

1 collaborative efforts, and case studies. The acceptable
2 double-blind approach to research, although appropriate
3 for traditional allopathic research, is not appropriate
4 for CAM procedures.

5 The ACA is encouraged by the agenda put forth
6 by the Commission and looks forward to working with you
7 on your formal recommendations. Thank you.

8 DR. GORDON: Thank you very much.

9 Are there questions from Commission members?

10 DR. JONAS: I just wanted to clarify a bit the
11 last statement about traditional double-blind procedures
12 not being appropriate for CAM practices.

13 Is that an official belief of the American
14 Chiropractic Association?

15 MS. LUCIS: If I could ask Dr. Rossner to
16 explain that, please. We were working with the
17 Federation on this.

18 DR. ROSSNER: I guess, just continuing from our
19 remarks of yesterday, to temper the interpretation of
20 randomized clinical trials with a touch of realism, not
21 to abandon it as invalid.

22 DR. JONAS: What I heard is that it is

1 inappropriate for CAM therapy, so perhaps the language
2 was not exactly correct.

3 DR. GORDON: Thank you.

4 Anything else?

5 [No response.]

6 DR. GORDON: Thank you very much.

7 Next, is Diana Chambers.

8 MS. CHAMBERS: Good afternoon. Thank you for
9 your time. I am Diana Chambers. I am the president of a
10 new 501(c)(3) organization called Friends of Health. We
11 are committed to fostering the art and science of
12 integrative medicine, to addressing the whole person,
13 body, mind, and spirit, and to advancing the overall
14 cause of integrated medicine.

15 Friends of Health does not speak for, practice,
16 or elaborate any individual modality, but we have
17 enlisted the collaboration of many of the major
18 distinguished figures in the field as members of our
19 advisory board.

20 Instead, Friends of Health seeks to create a
21 new attitude of cooperation and coordination among the
22 complementary and alternative practices themselves, and

1 between them all, and allopathic medicine. Friends of
2 Health also plans to partner with a different
3 constituency in specific ways to advance the movement
4 toward integrative medicine.

5 In response to some of the comments made
6 yesterday and today, given the breadth of representation
7 of the Friends of Health Advisory Board, we will seek, as
8 suggested by Dr. Claude Lenfant, to bring people from the
9 diverse alternative and complementary practices together
10 to express their views and to have a public voice, all
11 the while recognizing that members of the allopathic
12 community must be included in the gathering.

13 Also, yesterday and today, we heard several
14 references to the inadequacy of the language we are
15 currently using and the frustration that this engenders
16 in us. Friends of Health has begun a conversation on the
17 language and philosophy of healing, including
18 representatives from across the integrative healing
19 community as a service to the whole.

20 One of the areas we are looking at is the role
21 of poetry, drama, and metaphor in communicating about
22 ideas and practices that may be novel in society, rather

1 than assuming that our usual approach can readily
2 communicate the new.

3 So I would like to share with you a poem by
4 Edwin Markham that touches on one of the core issues
5 underlying the work of this commission:

6 "They drew a circle that shut me out;
7 Rebel, heretic, thing to flout.
8 Love and I had the wit to win.
9 We drew a circle that took them in."

10 Friends of Health is committed to drawing a
11 circle that takes in all the members of the healing
12 community, and it has been wonderful to hear that tone in
13 the Commission.

14 With regard to the specific focus of this
15 meeting on CAM research, Friends of Health is unique in
16 having established the services of a scientific advisory
17 committee to provide a continuing bridge to conventional
18 science. We are fortunate in having been able to secure
19 on this committee the active participation of eight
20 scientists and physicians of the first rank. Each holds
21 impeccable world-class credentials in their own field,
22 and in addition, brings a depth of reading, writing, and

1 background in the relation of modern science to
2 alternative healing practices.

3 I have several comments on your three questions
4 that you addressed to us, but as I am short of time, I
5 will do the last one only: How can we effectively
6 integrate the CAM and conventional research communities
7 to stimulate and coordinate research?

8 This integration cannot be a shotgun marriage,
9 with reluctant conventional researchers brought into
10 participation merely by the promise of money. As a
11 lecturer on this topic of integration, our chairperson,
12 Professor Rustin Roy, lectures on this topic at a major
13 university's college of medicine course, and it is clear
14 to him that this will be a stepwise process.

15 First, it would be unproductive to attempt to
16 integrate conventional researchers hostile to the data
17 and the paradigm of alternatives. Hence, documentary
18 evidence should be required from conventional
19 practitioners of their reading and writing and
20 understanding of alternative medicine.

21 Short courses such as those from the University
22 of Arizona and other sources should be made easily

1 accessible to all potential collaborators. In all such
2 coordinated research, it is absolutely essential that
3 reviewers be knowledgeable on both sides of the aisle.
4 Review of alternative practices by persons ignorant of
5 the theory and practice of the modality being reviewed
6 should be avoided at all costs.

7 Having said this specific comment, I would like
8 to close with a quote from Max Planck who said, "Science
9 cannot solve the ultimate mystery of nature. In the last
10 analysis, we ourselves are part of the mystery we are
11 trying to solve."

12 Thank you.

13 DR. GORDON: Thank you. Thank you for the
14 reminder.

15 Questions anyone? Yes, Charlotte.

16 MS. KERR: I would just like to use my time and
17 ask you to speak to No. 1, the question you couldn't get
18 in your time.

19 MS. CHAMBERS: Okay. The first question: What
20 can be done to expand the current research environment so
21 that practices and interventions that lie outside
22 conventional science are adequately and appropriately

1 addressed?

2 We feel this is of utmost importance. It
3 requires a considerable reeducation of the communities of
4 conventional science and derivatively science-based
5 medicine. Professor Roy, our chair, has learned in the
6 30 years of science and technology and society work that
7 he has done on the campuses, from Cornell, Penn State,
8 MIT, to Stanford, that only a very small percentage of
9 our practicing scientists are aware of the history,
10 philosophy, and social relations of science.

11 We have seen some success by having
12 presentations by highly respected and distinguished
13 scientists showing data observed in alternative healing
14 practices and presenting the case for the scientific
15 plausibility of the same.

16 We explicitly propose that exposure of the
17 medicine faculties of major universities to the views of
18 scientists familiar with both alternative medicine ideas
19 and data as well as fundamental science be strongly
20 encouraged. This will require only a search for well-
21 qualified bridge builders and a small organizational
22 effort.

1 Another easily accomplished approach is to
2 provide modest funds to support well-designed national
3 conferences to cover the same ground. For example,
4 Friends of Health recently cosponsored a conference at
5 Penn State that focused more narrowly on one modality of
6 Qigong.

7 Thank you.

8 DR. GORDON: Thank you.

9 Joe?

10 DR. FINS: I just want to endorse your comment
11 about the arts and the power of -- and its translation
12 into an artistic forum, and just say that the play "Wit,
13 the Pulitzer Prize-winning play, has done a lot to give
14 people an opportunity to voice their frustration with
15 conventional practitioners. I think, if we were to have
16 a second phase of "Wit," it would be when they went to
17 the alternative practitioner for assistance because they
18 didn't find comfort in the mainstream.

19 But I was wondering, specifically, whether or
20 not, in your view, one of our funding priorities might be
21 to fund, maybe through NEH or something, the National
22 Endowment for the Humanities, funding for these kinds of

1 activities. Would that be something that your
2 organization would endorse?

3 MS. CHAMBERS: I think that would be terrific.
4 I think that working with the language issue, we heard
5 from several people, how frustrating it has been and how
6 we need to find some language that is multilingual but
7 which can represent this movement toward integrated
8 medicine. I think it would be great.

9 DR. GORDON: Bill?

10 DR. FAIR: Well, since we are waxing poetic,
11 and especially Edwin Markham, another poem comes to mind
12 that more or less points out the opportunity of this
13 committee, and that is:

14 "For all your days prepare,
15 And treat them ever alike,
16 When you are the anvil there,
17 When you are the hammer strike."

18 I think this is a great opportunity for us to
19 strike for CAM.

20 DR. JONAS: We have been talking about science
21 and rigorous methodology, but what I heard from you,
22 really, is actually -- a quote from Harold Wallach here

1 -- that "Science is cooperative effort of scientists.
2 Thus, it is what people within science make out of it."

3 In other words, science is what scientists is
4 do. It is not necessarily a thing that you can aspire
5 to. Out of that also is the importance of credibility,
6 which is a social process. It is not a process of good,
7 rigorous methodology. It is really a who-do-know. It is
8 very much like politics.

9 MS. CHAMBERS: Right. Thank you.

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

11 MS. CHAMBERS: Thank you.

12 DR. GORDON: Next is Monica Lenz.

13 MS. LENZ: I would like to thank Dr. James
14 Gordon and all the committee. It is the first time that
15 somebody gives permission to talk about my experience and
16 about my research on cancer. It seems nobody is
17 interested in it because it is not the same research
18 which is normally done.

19 The group is a feminine white population of
20 cancer. It took me one year to do it, three years to see
21 if it is correct. At the end of this year, or beginning
22 of next year, it will be implemented in a larger group.

1 You will ask how many people did I analyze.
2 The only person I can analyze is myself. It is
3 impossible to comment to another person. I had cancer
4 three times myself. I didn't take the normal treatment
5 because my intuition told me it is not for me. I had to
6 flee my country to go up to Russia, where I hoped that
7 nobody would get in my way, and get me over to the
8 chemotherapy and to the other therapy.

9 The doctors could not explain how I created the
10 cancer. Interesting. I worked with creativity, so I
11 created something. If they would explain me how I
12 created it, I can decreate it. Since they couldn't
13 explain it, I had to find out. Day by day, I monitored
14 and I got the cancer away. I got a new cancer, but it
15 was faster to get rid of it.

16 So the point is, I don't come from a medical
17 background. I am a philosopher, and in philosophy we are
18 dealing with life and not with death. We know in
19 philosophy, the more intelligent the questions, the more
20 intelligent the answers will be.

21 So my invitation is for all of you who do
22 research to put up new questions, to go into a higher

1 level. I wasn't sick in the body. I was sick in the
2 spirit. I didn't live the life I came to live. I
3 thanked god every time I got cancer again because it
4 showed me, this is not your way, girl. Hands off. You
5 can do something more, something better.

6 Now, I will start with a group in Columbia,
7 where I live now, with children who can't pay the normal
8 treatment to get them off the cancer, but to get them off
9 of society who tells them, this is a deadly problem, a
10 deadly sickness.

11 I would say to each of you, cancer is a
12 wonderful experience, and it is not life-threatening. It
13 brings your life back. Thank you.

14 DR. GORDON: Thank you very much.

15 Charlotte?

16 MS. KERR: Thank you. Columbia where?
17 Columbia, the country?

18 MS. LENZ: Columbia, South America.

19 MS. KERR: I had a feeling you were going to be
20 far away.

21 MS. LENZ: It is not so far, a few hours of
22 plane ride.

1 DR. GORDON: Wayne?

2 DR. JONAS: With great trepidation, I ask, what
3 did you do to decrease the cancer?

4 MS. LENZ: You know, I had, first of all, to
5 think what I didn't like in life, because there is one
6 thing which breaks the cycle of cancer. If you find out
7 what you didn't accept, and accept it, then you stop the
8 cancer as you stop a car. It is easier to stop it.

