that deal
2 directly with botanical products. FDA was rumored to
3 have published GMPs, the four dietary supplements that
4 were supposed to be --

5 DR. CHAPPELL: You mean, Good Manufacturing
6 Practices?

7 MR. BLUMENTHAL: Yes, Good Manufacturing
8 Practices. Thank you. That deal with quality control,
9 quality assurance, standard operating procedures, et
10 cetera. FDA did release those in the last year. They
11 got slowed down at OMB, Office of Management and Budget.
12 Now, with a new administration, everything is up for
13 review, so we don't know. I think they were withdrawn, I
14 guess, or pulled back. We don't know where the GMPs are
15 at this time, as far as the process, if they will be
16 published in the original form that was recommended by
17 FDA last year, at the end of last year.

18 We don't have operative GMPs dealing with
19 herbal medicine, so the industry and various members of
20 the industry have had to ascribe to GMPs on their own on
21 a voluntary organizational level. The baseline being the
22 GMPs that are required for all conventional foods because

1 legally herbs are foods not drugs, except for the few
2 that are approved as over-the-counter drug ingredients
3 like cineole, aloe, cascara, et cetera, and psyllium.

4 DR. CHAPPELL: But there are GMPs for food,
5 drugs, beverages, everything else that we consume, and
6 herbs are the only ones that have no GMPs.

7 MR. BLUMENTHAL: Well, herbs do have GMPs, but
8 the GMPs are the default GMPs required for conventional
9 foods. There are no specific GMPs for herbs or dietary
10 supplements. Those are pending, but the GMPs that do
11 govern herbs are the same GMPs that govern tomato juice,
12 apple juice, fruit cocktail, salsa or anything else that
13 is a conventional food, until such time as these new GMPs
14 are released.

15 Even then, by the way, when those GMPs are
16 released by FDA, at whatever level they are going to come
17 out, based on what tinkering that may or may not happen
18 with the new administration, there is an exclusion for
19 small businesses that exempts various companies. I think
20 the small business exclusion under the federal government
21 definition is something like somebody with less than 300
22 employees which, as you know, is probably going to exempt

1 most of the people making herbal products except for a
2 very few.

3 So the real challenge here, I think the bottom
4 line is that there are a number of voluntary initiatives
5 by different individual manufacturers and organizations
6 to meet or exceed levels of GMP that are not yet required
7 by the government. It is voluntary.

8 DR. CHAPPELL: But the industry would not
9 resist --

10 DR. GORDON: Excuse me. I think we really need
11 to focus here on education and training. Afterwards,
12 Mark has already said that he would be available to us
13 for consultation on some of these other very important
14 issues.

15 DR. HELMS: Mr. Chairman?

16 DR. GORDON: I would like to go with Charlotte.
17 Joe, you would like to ask an herbal question?

18 DR. HELMS: No. I am wondering if I might be
19 given a moment to offer some recommendations from my
20 perspective as an educator in medical acupuncture that
21 ties into some of the discussions that were already
22 brought up this morning, at the conclusion or before the

1 discussion continues.

2 DR. GORDON: Sure, if it is brief, because I
3 want to give the Commissioners a chance.

4 DR. HELMS: I can be brief.

5 I think it is, first, important to identify
6 that, for physicians learning acupuncture, the
7 environment in which they are learning sophisticated
8 acupuncture is as a continuing medical education event.
9 We have spent a fair amount of time interviewing and
10 working with our clinical preceptors who are involved in
11 academic training programs, and the uniform conclusion is
12 that, in the case of exposure to medical acupuncture to
13 medical students, less is more. A brief exposure showing
14 the clinical value rather than trying to give a full
15 program would make sense. However, when one goes to the
16 resident level or to particularly the fellow level then
17 fuller programs can be done.

18 In the ideal of worlds, if we are going to open
19 up the spirit of integrating CAM disciplines and CAM
20 consciousness into medical training, I would love to have
21 access to all first-year medical students during the
22 first two weeks of their education so that I could expose

1 them to the philosophy of diagnosis and treatment models
2 contained in acupuncture so that they could have that in
3 mind as early steps of what they can do to better
4 understand their patients as they are seeing them and,
5 even if it were a fully integrated program, give them
6 gradually more complex therapeutic work as they go
7 through their training.