9 What I did is my treatment because this is my
10 life. I always do what I like to do. You should better
11 ask, what did I not do. I was singing with Pavarotti, of
12 course, on a CD.

13 [Laughter.]

14 MS. LENZ: I was dancing waltz. I threw away
15 all my dresses and got a new wardrobe because I started a
16 new life. Somebody told me I should make an Indian
17 treatment, but I went on my trip to Russia. I passed
18 through France. I said one must be crazy to do in France
19 an Indian treatment. I am in France. So, what did I do?
20 What I love is the sea, so I made thalassotherapy.

21 To get back to life, the most important
22 thing was the Buddhric, which is linseed oil with yogurt.

1 After one week, I wasn't tired anymore. The worst thing
2 is to be tired, and to kick off everybody around me,
3 family, friends, because a year later I found out what is
4 the bad thing about it. They are all afraid of their
5 death, not of yours. You are feeling so bad, and you
6 have all this energy on you. So you cannot even breathe.
7 I had the possibility to do it because I was the
8 instrument of my will, but I speak here in the name of
9 Bruna.

10 Bruna was, in my seminars, the youngest person.
11 She was 12. She passed away in the States with cancer,
12 having a normal treatment, and she didn't want to have
13 it, and nobody helped her. So I hope when this session
14 is over, that we have, soon, out on the streets, a
15 smorgasbord of possibilities so everybody can choose what
16 he likes because it is a one-person treatment. Everybody
17 must have his experience. We can't multiply the
18 experiences.

19 DR. GORDON: Great. Thank you for reminding us
20 of the mystery, and also of the uniqueness and the
21 playfulness.

22 We have another panel coming up. Thank you

1 very much, all four of you.

2 Ned Hartfield, Boyd Landry, Richard Pavek, and
3 Thomas Deboroski [ph].

4 So we will begin with Ned Hartfield, please.

5 MR. HARTFIELD: Thank you, Jim. Before I talk
6 a little bit about our work, I would like for everyone to
7 just take about 20 seconds and experience it. In order
8 to do this, I think it will feel nice after lunch break,
9 for everyone just to gently come up onto their feet.

10 Coming up onto your feet, just take a nice big
11 breath in and lift the hands up to the sky. That is
12 wonderful. Now, just take that right palm and just place
13 it on the ceiling, and left palm, just place it down
14 toward the floor. This is called the Heaven-and-Earth
15 Stretch.

16 Breathe in and just press that right palm to
17 the ceiling, left palm to the floor, feel that heart
18 expand. Exhale, soften the arms; inhale, lengthen.
19 Nice. Exhale, soften. Just one last time. Inhale,
20 lengthen. Press that right palm to the ceiling, left
21 palm to the floor. Wonderful.

22 Bring the hands back to heart center, and we

1 will just balance off on the left side. Inhale. Left
2 palm, lift it up toward the sky. Doesn't that feel good?
3 Your right palm to the floor. Exhale, soften; inhale,
4 lengthen, spine lengthens; exhale, soften.

5 Last time. Inhale, lengthen. Last time, go
6 for it. Exhale, soften. Bring the hands back to the
7 heart center and float the arms down, and come to your
8 seats.

9 My name is Ned Hartfield. I work with the Life
10 Foundation International. We are a team of doctors,
11 nurses -- my own background is in nursing -- and
12 complementary health specialists. We have been working
13 for 20 years in Europe, teaching what we call body-heart-
14 mind techniques.

15 Body-heart-mind techniques are a series of
16 movements, breath work, visualizes, affirmations, and
17 hand mudras that help to transform emotional pain. We
18 have compiled a lot of our teachings into a book which is
19 a bestseller in the Netherlands called the "The Dance
20 Between Joy and Pain."

21 Each chapter takes an emotion, like grief,
22 anger, fear, and shows what movements, affirmations,

1 techniques can be used to transform the energy of that
2 emotion into its positive counterpart. For example,
3 grief can become hope. Fear can be transformed into
4 courage. Anger can become a great source of creativity.

5 So over the last five years, our team has gone
6 to crisis areas of the world. We have gone to places
7 like Bosnia, Chechnya, the south Sudan, Northern Ireland,
8 into Nairobi to work with some of the Rhuwandan refugees
9 there, teaching these same kinds of movement to help
10 people heal from emotional pain.

11 One of our senior staff, who has been all over
12 the world, actually will be coming to the Washington area
13 in November on the 18th to teach some of the techniques
14 here. So anyone that is interested can see me.

15 But I really wanted to do was to give the
16 Commission a gift and to, on behalf of the Foundation,
17 just applaud you for what you are embarking on. I
18 brought with me on the table there a light in the
19 lantern. It is a light that has been lit from an eternal
20 flame of hope called the World Peace Flame. As our
21 therapists have been working all over the world over the
22 last five years, we are searching for a symbol of hope.

1 About a year and a half ago, we invited leaders from
2 seven continents to light a Flame of Hope, and the air
3 forces of the world helped us to transport these seven
4 flames to the United Kingdom where they were united to
5 form one World Peace Flame, the Flame of Hope.

6 I have a candle that has been lit from that
7 World Peace Flame. It is not lit right now, but the wick
8 has been lit. I would like to give it to Jim and the
9 Commission.

10 As you meet over the next several months,
11 please light it when you have important meetings, and may
12 it bring immunity, hope and direction, and light, to the
13 Commission and your work in making complementary health
14 possible to so many more people. Thank you.

15 DR. GORDON: Thank you very much, Ned.
16 Charlotte?

17 MS. KERR: Bless you, more than even thank you.
18 That was very moving.

19 How do you get support for going to these
20 places and doing this incredible work? How are you able
21 to do that?

22 MR. HARTFIELD: We have training centers in the

1 Netherlands and in England where we offer courses. So
2 people from all over Europe have come, many people with
3 cancer, actually, and other life-threatening illnesses
4 have come. We teach these body-heart-mind techniques and
5 we have had amazing results from people, as the woman who
6 just spoke, similar results to that.

7 We sell books like this, and tapes, and we get
8 contributions from loads of people that have benefitted
9 from our work as well.

10 DR. GORDON: Other questions?

11 [No response.]

12 DR. GORDON: Thanks so much. I look forward to
13 seeing you.

14 MR. HARTFIELD: Thank you.

15 DR. GORDON: Boyd Landry.

16 MR. LANDRY: Good afternoon. My name is Boyd
17 Landry, and I am executive director of the Coalition for
18 Natural Health, headquartered here in Washington. I
19 think, first of all, I would like to say I don't have a
20 poem or anything, but I do have one saying, and that is
21 that there are three stages in life. There is youth,
22 there is middle age, and there is, hey, you are looking

1 really good today.

2 [Laughter.]

3 MR. LANDRY: As I have been here over the last
4 day and a half, and I have listened to some very
5 compelling presentations and very provocative
6 presentations, I think one of the observations that I
7 have made is that vocabulary and the usage of the
8 vocabulary is extremely important.

9 Descriptions of Western medicine and
10 scientific-based medicine as being traditional is wrong.
11 It is conventional. Science-based medicine has about as
12 much claim to the word "traditional" as humans have for
13 being on earth the longest as a species. I think if you
14 think of it in terms of that, it comes to be very clear.

15 Therapies that fall under complementary and
16 alternative have more claim to the word "traditional"
17 because they have been around a lot longer. In terms of
18 research, and that is the topic of these sets of
19 meetings, the Inca civilization, Native American Indians,
20 French traders, and Old English herbalists didn't go
21 through a scientific model to prove what they already
22 knew worked.

1 I think that as long as we keep that in mind,
2 and there isn't a tremendous, or even a significant,
3 amount of harm, then people should have a right to access
4 those therapies, and those practitioners that provide
5 those therapies ought to have the free and open right to
6 do it. I think that is ultimately what is important.

7 We, as an organization, wholeheartedly favor
8 the medicine establishment's openness to natural health
9 approaches, however this must include a recognition of
10 the holistic philosophy behind natural health. The value
11 of complementary and alternative medicine will be lost if
12 natural health remedies are forced into the allopathic
13 box.

14 For example, if CAM research is simply
15 performed to the allopathic model, looking at herbs and
16 dietary supplements as substitutes for conventional drugs
17 to treat illness symptoms, it may come at the expense of
18 the focus on wholeness and wellness which makes holistic
19 therapies distinct.

20 I think that is the best way I can end my
21 presentation. Thank you.

22 DR. GORDON: Thank you. Can you just tell us a

1 couple words about your organization?

2 MR. LANDRY: We are a national organization
3 that represents natural and holistic practitioners that
4 look at their practice in a wholeness and holistic
5 aspect. We do a lot of our work on the state level
6 because that is generally where these types of issues are
7 typically discussed, but we also would like to provide as
8 much as we can to the Commission as you embark on this
9 process.

10 DR. GORDON: So it is a membership
11 organization?

12 MR. LANDRY: That is correct.

13 DR. GORDON: How many members do you have?

14 MR. LANDRY: We have about 2,500 nationwide.
15 There are thousands and thousands of people, and they
16 live in fear daily because of the onslaught of
17 conventional medical lobbying, and persecution and
18 prosecution that exists all over this country.

19 How we draw them out is, I think, one of the
20 things that you ought to look at. Without fear of having
21 the Medical Board knock on their door, seize all their
22 files, seize all their records, and threaten to put them

1 in jail, and that happens. There is a case in Michigan
2 that was just dismissed, where the woman's door was
3 knocked down and her home was raided by the Medical
4 Licensing Board, and she didn't do anything wrong.

5 DR. GORDON: I gather you were giving us a
6 recommendation, which was that in a case where no one has
7 done any harm, they should be allowed to practice,
8 whether or not they have any kind of license. I am not
9 trying to put words in your mouth.

10 MR. LANDRY: That discussion comes later in a
11 future meeting. I will have more and more to say about
12 that issue. But with respect to research, I think that
13 what is important, because that is the topic that is
14 being discussed these two days, that to force these
15 therapies into that strict and reductionistic procedure
16 which conventional medicine utilizes would totally
17 destroy what makes these therapies distinct.

18 It is what the public wants, and they will
19 figure out what works far faster than you can figure it
20 out by researching it.

21 DR. GORDON: Dean?

22 DR. ORNISH: Just two questions. What research

1 methodologies would you recommend, then, if not that?

2 MR. LANDRY: Well, this country was founded on
3 an open and free market. That is why the statement I
4 made just now, that the public would figure it out far
5 quicker than science would figure it out.

6 It is very easy to find 300 or 3,000 people
7 that have hypertension, for example. There is a drug out
8 there that purports to deal with hypertension and cure
9 hypertension, and you can determine whether or not that
10 works, but to find 3,000 people that have the same body
11 chemistry that will synthesize an herb or herbal product
12 the same to be able to get an actual study out of it,
13 isn't very likely.

14 DR. ORNISH: I understand what you are saying
15 about the limitations of science, but again, this is not
16 to judge, this is to try to understand. What you are
17 saying is that we shouldn't do any research at all, that
18 people should just go in the open market and figure out
19 what works best by trying them out?

20 MR. LANDRY: What you ought to try and research
21 is how you can best give the public greater access.

22 DR. ORNISH: Well, access is a separate issue.

1 As you say, we are focusing on research here. So just to
2 understand your position, you are saying that we
3 shouldn't do any research, that people should have access
4 to everything and sooner or later people will talk
5 amongst themselves and figure out what works and what
6 doesn't?

7 MR. LANDRY: Well, I guess, in essence, to
8 answer your question and not to go across the line I
9 probably don't want to go across, and that is that if
10 there is a propensity of harm, then something ought to be
11 determined what that propensity is.

12 I don't know, there are 140,000 deaths a year
13 that are caused by adverse drug reactions. I can't tell
14 you that there are very many, if any, from people dying
15 of --

16 DR. ORNISH: No, I understand all that. I am
17 just trying to get a clear answer to my clear question.
18 What are you recommending? We know what you are not
19 recommending. What are you recommending? Are you
20 recommending that there should be no research, that the
21 propensity to harm will come out, that the propensity to
22 benefit will come out by, just, people talking amongst

1 themselves that we don't really need any studies at all?

2 MR. LANDRY: Well, I think practitioners are
3 going to study amongst themselves. I don't know how to
4 clearly answer your question other than to say that the
5 current process isn't working. Now, what is the magic
6 crystal ball answer? I don't really know, but if you
7 simply focus on the same box that has existed for 75
8 years, I don't think you are going to get anywhere.

9 DR. ORNISH: Last quick question. I don't know
10 if you are going to be at the next session or not, but
11 just in a nutshell from the services standpoint, you are
12 also recommending there should be no regulation, no
13 licensure, that people should be able to practice
14 anything they want, and again, that people will somehow
15 find out what works amongst themselves.

16 MR. LANDRY: As long as it doesn't involve
17 things that are invasive, where the potential for harm is
18 of a serious nature, then the public domain works very
19 well with respect to complementary and alternative
20 therapies or holistic therapies, because we are simply
21 talking about giving people, empowering people with their
22 own individual health and giving them that, and let them

1 make their own decisions.

2 After all, there are many states in this
3 country that if you walk out of your doctor's office,
4 your physician's office, and you choose not to do what
5 they tell you to do, the only legal thing you can do is
6 go home and sit in your rocker.

7 DR. ORNISH: The final thing is that the
8 presumption in what you are saying is that unless there
9 is something invasive, that complementary and alternative
10 medicines are all safe.

11 MR. LANDRY: I didn't say that.

12 DR. ORNISH: Then, what are you saying?

13 MR. LANDRY: What I said was, if there is a
14 propensity for harm, or if the practice itself is
15 inherently harmful, then regulation probably should be
16 involved, but if there isn't any, then there ought not be
17 any regulation of a licensing nature.

18 DR. GORDON: Tieraona.

19 DR. LOW DOG: I am actually sympathetic to many
20 of the things that you are saying. I know that in
21 England, because of Henry the Eighth's charter,
22 herbalists can practice legally and freely in England

1 without any training, but even though, they have
2 restrictions and Part I and Part II poisons and who has
3 access to certain herbs.

4 I want to see if you agree. Part of the gift
5 that, perhaps, science can bring is establishing safety.
6 Efficacy, I think a lot of that will sift itself out in
7 the public. A good example for me has always been,
8 coming from a Native American community, that for
9 hundreds and hundreds, and possibly longer, hundreds of
10 years, women consumed alcohol during pregnancy. That is
11 not a Native American thing, but that is when it really
12 was realized to the extent that it was because of
13 alcoholism on the reservations.

14 There was evidence of fetal alcohol syndrome
15 500 years ago, but we didn't associate alcohol and birth
16 defects and fetal alcohol syndrome until 1972. It took a
17 long time to understand the harm that came from a
18 practice, even though it was prevalent in society.

19 So sometimes harm, and chronic harm, can be
20 difficult things to assess. I think science has a real
21 gift that it can play without impeding people's rights to
22 practice and rights to access.

1 Would you agree that, in perhaps that case,
2 science can be appropriate?

3 MR. LANDRY: Right. I think a lot of the
4 things that are commonly sold. If there was a tremendous
5 amount of problems associated with them, we would have
6 already found out.

7 Now, new things --

8 DR. GORDON: Excuse me. There is somebody who
9 is coming in to testify by phone and are scheduled to
10 call, and that is what is happening. So forgive us for
11 us for the --

12 [Interruption.]

13 MR. LANDRY: I think one of the things,
14 especially in nature, and you will probably understand
15 this more than anybody else, that within the confines,
16 and I believe it is about a 10-yard circumference around
17 a poisonous plant, is the anecdote. Just little things
18 like that.

19 DR. GORDON: What I would like is, at least if
20 you would come for public comment during the licensure
21 discussion.

22 MR. LANDRY: I would like to make a

1 presentation, if that is available. I was going to
2 contact Dr. Groft.

3 DR. GORDON: Contact Dr. Groft. That is
4 certainly a possibility.

5 MR. LANDRY: I would be glad to.

6 OPERATOR: I have a Dr. Cramer on the line.
7 Dr. Cramer, are you there?

8 DR. CRAMER: Yes.

9 DR. GROFT: Elaine? Hello?

10 DR. CRAMER: I was trying to call you guys for
11 the last 45 minutes.

12 DR. GROFT: Our apologies. We missed you.

13 DR. CRAMER: It's okay. I am here now.

14 DR. GROFT: Do you mind holding on? We are in
15 the midst of an open public session with speakers, and we
16 have, what, two more to go.

17 DR. GORDON: Two more speakers.

18 DR. GROFT: So maybe a total of 10 more
19 minutes. So just hold on, please.

20 DR. CRAMER: Sure.

21 DR. GORDON: Are there any other questions for
22 Boyd Landry at this point?

1 DR. LOW DOG: No.

2 DR. GORDON: All right. Thank you.

3 Next is Richard Pavek.

4 MR. PAVEK: I am Richard Pavek again. I want
5 to give you two intersecting thoughts. There is a
6 growing segment of the population that believes the fewer
7 medications, the better, and are turning wherever
8 possible to drugless therapies. Several of these fall
9 into the category of hands-on biofeel therapeutics. All
10 of these, therapeutic touch, healing touch, and my own
11 physiomuscular release therapy, have demonstrated the
12 ability to reduce or eliminate medications for anxiety,
13 pain, and mild sleep disorders, to name a few.

14 Taken together, there is a considerable body of
15 research to support efficacy, but the concept of
16 promoting research to reduce medications does not appear
17 to be a focus of the NIH.

18 There is a belief among a number of physician
19 that have personally spoken to me, and others as well,
20 that once we have a good drug for the condition, we don't
21 need to look any further. I think we do. I think
22 researching drugless treatments should be expedited.

1 Surely, this fits into the idea of bettering
2 the health of the people. Also, I submit that subjecting
3 therapies of this type to the same research review
4 process that was designed for dangerous toxins and
5 potentially damaging chemical products is totally
6 inappropriate. These therapies have demonstrated no
7 downside risk that I know of. There may be some, but it
8 certainly hasn't been very apparent.

9 There are estimates now of perhaps half a
10 million people trained in these various therapies,
11 utilizing them professionally and non-professionally for
12 treatments for friends, clients, and otherwise. I came
13 out of the fields of aeronautics and electronics. It is
14 inconceivable to me, from my experience, that there would
15 be one measuring tool that would measure everything that
16 I wanted to work with. It just doesn't make sense.

17 The idea of a randomized double-blind study
18 which was designed to commonize the study population by
19 filtering out individual characteristics, how can that be
20 applied to therapies that deal with individual
21 characteristics? It is upside-down. Now, I have no
22 quarrel with the double-blind randomized trials being

1 used for the places where they are appropriate, but it
2 simply isn't appropriate for work of this type.

3 I know that we are going to hear some
4 presentations on other approaches which fit this much
5 better, but as to the first thing that I had to say, I
6 really think this idea of getting rid of drugs wherever
7 possible is appropriate. I know that in my own life,
8 through these means, and other means as well, I take far
9 fewer pharmaceuticals than I had at any previous portion
10 in my life, and I am a lot more healthy.

11 DR. GORDON: Thank you, Richard.

12 Are there questions for Richard?

13 [No response.]

14 DR. GORDON: Thank you for coming again.

15 Thomas Deboroski.

16 MR. DEBOROSKI: Good afternoon. My name is
17 Thomas Deboroski, and I am a struggling entrepreneur.
18 There I have said it. I appreciate the opportunity to be
19 with you today, and I thank you for your efforts.

20 My company has developed some targeted
21 nutritional products, utilizing some rather unique
22 product design strategies that have been shown to be

1 pretty effective, in a pilot study, at migraine
2 prevention.

3 Prior to my present effort, I spent six years
4 helping to market a rather unique predigested fish powder
5 to the alternative doctor community. So I had the
6 opportunity to see the naturopaths and the chiropractors,
7 and the whole gamut, and it was all very interesting.
8 That followed a career in commercial lending in the
9 banking industry. There is a little divine inspiration
10 somewhere in there that changed my career.

11 I come to you today to share a few thoughts and
12 to ask a couple questions, for whatever you decide they
13 are worth. One of the things I was going mention, I will
14 just brush on quickly, is my concern that the gold
15 standard of scientific research, that being the blinded
16 study, may have a little fool's gold attached to it, in
17 that, we also can't ignore the second gold standard of
18 scientific research.

19 I don't come from a scientific or medical
20 background, which you will probably be able to tell. The
21 other gold standard in scientific research has always
22 been the individual practitioner or scientist's ability

1 to observe. I think this was brought up yesterday a
2 little bit. Certainly, outcomes-based instruments are an
3 option in allowing that to be recognized.

4 As a layman and a business man, I struggle with
5 the definition of the word "disease." One of the reasons
6 I am here is I am concerned as we accomplish what we
7 intend to accomplish relative to targeting nutritional
8 products for specific disease states, then I am not going
9 to be allowed to say it.

10 Now, if you go the American Medical Association
11 web site and you look up colitis, migraine, arthritis,
12 any number of chronic disease states, somewhere in the
13 midst of that literature, they will admit that this is a
14 disease that is incurable of unknown cause.

15 Now, if it is incurable of unknown cause, how
16 do you define it? And more importantly, how do you heal
17 it? In our targeted nutritional approach, we have had
18 success in people no longer getting migraine headaches.
19 I don't know where to go with the definition. Then the
20 FDA, of course, establishes their regulations based on
21 definitions that seem to be incomprehensible to me as a
22 business man and a layman.

1 I don't think we can underestimate the value of
2 empowering the patient. One of the things that I say to
3 my friends when they ask me how I am doing, I say, look,
4 what I have learned is that it is not important whether
5 you go to the doctor and get a drug, go to the naturopath
6 and get an herb, go to this guy and get that. What is
7 important is that as an individual you pursue all the
8 options that are out there for you.