8 Obviously, this needs supervision to make it
9 work, which is my second point. The area that needs most
10 attention in terms of growing, simple exposure or more
11 complex training, is trainers. Training trainers, I
12 think is a very important area for considering funding
13 and assistance. It is one of the areas that is
14 underdeveloped in the private sector involved in
15 acupuncture training. It is to be emphasized here that
16 academic centers, university academic centers are not
17 necessarily the best environments for creating
18 responsible exposure to CAM training, even for
19 physicians; hence, the value of the post-graduate CME
20 vehicles.

21 The other area that could be enhanced for
22 propagation and quality in physicians practicing

1 acupuncture are resident centers where clinics that are
2 supervised by trained trainers are available to graduates
3 of the CME programs for an extra week or a month or six
4 months of exposure to acupuncture practice. That is not
5 currently available because most of this work is done in
6 private environment. Again, I am not convinced that
7 academic centers are the most flexible to accommodate
8 this notion; hence, breaking some barriers in terms of
9 funding, training the trainers, funding resident programs
10 might need to be considered for most effective
11 integration.

12 Thank you.

13 DR. GORDON: Thank you. Charlotte, and then
14 Tieraona.

15 SISTER KERR: Thank you. This is specifically
16 to acupuncture. Thank you, first, to both of you, your
17 pioneering work. You are part of a long history in
18 America.

19 I want to follow up on what Effie said. Your
20 presentations, to me, were two of the clearest I have
21 heard on two particular visions on acupuncture education
22 and practice in America. The discussion about how many

1 hours with the physician and your opinion, we have heard
2 from other presenters in terms of the non-physician
3 acupuncturists.

4 It was not clear to me, Dr. Lao, when you
5 responded to Effie's question -- I was clear you say you
6 thought the physicians and the non-physician
7 acupuncturists worked together, the medical
8 acupuncturists, and that was working very well. It was
9 not clear to me what your opinion was as to whether or
10 not you thought that was enough hours.

11 I understood, Dr. Helms, that you felt that,
12 for example, the 2,000 hours, much of what is taught
13 would have been included in your preparations as a
14 primary care level as a physician.

15 So, I would like you to clarify further what
16 your opinion is on that.

17 The second, Dr. Helms, is for example, in the
18 2,000 hours, some people thought it would be -- I suspect
19 you might say it is not within your realm to comment on
20 nursing, particularly, for example, nurse-practitioners
21 have a lot of background and preparation. Do you feel,
22 perhaps, something like a 200-hour course could be

1 appropriate for other health care practitioners and have
2 you done any collaborative work in that area?

3 The other thing, Dr. Helms, is what would
4 happen if the recommendation came out that the 200 hours
5 for physicians was not felt to be broad enough for the
6 practice of acupuncture in America.

7 DR. LAO: Let me clarify my opinion. Actually,
8 I addressed it in the speech, but maybe too fast.

9 SISTER KERR: I got it. Your speech was
10 superb, but I still wasn't clear.

11 DR. LAO: As I mentioned, actually, I would
12 encourage it. I think it is very good, phenomenal, that
13 lots of physicians get interested in acupuncture
14 training. I think it is a very good thing because they
15 can significantly benefit the patients on a daily basis,
16 because lots of patients come with just with a headache,
17 toothache, and they can use acupuncture to relieve the
18 symptoms.

19 As I mentioned also in the speech, I will give
20 you an example, like family medicine practitioners, they
21 always refer patient with cardiovascular disorder to the
22 cardiologists. So everybody has specialists.

1 I think, in my opinion, that professional
2 acupuncture, that is like a specialty. In certain cases,
3 we can refer to each other, with physicians and medical
4 acupuncturists working together. This is my opinion.

5 I will give an example. At University of
6 Maryland, a complementary medicine program where I work,
7 we work together very nicely, and patients are very happy
8 about the collaboration that we have.

9 Is that clear enough?

10 SISTER KERR: So that, if there was
11 collaboration and understanding scope of practice, you
12 feel fine about it?

13 DR. LAO: Yes.

14 SISTER KERR: Okay.

15 DR. LAO: That is right.

16 DR. HELMS: To address my part of your
17 question, I think it is less important to compare hours
18 of training than it is to compare content of the material
19 covered and the evaluation of the mastery of the
20 knowledge base and the clinical skills through observed
21 evaluation and written examination.

22 The training that is expected for membership

1 eligibility. Ultimately, board certification by the
2 American Board of Medical Acupuncture is consistent with
3 World Health Organization guidelines for all acupuncture,
4 all core acupuncture training, not just physician
5 acupuncture training. This is consistent in the teaching
6 programs, as well as in the examination process. So, if
7 we compare content and performance, we are certainly
8 working on an equivalent product in terms of acupuncture
9 ability.

10 With respect to other medical disciplines that
11 have parallel training in the biomedical sciences,
12 certainly dentists, podiatrists, dental surgeons are
13 accepted into the programs because they fall under the
14 rubric of physician practitioners in the United States
15 and have parallel basic training and clinical training to
16 be able to integrate the material intelligently.

17 Nurse practitioners and physician assistants
18 because they have additional training beyond regular
19 nursing training probably would qualify for a modified
20 training program, modified from a TCM-based to a 3,000
21 hour program, if the goal of their practice is to work in
22 collaboration with a physician environment where the

1 physician is practicing acupuncture.

2 So, certainly, that would be a reasonable
3 avenue to explore. In fact, a couple of trial admissions
4 were made into the UCLA program of nurse-practitioners
5 and physician assistants. Certainly, those who came
6 through were qualified to handle the material. They
7 didn't have the clinical judgment that is assumed in a
8 physician that goes through it, so additional
9 modification would be necessary to make a program
10 worthwhile, probably an expansion of that.

11 Your third question of what would my response
12 be if the Commission recommended that 200 hours is not
13 adequate training for physicians in the United States; to
14 that, I would appeal; to that, I would ask you to appeal
15 to the weight of international accord. This issue has
16 been discussed, identified by national societies,
17 international meetings, international societies and
18 international medical organizations such as the World
19 Federation of Acupuncture Societies and the World Health
20 Organization. For the last 14 years, all formal
21 documentation addressing physician training for an
22 appropriate level of safe, responsible and effective

1 practice has come to the number of 200 hours of formal
2 acupuncture training.

3 DR. GORDON: Thank you. We have one very quick
4 question, one very quick answer. We are already behind
5 time and we need our full lunch hour, not just to eat in
6 peace but also we have some training that needs to be
7 done.

8 DR. LOW DOG: Mark, thank you again for coming
9 and for all the great work that the American Botanical
10 Council has done. You spoke about education for health
11 care practitioners which is very important, but I am a
12 little bit interested in your thoughts about education
13 and educational standards for herbalists because that has
14 been raised several times here about variation in
15 training, et cetera. I am not talking about an intact
16 cultural education; if you are a Navajo person training
17 on the reservation, you are going to get the education.
18 I am talking about everything else.

19 MR. BLUMENTHAL: Well, I wrote an article a few
20 years ago, I got a lot of heat and hate mail on it,
21 called "What is an Herbalist." Because that term is not
22 well-defined under any laws of licensure or practice that

1 I know of and it is basically used quite liberally by a
2 number of different people, including people who are
3 manufacturing or making products at home, people growing
4 herbs in their garden, people who have a clinical
5 herbalist or medical herbalist type of shingle out that
6 are unlicensedly doing some kind of health care guidance
7 counseling of some sort, some people who have gone to
8 become acupuncturists so they can have some legitimate
9 cache to deliver medicine but within the context of an
10 appropriately licensed modality.

11 For starting off with, it is unclear what an
12 "herbalist" is in legal terms. In practical terms, I
13 think you and I know that it is somebody who is trying to
14 use herbs for health care purposes. The herbalists
15 themselves, to my knowledge, the ones that get together
16 under the guise of the American Herbalist Guild, I don't
17 think can even agree on this issue is the problem. They
18 spend a lot of their time just discussing should there
19 even be licensure or not. That is one issue. And, to
20 what extent should there be some sort of training.

21 There is a group called the Botanical Medicine
22 Academy, which is comprised of herbalists and

1 naturopaths, and they have gotten together with the
2 American Herbalist Guild to try to put together some core
3 curriculum criteria for developing ways to communicate
4 outside the herbal community to health care
5 practitioners. I referenced that in my written remarks.
6 But I think the question you ask is global, and I think
7 it is very difficult to come down with succinct answers
8 to how one sets up criteria for evaluating and training
9 an herbalist because it is such a widespread area and it
10 covers many different modalities and cultural issues as
11 well.