9 In the path of learning, somewhere along the
10 way, you come to the place where you say, gee, that makes
11 sense. It is my belief that at that point you have
12 aligned mind, body, and spirit to accept that treatment,
13 and you have increased your chances of responding,
14 probably, by several hundred percent.

15 The last thing I wanted to mention was an
16 organization that may be of value, not only to the
17 committee, but to others who have spoken before me, and
18 that is an organization that I am aware of. I don't know
19 if your organization has talked to them or not. It is
20 Medical Outcomes Trust. They are an M.D. organization
21 out of Boston, and they have designed outcome-based
22 instruments. Fortunately, for us, one of them being the

1 migraine-specific Quality-of-Life Survey.

2 They have also designed other instruments,
3 which may be valuable in a clinical setting for looking
4 at health related, quality of life issues.

5 I want to mention the Medical Outcomes Trust
6 because I think it had value to people that are looking
7 for measurements. I don't know that their work has been
8 widely publicized. We use their migraine-specific
9 Quality-of-Life Survey in our migraine study. It was
10 actually designed by Glacxo when they got Imatrex
11 approved. It is a pretty simple instrument, and I know
12 they at least have an additional instrument called the
13 Health Related Quality of Life Survey.

14 The interesting thing about these instruments
15 is they have gone through scientific review. There are
16 research articles on assessing and establishing the
17 validity of the instruments.

18 DR. GORDON: Great. Thank you very much.

19 Are there questions? Wayne.

20 DR. JONAS: I just want to emphasize the
21 importance of outcomes measurement, because in all this
22 discussion we have had all day yesterday, I don't think

1 anybody really specifically talked about it. I think
2 outcomes issues are extremely important in terms of doing
3 research that addresses or provides a kind of information
4 that are important to certain types of audiences.
5 Different types of audiences want different types of
6 information.

7 If you are interested, and I am not saying this
8 is the only thing, but if you are interested in getting
9 patient-relevant outcomes, then obviously you have to
10 have validated outcome measures that also have face
11 validity and have been validated on the population that
12 you are going to study. So having instruments like this,
13 I think, is extremely important so that we don't do
14 surrogate measures that might not be relevant, in fact,
15 to the public, if that is what our target audiences are.

16 So I am glad you mentioned that. There are a
17 number of other groups. At least, I am very familiar
18 with Medical Outcomes Trust and the work of John Wehr
19 [ph] and many others that have done those types of
20 things. It has been mostly in the context, however, of
21 health services research, and very rarely is it brought
22 into efficacy and effectiveness trials. So I think doing

1 that and bringing those together is extremely important.

2 DR. GORDON: I also wanted to say I appreciate
3 all four presentations. The last three of you, in
4 particular, are bringing to our attention an issue we do
5 need to pay attention to, which are those people, call
6 them traditional healers, folk healers, unlicensed, or
7 uninterested in being licensed, healers. I think that
8 part of our mission is to understand who these people are
9 and how they function and how they do and how they might
10 fit into this whole health care scheme around the
11 country.

12 So I really appreciate it. All three of you
13 shed light on it from different perspectives, and I want
14 to thank you for that. And thank you, too, of course,
15 Ned. We will see you.

16 We are coming to a panel, and hopefully we will
17 be in touch with Spain very soon. This panel is on
18 outcomes research. There are three people who are
19 embodied in the room. If you three could come and sit at
20 the table, Leanna Standish, Lydia Segal, and Douglas
21 Lloyd.

22 So what we are going to do is wait for Elaine

1 Cramer to call in. We will begin the session, and then
2 when she calls, we will grab her. Steve says we will
3 grab her. So forgive us if technology is a little
4 imperfect here.

5 The first speaker is Dr. Leanna Standish from
6 Bastyr University.

7 DR. STANDISH: I want to take my first
8 opportunity to take just a moment to celebrate the
9 amazing successes that we have seen in the development of
10 CAM research since the establishment of the Office of
11 Alternative Medicine in 1992.

12 When I first got involved, and many of you in
13 the room have been involved since then, I think there
14 were two main obstacles before us, and those were a lack
15 of federal funding for CAM research, and the other one
16 was lack of fair peer review of CAM proposals at the NIH.
17 It appears as though those two obstacles have diminished
18 significantly in the last eight years, and I just want to
19 take a moment to thank Steve Groft and Wayne Jonas for
20 their wonderful in accomplishing both of those goals.

21 In my estimation, we now face four main
22 obstacles in front of us around CAM research, and they

1 are a need for infrastructure and research training at
2 CAM institutions, CAM academic centers, that have true
3 CAM expertise.

4 Much has already been said about this. I am
5 not going to dwell upon it. When you come to Seattle at
6 the end of October -- some of you will be visiting us in
7 Seattle -- I am sure there will be more opportunity to
8 talk about that. I would rather focus my comments on the
9 other three obstacles, the first one being FDA policies
10 and procedures.

11 Despite the fact that we have made great
12 progress in the relationship between CAM researchers and
13 CAM practitioners in the FDA, I think we have a long way
14 to go. I thought I would make this alive for you by just
15 telling a story of an actual thing that happened in my
16 research domain. In 1994, the Office of Alternative
17 Medicine, through a cooperative agreement with the
18 National Institute of Allergy and Infectious Disease,
19 gave a grant to Bastyr University to form an AIDS
20 research center focused on CAM.

21 One of our early actions was to fund a few
22 small pilot projects of innovative CAM research in HIV

1 AIDS. We put out an RFA, we assembled a peer review
2 committee. There was one proposal that got a very high
3 priority score and we wished to fund it, and it was a
4 double-blind, placebo-controlled trial of
5 homeopathically-prepared insulin like growth factor in
6 AIDS-related wasting.

7 Now, the reason why I want to tell this story
8 is because what happens when you are funded by the NIH,
9 and this happens to all of us who are PIs, principal
10 investigators, is you get a letter from the NIH that says
11 congratulations. You have been funded to do this
12 clinical trial, and now you need to get an IND, an
13 investigational new drug approval and license number from
14 the FDA to conduct this trial.

15 The principal investigator of this study, and I
16 as her project officer, decided the best course was to
17 request a waiver of an IND. So she went ahead and
18 submitted a letter with a half-inch pile of documentation
19 around this issue. The reason we wanted a waiver and we
20 thought that it was appropriate, is that, as most of you
21 know, in many homeopathic dilutions there are no original
22 molecules of the substance that was going to be delivered

1 orally.

2 This was five years ago. The FDA has not yet
3 made a judgement on this. It has been five years. Now,
4 I don't want to suggest in any way that there is
5 malintent at the FDA. I think the problem is that in
6 this particular area, ultra-high dilutional or
7 homeopathic preparations, there just isn't a box. There
8 isn't an office. There just wasn't a place, a desk, for
9 this to sit on. Even though there were many
10 conversations, there has really been no action.

11 So the answer to this question has not yet been
12 answered. This is not an isolated problem. In November
13 of 1999, in anticipation myself of doing a study in this
14 area of ultra-high dilutional biology, I wrote a letter
15 to the FDA, asking about an IND waiver for ultra-high
16 dilutional interleukin-2, which I think might be something
17 to look at in HIV disease. I still haven't gotten an
18 answer. Almost 11 months have gone by and there is just
19 no response, despite repeated attempts at contact.

20 I feel like this will improve significantly.
21 It was just so wonderful yesterday to see FDA, fairly
22 high-level, staffers here talking to us. It is a great

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1 moment.

2 My other issue that I wanted to bring up,
3 another obstacle, is the need for CAM understanding at
4 institutional review boards. Mostly at conventional
5 universities and medical schools that make go/no-go
6 decisions about CAM clinical trials.

7 I just want to give you a real-life example.
8 Hepatitis-C study. Bastyr University scientists thought
9 it was really appropriate to do a study on an eight-
10 medicine combination therapy that is used in clinical
11 practice all the time. We thought it was time for us to
12 actually do an evaluation of this program of treatment.

13 The Bastyr University IRB did a very vigorous
14 and thoughtful review, and ultimately approved the study.
15 Because we are collaborating with the University of
16 Washington, which is about 15 minutes away, the
17 Hepatology Department, we needed to go through the IRB as
18 well because we are doing biopsies that are totally
19 appropriate. Well, the IRB there, they are balking.

20 The reason they are balking is around this
21 combination thing, and we have gotten a letter saying,
22 well, we don't understand how you are going to know about

1 the independent effect of any one of these eight items.
2 Of course, our response is, that is not the research
3 question being asked. It is like a conceptual block, and
4 I can remember that block when I was on the other side of
5 the aisle.

6 The fourth obstacle is the one that I really
7 want to spend the remainder of my time on. It is the one
8 that this panel is about, which about practice-based
9 outcomes research. So I want to pose the question, why
10 have we made so little progress in the last eight years
11 in this area? I want to suggest some solutions to this
12 problem.

13 We have an excellent program at the National
14 Cancer Institute called the Best Case Series program. It
15 was started, as most of you know, in 1992, I believe. In
16 the last eight years -- I was just talking with Dr.
17 White, and he tells me -- there have been 30 contacts
18 made. Yet, out of those 30, only four Best Case Series
19 have been submitted in the last eight years.

20 Now, it is not for lack of trying. The Best
21 Case Series program needs not only advertising, which is
22 now being quite aggressive, and I really want to applaud

1 Dr. White and his office staff for initiating that, but I
2 think this program needs funding, and I think it needs
3 trust-building.

4 I would like to give you a little story.
5 Bastyr University was contacted about a year ago by a
6 rather well known, maybe notorious even, CAM clinician in
7 California who has been claiming to cure cancer. This
8 clinic called us up and said, would you help us do a Best
9 Case Series. I said I would love to, and I meant it. I
10 would love to do this. So they said, well, okay, what is
11 it going to cost.

12 So I sat at my desk and I really thought about
13 what would it take to choose the inclusion criteria, do
14 the chart reviews, find the pathology reports, get the
15 slides from the pathology departments, contact the
16 patients who are no longer in the state, search death
17 records, putting together a cogent document at the end to
18 submit to the NCI.

19 My estimated cost of that was between \$35- and
20 \$75,000. It takes time. Yesterday, we heard from Dr.
21 McCombs, who is sitting right here in your spot, and she
22 was telling us, I think, a very powerful story about the

1 difficulties of doing this kind of practice-based
2 research.

3 I don't really think it is feasible for someone
4 like Dr. McCombs to do a Best Case Series. It takes a
5 lot of time. So what I would like to see is partnerships
6 between CAM academic centers and CAM practitioners,
7 especially in the cancer area, to come together and to
8 have that collaborative work be funded by the NCI. I
9 think that kind of an approach would bring into the
10 arena, not only the funding necessary to do this
11 important work, but also the trust-building.

12 Then finally, I want to talk just briefly about
13 prospective outcome studies. They are hard. They are
14 very hard to do. I just want to give you an example.
15 One of the most pressing questions in my mind is, does it
16 really make a difference when a woman with breast cancer
17 goes to a naturopathic physician, receives comprehensive
18 care, and gets a treatment program? Does this make a
19 difference in terms of quality of life, survival,
20 progression, the kinds of things that we are interested
21 in?