12 DR. GORDON: We are going to have to stop. I
13 know we could go on for a long time, but we would like to
14 be able, with all three of you, if we have further
15 questions, to be able to ask you about some of these
16 issue. I think you really presented a very good
17 groundwork for us to begin with, so thank you very much.

18 MS. CHANG: If the last panel would come up to
19 the table before we break for lunch: Denise Murray
20 Edwards, Sue South and Dr. Murray Kopelow.

21 DR. GORDON: Dr. Kopelow, is the information
22 correct that you have to leave at 12:30? I would like to

1 ask you to present first, and we will have a few minutes
2 for questions for you specifically. Then, we will ask
3 the other two presenters.

4 I appreciate your indulgence on this.

5 DR. KOPELOW: Thank you very much, Dr. Gordon.

6 For the first person who held up the picture of
7 the new member of the Commission, I have to be home to
8 watch my son run a meet at 4:00 this afternoon. It is
9 incredibly important, and I am grateful for all of you
10 for changing your schedule.

11 This has been a very exciting morning. I want
12 to thank you, on behalf of the Accreditation Council for
13 Continuing Medical Education, and Tom Kirksey from Texas,
14 the chair, for inviting us to participate. I have
15 submitted some materials and some of our background for
16 you to review and to read.

17 My goal here in my comments is to explain the
18 Accreditation Counsel for Continuing Medical Education,
19 to answer your questions, and maybe make some comments
20 about some of the interesting things that have already
21 been said. I don't mean to present myself as
22 representing the entire continuing medical education

1 enterprise. I am the staff person, the chief executive
2 officer of the accrediting body, and my expertise is
3 limited to the operations of the ACCME.

4 That organization was created in 1981, and
5 actually today is the 20th anniversary of the first
6 meeting of the Accreditation Council for Continuing
7 Medical Education, an organization that is a council of
8 the American Board of Medical Specialties, the American
9 Hospital Association, American Medical Association, the
10 Association of American Medical Colleges, Association of
11 Hospital Medical Education, the Federation of State
12 Medical Boards, the Council of Medical Specialty
13 Societies, representation from the government and Health
14 and Human Services and the public. Those organizations
15 get the credit for our accomplishments. I get the blame
16 for our problems.

17 The ACCME's purpose is to promote and develop
18 and encourage the development --

19 DR. GORDON: Excuse me, just one moment. Dr.
20 Kopelow's testimony is under discussion group 1. So if
21 you are looking and wondering, that is where it is, Tab
22 1.

1 DR. KOPELOW: It is always nice to be first or
2 maybe not.

3 So our purpose is to promote and develop and
4 encourage the development of principles, policies and
5 standards for continuing medical education, very much
6 what you have been talking about so far this morning.

7 Our mission is in the development of these
8 standards for continuing medical education that are
9 utilized by physicians in their maintenance of competence
10 and incorporation of new knowledge to ensure quality
11 medical care for patients and the communities in which
12 those physicians operate.

13 We fulfill this mission through a voluntary
14 self-regulating system of accreditation, a peer-review
15 process. We have as our prime responsibility to set
16 standards and certify whether or not institutions and
17 organizations meet those standards. Many of you on the
18 Commission are accredited by us or your institutions and
19 organizations are. Many of the previous speakers have
20 been accredited by our organization.

21 In addition to the setting and certifying with
22 respect to standards, it is important that we relate

1 continuing medical education to the continuum of medical
2 education, as Dr. Danoff started to talk about this
3 morning, the continuum of medical education. It is
4 important that we evaluate our effectiveness, and that we
5 assist our providers in continuously improving.

6 You have talked about needs for our providers
7 in the improvement of the continuing medical education
8 enterprise. The whole purpose of this is to assure the
9 physicians and the public and the CME community that CME
10 programs meet the ACCME's criteria for compliance with
11 our rules and regulations, which you have got.

12 Our system is a national system. We accredit,
13 directly, over 600 organizations. Our state medical
14 providers accredit another 2,000 organizations. Our
15 accreditor-providers put on 50,000 activities a year,
16 600,000 hours of continuing medical education to 6
17 million physician and non-physician registrants, and it
18 is an important delivery system for the content, the
19 accountability, and the issues of the content that you
20 referred to today.

21 An important part of our interface is the
22 eligibility for ACCME accreditation. An organization or

1 group that puts on continuing medical education for
2 physicians in a medical or medically-related field who
3 can document that it has adopted our policies and a
4 commitment to continuing medical education can be
5 accredited by us.

6 CME activities are distinguished from
7 activities which are promotional or appear to be intended
8 for the purpose simply of creating familiarity with a
9 specific commercial product.

10 An organization is not eligible for
11 accreditation by ACCME if, in the judgment of the ACCME,
12 its program is devoted to the advocacy of unscientific
13 modalities of diagnosis or therapy, very much to the
14 point that you spoke about today. You talked about
15 evidence-based. Evidence-based is not a zero or one
16 system. Evidence-based is a grading system where the
17 evidence is graded from anecdotal to the meta-analysis
18 that was referred to earlier, and that is the system that
19 we use.

20 You asked some specific questions of ACCME:
21 What is the status of CAM in continuing medical
22 education? I don't have the answer in a quantitative

1 way. We do not keep records of how much of each topic
2 our providers present. If it is something that you need,
3 I can work with you to suggest mechanisms to get that
4 information.

5 I think it is interesting that we don't have
6 it, that this is not a marginalized or identified group
7 that we know everything about, which is interesting. So
8 we don't have that kind of database, and we do look
9 directly at activities at the time of accreditation.

10 You also asked: What are the barriers to
11 inclusion of CAM in CME curricula? Well, from all the
12 barriers, we are a regulatory body and we have regulatory
13 requirements. We have eligibility requirements.

14 So they, theoretically, can be barriers to
15 entry of providers who teach about this content in
16 continuing medical education. There is that potential,
17 and it has to be kept in mind. The incentive is that
18 there is a great need for information exchange about CAM
19 for physicians and all health care practitioners, so
20 there is a great incentive to enter.

21 Of note, the ACCME went through a strategic
22 planning process in the last year and identified as one

1 of its imperatives to examine how it deals with the
2 content of continuing medical education. We reward with
3 exemplary compliance and long terms of accreditation if
4 our practitioners can demonstrate the effectiveness of
5 that education in changing physician practice or health
6 status improvements.

7 It would be interesting, in that task force and
8 deliberative process, if we switched sides and your
9 Commission talked to our process about the value of the
10 content in changing physician practice and health status
11 improvements.

12 That is the second thing, Dr. Gordon, I invite
13 us to talk about, perhaps, in the future. Those are my
14 comments and thank you for the opportunity.

15 DR. GORDON: Thank you very much.

16 Questions from Commissioners. Joe.

17 Panel Discussion

18 DR. PIZZORNO: I read, with quite a bit of
19 interest, your written presentation, and ask you to help
20 us deal with a quandary. That is, while CAM continuing
21 education seems to have considerable interest amongst
22 health care professionals and medical doctors in

1 particular, if you look at the standards here, by
2 defining things as not acceptable, those which are not
3 commonly taught in medical schools, and by defining them
4 also having to meet a standard of evidence -- which, a
5 case could be made that in conventional medical schools
6 right now many things are taught which don't meet that
7 standard of evidence -- it seems like CAM is being
8 arbitrarily excluded from CME.

9 I speak from personal experience here, having
10 actually approached your organization about getting
11 approved for CME and getting quite discouraged in that
12 process. So there is a problem here. We know medical
13 doctors need education in this area, and yet CME doesn't
14 seem to have standards that allow that to happen.

15 How do we resolve this problem?

16 DR. KOPELOW: You have identified the fact that
17 the language that you are reading is 1981 language. The
18 scientific evidence is more popularly dealt with in the
19 context of evidence-based medicine and the grading of
20 evidence. We are working closely with the American
21 Academy of Family Practice who is constructing a system
22 whereby the content of continuing medical education

1 activities can be looked at in the context of what is the
2 grade of evidence in support of the recommendations for
3 diagnosis or therapy that are being made.

4 So there is a standard for that that is very
5 important, in addition to the content exchange that was
6 referred to before. I think that that perspective
7 removes some of those perceived barriers-to-entry that
8 are based on the fact that evidence is often taken as
9 meta-analysis of double-blind, randomized control trials.

10 There are is lot of anecdotal evidence and
11 other scientific and qualitative evidence in supportive
12 of the use thereof which needs to be brought to bear, to
13 be brought out, and to be part of the discussion. That
14 is what our task force is going to look at.