22 We don't know the answer to that question. I

1 have done some thinking and some very deep consultation
2 about this, the same size. In order to know whether it
3 really does make a difference in, say, Stage 1, Stage 2
4 breast cancer, we would need a sample size of 2,500
5 patients. Now, to do that we need a network of
6 naturopathic clinics all over North America to
7 collaborate. We need a data central. This is going to
8 take money, it is going to take networking, and it is
9 going to take research clinical trials consortium
10 development.

11 I think we need to do that, not only in
12 naturopathic medicine, but in Chinese medicine, the
13 massage community. The chiropractic community has
14 already shown great leadership in this area. All the CAM
15 professions need to do this.

16 I just want to summarize -- not summarize, but
17 I want to say one last sentence, which is that we are at
18 a time now, all the issues are on the table. This has
19 been an incredible two days. I think every single issue
20 that we know is important as an obstacle to CAM research
21 has been discussed or mentioned in the last two days.

22 For the first time this year, I feel a

1 wonderful optimism about our ability to solve them.

2 Thank you.

3 DR. GORDON: Thank you very much, Leanna.

4 Dr. Lydia Segal, please, from Kaiser
5 Permanente.

6 DR. SEGAL: As Jim says, I am a physician
7 representing Kaiser Permanente. I would like to start by
8 having you all imagine that you have back pain. You have
9 been sitting here for two days now, and some of you
10 actually probably do have back pain. Imagine that this
11 back pain started a year ago.

12 After trying some over-the-counter ibuprofen,
13 some rest, doing all the logical stuff, you went to see
14 your primary care doc. Your primary care doc gave you
15 slightly stronger medication, maybe recommended some back
16 exercises, and you went home. Yes, you did some of them,
17 you didn't do some of them, but you didn't get a whole
18 lot better.

19 So you did what an otherwise intelligent person
20 would do, you went and asked your neighbors, your
21 colleagues, you checked the Internet, and, lo and behold,
22 there were all these other kinds of modalities. There

1 was chiropractic care, acupuncture care, massage. My
2 god, there were these supplements you didn't know
3 anything about.

4 You thought to yourself, does any of this stuff
5 work? My doc didn't recommend them. I don't know. So
6 with trepidation, you go back. Your doctor doesn't even
7 go there with you on that second visit, actually sends
8 you to the specialist who wants more tests and more
9 medication that you are actually not interested in doing.

10 You don't raise the issue, and maybe they don't
11 raise the issue either because maybe they are not so sure
12 about this stuff. They don't know what their colleague
13 is going think. They don't know whether their income
14 stream is going somewhere else. In the end, none of us
15 knows, the patient, the providers, we just don't know
16 what works.

17 Unless we do clinical outcomes research, we
18 will not know what is efficacious, what is effective,
19 what is safe, to respond to the conversations that were
20 just happening. We need to know that because the
21 ultimate value to the patient is being able to have a
22 wider choice of treatment modalities to help your back

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1 pain, and yours, and so forth, and to know which one is
2 effective.

3 [Interruption.]

4 DR. GORDON: We will hold the thought. Thank
5 you.

6 On the phone is Dr. Elaine Cramer, a medical
7 epidemiologist at the CDC from Spain.

8 Dr. Cramer, hi. This is Jim Gordon here.
9 Welcome. I think we are actually ready, willing, and
10 eager to hear you. We are waiting. What we have here is
11 the Commission sitting here. There are three other
12 panelists on the panel on Outcomes Research. We have a
13 number of people who are in the audience as well.

14 DR. CRAMER: Okay. You asked me to speak to
15 the issue of alternative research. In 1997, the CDC was
16 asked by a representative of the Office of Alternative
17 Medicine at the NIH to conduct some pilot studies to
18 assess the feasibility of a field investigation-style
19 approach to the evaluation of complementary and
20 alternative medicine.

21 Do you have that study in front of you?

22 MS. CHANG: Yes, we do.

1 DR. CRAMER: The study that is in front of you
2 is one of two of the studies that we conducted. The
3 first is a -- investigation that drew a number of
4 conclusions about the role of observational research in
5 the evaluation of the effectiveness of CAM therapies in
6 the clinical setting.

7 MS. CHANG: Yes. Go ahead.

8 DR. CRAMER: Conducting analytic observational
9 studies called, chart abstractional, by surveying
10 incoming patients in a clinical setting is relatively
11 easy, either retrospectively or prospectively, and I
12 think it is also relatively inexpensive. Using these
13 observational methods, we can characterize the scope and
14 practice of CAM, as well as describe patient socio-
15 demographics.

16 These data are useful for understanding the
17 spectrum of therapies and modalities that are used by
18 patients, and also for profiling the treatments
19 prescribed by practitioners. I think these data will lay
20 the foundation for priority-setting with respect to
21 identifying the most commonly used modalities and systems
22 of care, and also the populations who are using them for

1 directing funding and research efforts.

2 I think most of the limitations are inherent in
3 data collection and in interpretation using observational
4 studies designs involved, such as cohortive case-
5 controlled studies. With observational methods, we
6 generally analyze data collected from patients in a study
7 where we don't control the exposures, but from patients
8 who naturally select their own exposures. We simply
9 describe and document the outcomes.

10 I conclude that the experimental study design,
11 such as randomization of patients to various treatment
12 arms are the most useful and the most preferred methods
13 for evaluating CAM therapies for several reasons. First,
14 because of the limitations of abstraction based on
15 retrospective chart review, we are able to access all the
16 information that is adequately documented in the patient
17 chart. As you know, providers don't always write
18 detailed notes about all their symptoms, and it depends
19 on the priorities of the group.

20 So chart documentation varies greatly among
21 various providers, and it makes interpretation of
22 findings in charts, a mathematical analysis, limited. So

1 unless we actually collect specific data elements which
2 are planned for in advance using a -- collection tool,
3 the data collection will be -- and actually will probably
4 be limited by the lowest common denominators that are
5 available on all the charts. So it may not be as
6 detailed as we would like.

7 The second reason for experimental study
8 designs being preferable is that we know that there are
9 inherent differences which exist between patient
10 populations who seek CAM therapies.

11 We can address the differences we know about,
12 which are called confounders, such as the differences in
13 mean monthly income, average age at the time of
14 treatment, or the use of blood pressure medication among
15 patient groups, and we can factor those that we know
16 about into a statistical comparison, but it is the
17 unknown differences that challenge the validity to the
18 studies. The only way to sufficiently direct the
19 unidentified differences is to randomize the patients to
20 treatment arms.

21 Thirdly, I think that when we are evaluating
22 any therapy, including CAM therapies, we are equally

1 interested in qualitative as well as quantitative outcome
2 measures. For example, if two patients are receiving
3 treatment for breast cancer, they may actually survive,
4 possibly, the same amount of time, but let's say in mind-
5 body therapy, for example, we could have a therapy, use
6 it on these patients, and it might result in an improved
7 quality of life during the course of treatment for one of
8 them.

9 So we need to design a study to evaluate the
10 measures which involve using qualitative survey
11 instruments and those have to be incorporated into
12 studies designed at the outset. We might also be
13 interested in cost benefit and cost effectiveness
14 measures. Those really need to be built into a study, so
15 that there aren't inherent inaccuracies in collecting
16 those data.

17 I think the final argument for experimental
18 study design is that it is an important feature of
19 evaluating effective therapies is the choice of a
20 comparison group. That is really the essence of a valid
21 study, and we want that comparison group to, as closely
22 as possible, resemble those who receive the CAM

1 therapies.

2 There really aren't very many -- in the United
3 States where patients receive CAM therapies or integrated
4 therapies side by side with patients who receive only
5 conventional treatments. So in order to identify --
6 really requires expanding the study arena beyond just the
7 office of one CAM practitioner.

8 So for all those reasons, we elected to move to
9 the experimental study design. As some of you may know,
10 that is where the experimenter, as one example, may
11 randomize patients to different treatment arms. One of
12 those, of course, could be a CAM system of care or a
13 modality.

14 Whether it is designing a study, designing a
15 CAM, as long as the experimenter keeps in mind the
16 essence of integrated herbalistic medicine, and then even
17 imposed system of care, such as naturopathy or entire
18 modalities, say, such as acupuncture which is the unit of
19 measure being evaluated, then we don't really use
20 alternative scientific methods. There are good
21 epidemiological statistical methods that exist, and in my
22 view we don't need to redesign those methods.

1 Let me give you an example of an aggregate
2 system of care and tell you what I mean by taking into
3 account the unit of measure. If you look at something
4 like classical homeopathy -- I am going to refer to it as
5 an aggregate system of care -- patients are treated on
6 the basis of their own constitutional profiles, which are
7 determined by a homeopath on the basis of characteristics
8 that are unique to each patient.

9 So the patient is assessed, for example, as to
10 whether he or she tends to be thirsty or whether they
11 prefer sweet or salty foods, what fears they might have
12 in the experience, plus the symptoms that they present to
13 the office with. The homeopath, based on a classical
14 approach, would actually give different remedies to a
15 patient who presents with the same complaints.

16 So let's say with shoulder pain, if we rush to
17 evaluate only one homeopathic remedy for shoulder pain,
18 we are going to miss evaluating the essence of the
19 homeopathic system of care by only focusing on one unit
20 of measure. In the example I am giving you, the exposure
21 in this case is the constitutional homeopathic remedy,
22 and the effect on the shoulder pain is really the

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1 outcome.

2 So in the aggregate system of naturopathy, if
3 you only evaluate just the mechanical -- and we don't
4 take a step back, we are going to find, sure, that the
5 substance may not be inert if we have bioactivity, but we
6 are also going to be evaluating the effects of the
7 aggregate system of naturopathy.

8 So basically, it is the entire system, like
9 lifestyle, exercise, plus the addition of dietary
10 modification that really comprises -- and we really need
11 to analyze a therapeutic approach that is not too
12 refined, otherwise we will really miss the forest for the
13 trees.

14 Now, I am almost wrapping up, and then I
15 presume that you will want me to stay on the phone and be
16 on the panel.

17 DR. GORDON: We will have a few questions, I am
18 sure.

19 DR. CRAMER: So let me just say that the other
20 advantage of using an outcome-based approach is that we
21 can really evaluate systems or modalities that have no
22 scientific explanation. If findings from the evaluation

1 of an entire system or modality shows promise, then I
2 think we need to go in -- and use existing scientific
3 methods to dissect all the components, and then go to a
4 laboratory-based analysis of botanicals or substances.

5 We probably would expect those to display some
6 biochemical activity, but start with a clinical study,
7 and then move backwards to a basic science approach.

8 So finally, for a clinical study, the findings
9 should be as valid and as reproducible as possible and,
10 really, that is best accomplished by assembling an
11 integrated team of clinicians with both clinical and
12 subject matter expertise. It requires involvement of a
13 set of statisticians and programmers, et cetera.