15 I heard talk of accountability, and it is
16 important. It is just very important, and there is a
17 separation and often a fine line between a firmly held
18 belief and something that has a grade of evidence in the
19 evidence-grading system. It is at that boundary where we
20 engage in this deliberation. You expect the regulatory
21 body to have standards, and we hold them. You also
22 expect them to change, not necessarily at the rate of the

1 paleontologic record but in some sort of way, but you do
2 expect us to be firm in what we have. Good question.

3 DR. GORDON: Effie.

4 DR. CHOW: Thank you. You mentioned in your
5 delivery about assessing the need or interest and that is
6 how continuing medical education is developed. Do you
7 look at the increase in the development and presentation
8 of complementary and alternative medicine in the medical
9 schools? It has been noted that over 65 percent of
10 medical schools now include it in their curriculum one
11 way or another.

12 Does that not influence your thought about the
13 CME's need, then, to have programs in this area?

14 DR. KOPELOW: You don't need to convince us or
15 the continuing medical education enterprise. I mean, 75
16 percent was the highest number I have ever heard, but it
17 is a substantial amount. We have known that for a long
18 time. That is why complementary and alternative
19 practitioners have been part of our group of accredited
20 providers for many years.

21 They are not prohibited on the basis of the
22 topic, but rather the approach and the firmly held belief

1 as opposed to the firmly held belief in the context of
2 some evidence, and that kind of medical context is what
3 we see as the level of practice for the educator that we
4 need.

5 DR. CHOW: I was interested in what you were
6 saying as evidence-based right from --

7 DR. KOPELOW: Anecdote?

8 DR. CHOW: Anecdotal, all the way. You do
9 place importance on the anecdotal aspect of it, as much
10 as the meta-analysis?

11 DR. KOPELOW: Well, didn't you all, when my
12 colleague told her anecdote about her dad and the Vitamin
13 B? I mean, that was an anecdote. That was a story, and
14 you take all of those and thousands of those together and
15 you have anecdotal evidence. One anecdote is --

16 DR. CHOW: Is one.

17 DR. KOPELOW: Is one, exactly.

18 DR. GORDON: I wanted to say a couple of
19 things. One, I would be very interested in taking you up
20 on your offer and talking with you about issues related
21 to CME. So I am happy to come personally as a
22 representative of the Commission. I appreciate that

1 offer very much.

2 I also have a question, though. One of the
3 issues that has come up and that we have heard about
4 around the country is that physicians are able to obtain
5 CME, and I have seen this in my own programs as well.
6 Physicians are able to obtain CME for learning about a
7 procedure, a therapy, a technique, a world view, but they
8 are often not able to get CME for learning how to use the
9 practice, whether it is a mind-body practice or herbal
10 practice or traditional Chinese medicine practice.

11 Sometimes, there is difficulty there. I wonder
12 if you have any thoughts about that and any way that we
13 can bridge that gap between theory and practice.

14 DR. KOPELOW: Another toughie. You people are
15 definitely paying attention to the material that you are
16 reading.

17 One thing I can gladly say is, that is mostly
18 an American Medical Association rule, as opposed to an
19 ACCME rule. So I can deflect that somewhat.

20 The issue is that, what is most important, most
21 important in the medical world that I operate in, is that
22 the medical practitioners know about that which their

1 clients are participating in and asking about and which
2 their colleagues are prescribing and doing. From a
3 priority perspective, the physicians can't operate in
4 ignorance.

5 Then, you cross a line as to whose needs the
6 accreditation system for continuing medical education is
7 meeting and what the range and limits that are applied to
8 us. The Federation of State Medical Boards is one of our
9 parent organizations who are responsible for ensuring
10 that physicians are in the continuing medical education
11 that their member boards are using to maintain license,
12 that the content is applicable to what their credentialed
13 and licensed to do. We are accountable to that
14 organization, and we are accountable for our system to
15 meet that need.

16 The American Medical Association is, again, one
17 of our member organizations, and we are accountable to
18 meet the need of the system in which they work. It also
19 goes to the definition that I talked about, the program
20 needs can't be devoted to the advocacy of unscientific
21 modalities of diagnosis or therapy.

22 So it isn't fair to generalize all of the

1 content that we have been talking about today into that
2 restriction because some of it that is considered
3 alternative and complementary has scientific evidence,
4 like some of the acupuncture that we heard about today
5 for which there is no restriction or negative response
6 to.