14 So to offer a margin of sample size in patients
15 with multiple treatments arms and a comparison group, you
16 really need to put together an integrated team of
17 researchers from both the CAM and conventional
18 communities who are open-minded practitioners, who are
19 really willing to collaborate and randomize patients to
20 CAM treatment arms as well.

21 So in conclusion, descriptive epidemiology is
22 good. It is good for characterizing patients and

1 therapies, for diseases which are most commonly treated
2 by CAM, it helps to identifies those suitable for further
3 evaluation, but it is really the experimental study
4 design that is the gold standard to address both the
5 identified and the unidentified sources of consignment,
6 which would really move the validity of the study if it
7 is only conducted by observational methods.

8 By keeping in mind the objectives, in the
9 absence of integrated and holistic medicine, we should be
10 -- that the unit of measure and the evaluation is the
11 aggregate system, and not simply a -- therapy or we will
12 really miss the essence of what the CAM practitioners are
13 doing and providing in the community.

14 Finally, integrative medicine requires
15 integrative research, and the way to properly evaluate
16 any exposures through a team-based approach using
17 existing methods.

18 I have come up with, I think, three possible
19 ways that I think will help to implement these strategies
20 in a community setting. One is to solicit proposals from
21 integrated research teams which are comprised of both CAM
22 and conventional practitioners who demonstrate the

1 ability to collaborate on, not just the study design, but
2 case definitions, the selection of exposures, and the
3 designation of CAM and conventional treatment sites.

4 The second possible approach is to assign a
5 research mentor to CAM practitioners who are interested
6 in evaluating CAM therapies, but whoever needs research
7 and who really needs some assistance with both protocol
8 and study design development. I think there are many of
9 those in the community.

10 The third approach may seem impractical, but it
11 is possible to establish experienced research teams that
12 are comprised of scientists, subject matter experts.
13 Instead of -- them, actually send them out en masse to
14 selected research sites to really expedite development
15 and implementation of the protocols for CAM evaluation.

16 I think I will stop at this point.

17 DR. GORDON: Thank you very much for sharing
18 your experience and your thoughts with us, and thanks so
19 much for overcoming the technological obstacles.

20 The first questioner is Dean Ornish.

21 DR. ORNISH: Thanks for your time. We really
22 appreciate it.

1 DR. CRAMER: Sure.

2 DR. ORNISH: My name is Dean Ornish. We
3 struggle with the same kind of issues, methodologically,
4 that you have talked about here. You have identified
5 that when you don't do randomized trial, you have the
6 unknown variance from factors that you don't identify.

7 When you are doing this study, that we have a
8 copy of the pilot study, you adjust for a number of
9 different factors, but there is a presumption that one
10 knows how much to adjust for, particularly on the kind of
11 outcomes that you are looking at. I am not sure that we
12 really do have that data, plus you don't know how to
13 adjust for the fact that there is positive expectations
14 and placebo factors and other things that go into
15 something like this.

16 I am just wondering, do you just say, well,
17 there are limitations and that is all we can do, or is
18 there some methodology to compensate for these things
19 that I am not aware of?

20 DR. CRAMER: Do you methodology to compensate
21 apart from randomizing patients?

22 DR. ORNISH: Apart from randomizing. Part of

1 what we have talked about the last couple of days is
2 that, as you said, integrative medicine requires
3 research. One of the questions is, are there
4 methodologies that maybe we haven't considered that might
5 be somewhere between a randomized-controlled trial and a
6 case-matched or adjusted study that you are talking
7 about.

8 You have obviously given a lot of thought to
9 these areas, and I am just curious to know what you might
10 have come up with.

11 DR. CRAMER: Well, first, let me just talk
12 about doing some observational research to try and adjust
13 for some of the factors that we are talking about, then I
14 will actually address the issue of a case-matched study.

15 One of the things I found in the study that you
16 have in front of you was that a lot of the data were
17 present that were objective data, such as mean monthly
18 incomes, blood pressure, medication use. Actually, in
19 the second study, which was the community health centers
20 of King County, we actually had a formulary so we could
21 find out all the medications that the patients were on.

22 All of the things that turned out to be

1 different among three patient groups, in other words,
2 when we compared the conventional patients to care users,
3 there were many things that we could identify, and we
4 were able to, as you say, adjust for those things with
5 the three-dimensional logistic regression model.

6 It took a lot of fancy work to do that,
7 mathematically, which is not uncommon and it is doable,
8 but the problem is in over-interpreting data. When you
9 look through a chart and you see that a conventional
10 doctor writes "patient is feeling better," and then you
11 look through another chart and the naturopath writes down
12 three paragraphs, there is already an inherent bias in
13 the data collection. So it is very limited.

14 I think I am able to over-interpret those data,
15 and they become basically dichotomous. It is going to be
16 either yes, they do, or no, they don't have any symptoms,
17 because we will actually build into our interpretation
18 all kinds of biases.

19 So I think no matter what we do, we are going
20 to have trouble adjusting for all of the differences,
21 even in the setting which I evaluated, where, actually,
22 the context was the same. It was the same

1 administration, the same roof over the two clinics, the
2 same secretarial staff.

3 DR. ORNISH: So recognizing the limitations,
4 which I think we all do --

5 DR. CRAMER: Right. You could, theoretically,
6 try and compensate for that. You could actually collect
7 data from patients who come through the door, and try and
8 capture the data in a more standardized fashion. So have
9 both CAM providers and conventional physicians filling
10 out a standardized survey form.

11 If they are randomizing patients where they are
12 still selecting their own treatment group, the physicians
13 and all the CAM providers could be more standardized in
14 the way they collect data, and then what could happen is,
15 the patients themselves could fill out an evaluation
16 after they are seen. Those data would be subject to,
17 certainly, interviewer bias.

18 DR. ORNISH: Are you familiar with Zelin's
19 work, using the NF-1 studies, those kinds of things?

20 DR. CRAMER: No, I am not.

21 DR. ORNISH: Just curious.

22 DR. CRAMER: There are also studies where you

1 could actually use the patient as his or her own control
2 group.

3 The truth is that no matter how you slice it,
4 what happens is that in my discussions with reviewers,
5 peer reviewers from all of the major journals, they
6 always come back with the same thing, and that is that
7 these patients are home schooled, they are drinking more
8 water from wells that they have on their own property,
9 and there are so many problems that we can't identify,
10 that, I think, make, not only the validity challenge, but
11 certainly when it comes to CAM therapy, it has to be
12 twice as valid to be considered equal. That is just the
13 truth of the matter.

14 DR. ORNISH: Exactly. Thank you. That was
15 very helpful. I appreciate it.

16 DR. GORDON: Another question coming up from
17 Wayne Jonas.

18 DR. JONAS: Hello, Elaine. Can you hear me?

19 DR. CRAMER: Hi, Wayne.

20 DR. JONAS: Welcome back from the bowels of
21 Harvard.

22 DR. CRAMER: Well, thank you.

1 DR. JONAS: I see you have learned a few things
2 there. You even said some words I didn't understand.

3 I had a focused question, hopefully, here,
4 because I want to make sure that we are not
5 misinterpreting you here. That is that my feel from what
6 you said is that you would not recommend observational
7 research in these complex areas, and I want to see if
8 that is correct. I understand that you think, and we
9 have discussed, really, a lot in the last couple of days,
10 the importance of randomization and balanced group
11 designs, and this type of thing, and also its problems.

12 Is your sense now, after having been one of the
13 few people, other than at some of the centers, to truly
14 attempt to do observational practice-based CAM research,
15 that this is not a very viable approach and that you
16 would abandon it? Let me be very clear.

17 DR. CRAMER: Well, I would say that it is
18 limited, Wayne.

19 DR. JONAS: I understand the limitations, but
20 is this -- go ahead. I'm sorry. I don't want to
21 interrupt you.

22 DR. CRAMER: That's okay. I think it is very

1 good descriptive studies. It is even possible to do the
2 studies prospectively, but the original intent was to go
3 into these practices and try and do, what we say in CDC,
4 is a quick and dirty study, which is basically use the
5 data that are there in the clinic, whether we use their
6 computer system for billing to identify cases, or whether
7 we use the charts and abstract them, or do random chart-
8 polling, or review every case that has ever walked
9 through the door, I still think it is limited.

10 If we set something up prospectively, it is
11 possible to do that in such a way where with a lot of
12 manpower, we can actually do what Dr. Ornish suggests,
13 which is to do a case-matched approach, but I am not sure
14 the juice is worth the squeeze on doing case-matched
15 approaches where we are looking for matching comparison
16 group outside of the practice, because even so, there
17 will be limitations to the validity.

18 DR. JONAS: That is a rock. You might not get
19 a lot of juice out of it.

20 DR. CRAMER: I am not sure that juice is really
21 descriptive in terms of being able to use the data. What
22 will happen is, we will come up with an answer, but it

1 will only be a suggestion looking for a future study.

2 I will just give you a quick example. One of
3 the other places that I evaluated was an oncology clinic,
4 which was an integrative setting where one of the
5 practitioners was treating a variety of cancers. I
6 looked at all the charts in the practice, and there was a
7 whole list of patients who had a variety of diagnoses:
8 breast cancer; prostate cancer.

9 The data were all there, not only that, but all
10 of the laboratory studies. There was no paucity of
11 information, but the problem was even in trying to do a
12 survivor analysis, even in trying to say, do these
13 patients live longer, what we wanted to do was go to
14 national database and look at survival of comparable
15 patients.

16 It is very difficult to identify a comparison
17 group, even using a national database, because a lot of
18 the patients in these practices, they have tried
19 everything else, and they either end up there by virtue
20 of finding that this is their last hope, or it is
21 unclear, actually. This is something I found even more
22 often, it was unclear what their previous series of

1 treatments were.

2 So even looking at a national database, we were
3 not able to see whether they are comparable.

4 DR. JONAS: So I understand, what you are
5 saying is it is a very complex phenomena. It is not a
6 simple phenomena to do, even prospective or retrospective
7 observational research from practices, and you have made
8 some recommendations here as to actually how to possibly
9 do that. So I assume that you don't think it should be
10 abandoned.

11 DR. CRAMER: No. I don't think it should be
12 abandoned.

13 DR. JONAS: Okay, because that was my question.
14 Let me ask a little bit on resources, then, because you
15 said the juice is not worth the squeeze, or may not be
16 worth the squeeze.

17 In your specific study at the King County
18 Clinic, what was the total number that you had? What
19 estimate of time and cost went into that?

20 DR. CRAMER: At the King County Clinic, what I
21 did was I talked to all the patients who met the case
22 definition from the start of the clinic right up until

1 the time when the study was conducted, and I was able to
2 identify 80 patients who met the case definition, after
3 reviewing, probably, more than 600 charts.

4 So we cast a broad net and found 80 who met the
5 case definition. Then what I did identified 160 in the
6 comparison group. So there were 240 total charts that we
7 ended up abstracting and including in the study.

8 DR. JONAS: So you had 600 you screened, 240
9 that you actually went through the problem of
10 abstracting, and then 80 that actually entered into
11 study. This took you how many years?