7 So it is, as you know, too complicated to
8 generalize.

9 DR. GORDON: I am wondering, though, if you
10 think it might make sense that where there is an evidence
11 base, generally speaking, to look at broadening it, so
12 that one can include the practice as well as the hearing.

13 DR. KOPELOW: That is a wise suggestion.

14 DR. GORDON: Thank you.

15 DR. KOPELOW: And a safe response.

16 [Laughter.]

17 DR. GORDON: Thank you very much. I hope you
18 enjoy the meet. I look forward to seeing you again.

19 DR. KOPELOW: Thank you very much.

20 DR. GORDON: Thank you for your forbearance.

21 We are running a little late so that is why we got into
22 this bind.

1 Denise Edwards.

2 MS. EDWARDS: I want to thank you for inviting
3 the Oncology Nursing Society to be part of this meeting.
4 We are certainly honored to be part of this group who
5 have done so much and is going to do more for
6 complementary medicine.

7 The Oncology Nursing Society has had a
8 commitment to education in complementary medicine for at
9 least 20 years, and that is partially I think because it
10 has always been tied to aggressive symptom management, so
11 it has always made sense to provide continuing education
12 in this area. Also, the Oncology Nursing Society has
13 been very responsive to the demand of its members, and
14 they have requested to have sessions on complementary
15 medicine and some skills training at all the annual
16 meetings.

17 I am also a mental health nurse-practitioner in
18 a complementary medicine center, the Center for Health
19 and Well-Being. That is a center in Des Moines, Iowa.
20 Nice of you to give me the same weather. I wanted
21 alternative weather when I got here.

22 [Laughter.]

1 MS. EDWARDS: It has been very consumer driven.
2 It was established by two of the major hospitals in Des
3 Moines and has been very responsive to the consumer
4 needs.

5 I am going to modify my written remarks, really
6 so I don't overlap and, also, so I avoid that adverse of
7 stimulus that you have set up to keep us on track within
8 time limits.

9 Education in nursing programs, as you have
10 heard, has been very inconsistent. It is somewhat driven
11 by faculty teach what they know well, and one of the
12 things that they may know well is complementary medicine,
13 but they may in fact not know that very well. So you end
14 up with nursing students as well as faculty who are just
15 as vulnerable as the consumer to misinformation.

16 So one of the recommendations that I would make
17 is to have training programs -- and let me say a little
18 bit more about train-the-trainer. I think the mistake
19 sometimes, from my perspective, has been to set up
20 discipline-specific models, and that is not necessary.
21 We have some wonderful models out there for pain
22 management that invite all members of the health care

1 team to learn at the same time.

2 There is a great model in a different field
3 which is ethics which has really helped faculty, and that
4 is the one that is offered at Georgetown, where you bring
5 all the disciplines together to learn the information.
6 The Georgetown model doesn't create an ethicist, it
7 creates somebody who has got a model to bring back for
8 good decision making.

9 These programs wouldn't train skilled
10 practitioners, they would educate people who could then
11 come back and educate other people in the field. That
12 has certainly been a lack in some of the nursing
13 programs, although you have heard some of them are very
14 exceptional. A good example is the University of
15 Minnesota that offers 11 interdisciplinary CAM
16 interventions, so that nursing students are with medical
17 students are with pharmacy students.

18 I would also go a step further with that
19 recommendation. For several years, I had the opportunity
20 to teach a wonderful course called "Ethics in Medicine"
21 that was offered through Harvard Divinity School, in
22 extension. So, in addition to the traditional learners

1 that you would expect to have there, there were many
2 adult learners who came to take the course. There has
3 been a lot of emphasis on bringing back adult learners at
4 reduced rates, senior rates, into the academic community.
5 This way the students not only hear the content, they are
6 interacting with people who are the consumers of the
7 system and can give them a very good idea of what the
8 cultural concerns are in their environment.

9 To be culturally competent today, you have to
10 know about CAM interventions. That is mainstream
11 culture. That is not even talking about specific
12 entities that come from diverse cultures. We really need
13 to be familiar with that. An example for me recently was
14 when we offered an infertility program and part of it was
15 incorporating yoga, and that was not comfortable for many
16 people for religious reasons in my community. I hadn't
17 anticipated that. I didn't know that that would be a
18 barrier to care. So even, I think, those of us who have
19 been involved in CAM practice for many years may find, as
20 we move around the country, there are particular cultural
21 concerns.

22 I would also recommend that a core curriculum