12 DR. CRAMER: Well, it didn't take years. The
13 analysis took years. The actual study was quick. I
14 probably was in Seattle for three weeks. We were able to
15 abstract the data in a little over three months.

16 DR. JONAS: I understand, but the process that
17 you had to go through, including all the approvals and
18 the IRBs, and all this type of stuff at the CDC to do
19 this, from the time we told you we would like you to do
20 this and supplied some of the money for it, was about
21 what period of time?

22 DR. CRAMER: January through September of '98

1 for actual data collection, and September of '98 until
2 September of '99 for analysis, not including the fact
3 that I wasn't working on it full time.

4 DR. JONAS: And that was obtaining a subgroup
5 of 80, which is, as we have already discussed, was real
6 problematic in terms of analyzing any of the subgroups or
7 other types of confounders.

8 DR. CRAMER: I don't think the sample size in
9 itself was large enough.

10 DR. JONAS: I will stop now. I won't ask you
11 to elaborate all the other complications that you had in
12 terms of making the arrangements and the practitioner
13 issues, and this type of thing. Thank you very much. It
14 is very good.

15 DR. CRAMER: I will just mention one thing. I
16 think it cost probably about \$60,000 total.

17 DR. JONAS: The point is -- and Elaine, I think
18 you have made some suggestions to set up teams, for
19 example, that involve statisticians and methodologists,
20 and this type of thing -- is that it is a very
21 substantial effort, even if you are collecting what would
22 be considered pilot data for analysis for making

1 decisions about where we would do a controlled trial.

2 In your trial, you found improved outcomes in
3 the naturopathic for certain symptoms, but not improved
4 in other areas. So perhaps, one would consider, then, a
5 controlled trial for looking at the value of naturopathic
6 treatment and those particular symptoms.

7 Is that correct?

8 DR. CRAMER: That is correct.

9 DR. GORDON: Thank you very much. When will
10 you be back?

11 DR. CRAMER: From Spain?

12 DR. GORDON: Yes.

13 DR. CRAMER: I am coming back on Tuesday.

14 DR. GORDON: Tuesday. Well, then, certainly by
15 the next time we have research discussion, we will be
16 able to talk with you.

17 Maybe if some of our members want to give you a
18 call to discuss some of these issues further, would that
19 be okay?

20 DR. CRAMER: It would be absolutely fine. I am
21 sure Michele and the rest of the team knows where to
22 reach me.

1 The last thing I just wanted to mention in
2 response to Wayne's inquiry was that, the three
3 recommendations I made, while it is true that I think
4 they would lay the foundation for a real trial, I think
5 that these recommendations probably go directly into Step
6 B, where you are going with a team and actually set up a
7 very sound study to start with.

8 DR. JONAS: I like that one the best.

9 DR. GORDON: Okay, thank you.

10 DR. CRAMER: Sure.

11 DR. GORDON: Dr. Segal.

12 DR. SEGAL: I can go now because Elaine Cramer
13 said everything I needed to say.

14 It is a collaboration with someone who has that
15 kind of expertise that I, as a clinician, I, as the
16 founder of the Kaiser Permanente's alternative medicine
17 in this area of Virginia, Maryland and the District, I
18 don't have that, and it is that kind of quality research
19 that allows us to establish a level of credibility. That
20 credibility allows you, as that person with back pain, to
21 come to me, the clinician, and say I don't want all that
22 other stuff. Which one of us passes Elaine Cramer's

1 strict credibility? Which one has the validity and
2 reliability that meets strict standards?

3 Once you have the credibility and the
4 acceptance both by the patient, by the provider, then,
5 the medical community and even the insurers are going to
6 start rolling in, where it is appropriate, different
7 modalities for different disorders, and once they do, and
8 they roll things into the base product, something I am
9 sure you are all familiar with in an insurance industry,
10 then, the big time payers, employers, government will
11 make sure that you have access to that alternative
12 modality, assuming you have insurance -- not having
13 insurance is not an issue in today's conversation -- and
14 that access won't be an issue anymore because you all who
15 have insurance, if you do, will have access to it.

16 So, credibility based on really quality
17 research, that people like Elaine Cramer can help us
18 design, leads to a level of acceptance both by the
19 medical community and the patient, leads to an
20 integration of service into the medical community, and
21 then issues of access almost go away because it becomes
22 established as routine care, but it is another modality

1 that can be used.

2 So, you may all say so why is this not
3 happening although you have sat here for the last two
4 days and you probably know why it is not happening, from
5 my perspective there is four general reasons why it is
6 not happening.

7 You may say, Lydia, you are sitting on 8 1/2
8 million covered lives in the largest nonprofit HMO in the
9 country, we have no vested interest in going after one
10 modality or not going after another. It is a total wide-
11 open ballpark here.

12 I am sitting on half a million lives locally
13 that I can do big, large population studies. I have
14 multicenter I can go after. I have got an electronic
15 medical record. I can go after demographics, I can
16 randomize, I can look at utilization, so why the heck
17 aren't I doing it?

18 Well, I am doing a little of it, but I and my
19 colleagues, my equivalents across the country, have had
20 this conversation more than once, and I can tell you that
21 although it looks real easy, it is not, and it comes down
22 to three things in our lives.

1 Jim is writing this down, but he really doesn't
2 have to, because it's just so simple. It is time, it is
3 energy, sort of finding the energy to do it, and it is
4 expertise. It is I, as a clinician, and my partners, you
5 know, we are pretty smart. I am not bragging, but we do
6 what we do. I am a physician, I am an acupuncturist, we
7 do what we do pretty well.

8 But you come to me and you have this idea, and
9 I say great, design that research project. I need an
10 Elaine Cramer to help me design that research project.
11 But let's say all on my own I do, then, I have got to sit
12 down and fill out that 30-page grant application. I have
13 just listened to one of my partners yell about a 30-page
14 grant application.

15 Then, after I get to that point and they give
16 me the money, then, I have got to set up the research --
17 Dean is going yeah, yeah, he has been there -- have got
18 to set up the research, collect the data, analyze it,
19 then, I have got to write it, and I have got to write it
20 so well, and it has got to be done with such rigor that
21 it gets accepted at a credible journal, because without
22 it being accepted at a credible journal, it doesn't go

1 back and establish the credibility that needs to be there
2 to expand the modality, so that your back pain or your
3 back pain has more options now to go after.

4 So, one of those limitations is strictly
5 practical, it is the time, the energy, the expertise.

6 The next is a theoretical one, and Dr. Strauss
7 mentioned this yesterday. When we look at cause and
8 effect, and we look at this whole body, you are not going
9 to get cause and effect when you look at an outcomes
10 trial. When you are at the bench in the lab and you are
11 looking a molecule or a mouse, you might get cause and
12 effect, but if I send you to the acupuncturist for your
13 back and you come back and you are better, and you get
14 back to work sooner, your employer will be happy.

15 And your family sees you and your functional
16 status is improved, you are happier, you can do more
17 around the house, your quality of life is increased,
18 that's great, and, you know, I, as a clinician, may
19 actually not care whether it's electromagnetic waves,
20 whether it's this cheese stuff -- what is this cheese
21 stuff -- I may not actually care, because you have gotten
22 better, and I have an extra modality to go after your

1 back pain with.

2 So, I think we have a real reason to use
3 outcomes measures. We have got them, we can randomize.
4 We have challenges, but we have got smart people like
5 Elaine Cramer to go after and help us with those
6 challenges.

7 So, that is a theoretical question. On a more
8 technical level, these studies need to be huge. No
9 matter how much they cost, they need to be huge. It is
10 nice to have anecdotal reports, it is nice to have case
11 reports, it is nice to have pilot reports with 12 and 20
12 and 50 patients, like I have in some of my research.

13 Those are building blocks, but we need really
14 big studies, big populations in my view, to be able to
15 establish again that credibility that leads to that
16 acceptance.

17 So, now we come to the last of my obstacles,
18 and that is a paradigm shift that others in this room
19 have spoken of, and that is having respect for that
20 particular modality that you are looking at, and taking
21 respect for that modality and weaving it into the actual
22 research.

1 Jim, I am going to use you as an example. You
2 have come to me with that back pain, and I have done a
3 history and physical on you, and I have even done x-rays,
4 and I have made a diagnosis that you have age-related,
5 age-appropriate arthritis of your back.

6 I am going to send you out to one of my
7 favorite acupuncturists who happens to be in the
8 audience. When I send you, I don't just send you, but I
9 happen to send your twin brother out, as well. Maybe you
10 don't have one, I don't know, I am making one up.

11 When I look at you and your twin, to me, you
12 both have the same demographics, your age, sex, your x-
13 rays look almost identical, but the acupuncturist, that
14 is not what she sees. She sees two individuals. She
15 does a very different history from I, as a westerner,
16 that may be doing a history.

17 She sees in one of you an excess of maybe
18 dampness and another one of you, maybe a deficiency in
19 your wind. I don't know what she sees, because she is
20 seeing it with a totally different set of eyes, and as
21 she sees it with different eyes, she is putting needles
22 in different spots.

1 Now, if she is my colleague in a research
2 project and I am sending her back pain, I really want her
3 to put those needles in exactly the same spot, so we can
4 have an absolutely perfect study, and we can say, well,
5 you have to put them in this spot, this, and this, and
6 that is not going to happen if we come to respect the
7 modality that we are working with.

8 I think that we can respect those other
9 modalities and still design very rigorous trials.

10 So, my suggestions here are that we have some
11 kind of a research training program for clinicians that
12 allow the clinicians to stay in their practice, be it a
13 mentoring program like Elaine mentioned, or we have a
14 partnership with academic institutions, with government
15 institutions, that hopefully brings those researchers
16 into the clinical environment, and with clinical research
17 outcomes that we can establish a more effective, broader
18 array of treatment modalities that get integrated into
19 the medical care delivery system, and that might even
20 potentially be cost effective, so that your back pain,
21 and yours, and yours, all have other and additional
22 modalities to be treated with.

1 Thank you.

2 DR. GORDON: Thank you very much, and thank you
3 for your forbearance.

4 DR. SEGAL: Not a problem. I learned a lot
5 from Elaine.

6 DR. GORDON: The final person on this panel,
7 the final speaker will be Douglas Lloyd, who is speaking
8 on behalf of the Association of Schools of Public Health.

9 DR. LLOYD: Thank you, Mr. Chairman.

10 My name is Doug Lloyd. I am a preventive
11 medicine and public health physician and I am appearing
12 here today representing the Association of the Schools of
13 Public Health. We are a membership organization of the
14 Nation's 28 accredited schools of public health, and our
15 interests span contemporary health problems facing the
16 country today.

17 If you quickly scan the volumes of Healthy
18 People 2010, you will find the topics listed are the
19 research activities of our academic public health
20 institutions.

21 It was a little over a decade ago that the
22 Institute of Medicine took us to task for having faculty

1 isolated from public health practice and unresponsive to
2 public health professional education and training.

3 Since the publication of The Future of Public
4 Health, much progress has been made in reaching out to
5 those practitioners in public health and including them
6 in the curriculum reform and the development of our
7 professional competencies.

8 New training centers funded by the Health
9 Resources and Services Administration and the Centers for
10 Disease Control and Prevention have recently been
11 designated to devise new approaches to training today's
12 public health practitioners who may have had a career
13 that spans many different fields and responsibilities.

14 Preliminary work at the training centers
15 indicate that new efforts will tailor courses in skill
16 building to a work force in need of rapid access to
17 solving developing community health challenges.

18 A distance education, once an experimental
19 approach to conveying information, is now part of many
20 schools teaching methods and even degree-conveying
21 programs, flexibility in our scheduling sites to help the
22 students who may have full-time practitioner, balancing

1 job and family demands with the needs to keep up.

2 Over the past 10 years, all the schools are now
3 involved in the community with students and faculty
4 routinely taking part in programs of local health
5 departments and other organizations, working with
6 disadvantaged communities and analyzing tough health
7 problems from AIDS through substance abuse to child
8 neglect and abuse.

9 Public health is truly a multidisciplinary
10 field and the scope of community issues requires a
11 variety of talents, so schools of public health maintain
12 experts in many different fields.

13 Departments of biostatistics, epidemiology, and
14 behavioral sciences are found in all of our schools.
15 These areas are key to the most recent research done in
16 the community, and it is likely, as I found out again
17 last night, that many of our faculty are involved in
18 complementary and alternative medicine projects.

19 Certainly, the disciplines and the faculty from
20 them can be very helpful in future research and education
21 in CAM, and that brings us to today's conference. The
22 deans in the schools, of the schools of public health,

1 have established a research agenda. It is a process not
2 unfamiliar to many health professional schools.

3 We meet frequently with our main funding
4 agencies, the NIH, CDC, HRSA, ATSDR, and EPA. Each
5 federal agency has its own set of priorities, and we
6 attempt to match them with those of our researchers, and
7 I was thinking of that today when I heard Dr. Cramer talk
8 as one of our biggest funders across our 28 schools is
9 the CDC, and we work closely with them.

10 Overall, these priorities tend to reflect the
11 contemporary health problems that faced our country,
12 schools like the federal government underscore the need
13 to conduct research which is found to be safe and
14 effective.

15 But as our laboratories, the community, and our
16 discipline population-based research, we are always
17 interested in new questions to be answered, and it is in
18 this spirit I want to tell you about a new project that
19 we have started with HRSA, the Health Resources and
20 Services Administration, under our cooperative agreement
21 with them involves public health and chiropractic.

22 Chiropractic is one of the largest direct

1 access health care disciplines in the U.S. with about 50-
2 or 60,000 licensed practitioners in 50 states. There are
3 all things that you have heard repeatedly over the last
4 couple days.

5 There are 16 accredited colleges, 14,000
6 students. Most of the schools of chiropractory have had
7 at least some coursework in public health although the
8 coursework is not standardized and the content varies
9 widely depending on the instructor interest and the
10 expertise.

11 Observers have remarked that these courses
12 often do not cover prevention topics and the role of the
13 chiropractor in public health.

14 Chiropractors have been involved with the APHA,
15 the American Public Health Association, for some 25
16 years, and have been recognized as a special interest
17 section since 1984, but more significantly, since 1998,
18 chiropractic health care section has been developing a
19 plan for a modern syllabus in public health education for
20 chiropractic colleges.

21 The Association of Chiropractic Colleges
22 suggests in a policy statement that the purpose of

1 chiropractic, of course, is to optimize health. With
2 this background, a project has begun this summer that
3 will develop a model for teaching chiropractic students
4 public health.

5 The Yale School of Public Health and the
6 Bridgeport, Connecticut College of Chiropractic are
7 developing a working group composed of chiropractors and
8 public health experts. This panel will assess the
9 baseline attitudes, knowledge, and behavior of students,
10 faculty, and practitioners in chiropractic towards public
11 health.

12 Based on these findings, a workshop will be
13 convened to analyze and begin the task of developing a
14 curriculum and a workbook for future students. The
15 working group has committed to dissemination of findings
16 and the workbook for all chiropractic colleges. Yale and
17 Bridgeport have indicated that they will evaluate this
18 process and the outcome of the project.

19 While it is too early to say, it would appear
20 that the spirit of cooperation between two academic
21 institutions and two very different disciplines would
22 benefit both and lead to a beneficial dialogue in both

1 disciplines. The result we feel will be a healthier
2 community.

3 This brings us back to ASPH and my concluding
4 remarks. Our member schools recognize that complementary
5 and alternative medicine is in a growth phase. The
6 public interest has been well established. Conferences,
7 such as this one, underscore the awareness and the
8 involvement of the NIH, the FDA, many other federal
9 agencies, universities, foundations, and the private
10 sector.

11 As the research agenda grows, and it will, we
12 wish to once again remember to ask our colleagues to
13 remember that the Nation's schools of public health are,
14 in fact, an ideal environment for complementary and
15 alternative medicine research.

16 Thank you.

17 DR. GORDON: Thank you very much. Thank you
18 all for your different, and again, complementary
19 perspectives.

20 Are there questions? Yes, Bill.

21 DR. FAIR: I guess not so much a question as a
22 comment. Dr. Segal, I really enjoyed your presentation.

1 I think you covered in that presentation about all of the
2 problems that one deals with in trying to do this type of
3 research, but it seems to me that you also provided a
4 solution, and Dr. Cramer alluded to it, and Dr. Lloyd
5 mentioned it right now.

6 It would seem that the natural solution to this
7 problem is to integrate or to collaborate with the school
8 of public health or a Bastyr University, although I
9 recognize it is the wrong area of the country, but it
10 would seem to me there it wouldn't give you any more time
11 perhaps, but you could get the energy and the expertise
12 that may not be inherent in an individual practitioner's
13 backyard.

14 What are your thoughts on that?

15 DR. SEGAL: And, in fact, in the Northwest
16 regions, we have -- I don't know if we have a
17 relationship right now with Bastyr, I think we have, or
18 my sister organization of Puget Sound has -- there are in
19 some areas of the organization, relationships. For me,
20 those are just scratching the surface.

21 We have the opportunity to do much more
22 research given the population that I have got.

1 DR. FAIR: So, would one of the things this
2 commission might consider recommending is ways to improve
3 the access to investigators like yourself with
4 institutions or organizations that have the expertise,
5 would that be a recommendation we should make?

6 DR. SEGAL: One of my fantasies would be give
7 me a researcher who knows their epi, who knows their
8 biostats, more than a level of just an MPH, who has a
9 Ph.D. and is really skilled, and I will facilitate
10 getting the patients, I will facilitate the alternative
11 practitioners, and we can put that together.

12 I can do it independently within my system, but
13 on a much smaller scale, but now when we need the huge
14 numbers that I think that we all feel that we need.

15 DR. FAIR: Would you share your other fantasies
16 with us as relates to this subject?

17 DR. SEGAL: No.

18 [Laughter.]

19 DR. SEGAL: But I will tell you that if you
20 take the shuttle to New York and if you tell the gal who
21 is checking you in that your fantasy is you want a
22 certain seat, she will usually give it to you.

1 DR. GORDON: Wayne and then Joe.

2 DR. JONAS: Also, Dr. Segal, what is the
3 umbrella organization for the health insurance, what is
4 the name of that health insurance?

5 DR. SEGAL: It's called the Health Plan.

6 DR. JONAS: Not for Kaiser, but for the
7 umbrella organization for all of the health insurance
8 plans, there is an organization -- HIA, which stands for
9 the Health Insurance Association, yes. Thank you very
10 much. I couldn't remember that.

11 I am wondering, first of all, if it would be
12 possible or why it isn't, that the health insurance plans
13 aren't already collecting and funding observational data
14 collection on complementary and alternative medicine to
15 find out if it is something that might be useful or not
16 useful for them.

17 In Germany, this is occurring, for example, a
18 number of health plans support and pay for these types of
19 practices provided that there is an evaluation component
20 to it, in other words, a good epidemiological or research
21 group -- you need more than a statistician to do this --
22 comes in and does that, and they actually pay for that.

1 It seems to me that this goes on in
2 conventional medicine all the time where they are
3 monitoring and collecting data on their own outcomes and
4 that this would be perhaps something that should be
5 explored.

6 I would be very curious to know how this can be
7 stimulated, again, through what policy mechanisms that
8 could be stimulated, probably not by providing money, but
9 whatever, and who should we go to, to find that out.

10 DR. SEGAL: Is that the bottom line question is
11 who do we go to?

12 DR. JONAS: Yes, that is the question.

13 DR. GORDON: The earlier question you asked,
14 Wayne, is why aren't they doing it.

15 DR. JONAS: Yes.

16 DR. GORDON: So, any ideas you have about that.

17 DR. SEGAL: I can't answer the question about
18 why the health plans aren't funding it. I mean if that
19 is the first question, why health plans aren't funding
20 this kind of research, I don't have any answer for you.

21 My second answer would be the National Trade
22 Organization exists right here in D.C., and it would take

1 a phone call or two for me to actually get the answer to
2 your question about why they are not doing it on a
3 national level.

4 I can say that within my organization, there is
5 a small amount of dollars going for research. I think if
6 I was sitting in their shoes, they would say we have got
7 dollars going for all sorts of research, this is just one
8 piece of it.

9 DR. JONAS: Sure, and to how to facilitate
10 that, I think is a big question.

11 Dr. Lloyd, I think the public health schools is
12 the ideal place to begin to do this, and I am just
13 wondering, certainly there could be some simple ways that
14 some of your main funding agencies could stimulate this,
15 and I bet a lot of the schools would respond.

16 Do you have any thoughts about how that could
17 best be approached for the schools?

18 DR. LLOYD: Well, I think we have already heard
19 some reasons in the last couple of days what we can do.
20 For instance, we need to clone Elaine Cramer and take her
21 around more to talk to more of the schools of public
22 health.

1 I think there is often a question of the
2 possibility of studies that is not broached, that needs
3 to be broached. I think the step by Yale and by
4 Bridgeport towards bringing people together, where they
5 will not only obviously talk about education, they will
6 talk about ways of answering questions, does it work, is
7 it safe, et cetera, which is part of the research
8 protocol. I think all those things are beginning to
9 evolve, but I think it probably could take a little
10 nudge.

11 DR. JONAS: Are the schools at a point now
12 where an RFA, for example, soliciting projects of a
13 collaborative nature like this would be appropriate and
14 could be responded to?

15 DR. LLOYD: Yes, absolutely. I think, as a
16 matter of fact, it happens to be that one of the senior
17 public health people at Georgetown told me that their
18 biostatistician is in the midst of just writing something
19 up right now. I am not sure what aspect that this is,
20 but it is happening. We don't have any way of knowing
21 exactly where it is happening and how large.

22 DR. JONAS: In terms of a federal agency that

1 might perhaps come out with such an RFA, where, from the
2 school's perspective, would be the best place for that to
3 come from?

4 DR. LLOYD: Well, again, the money for the
5 project with Bridgeport and Yale is coming from HRSA. A
6 lot of these research questions about what works in the
7 community comes from CDC, and a lot of the funding comes
8 from NIH also.

9 DR. JONAS: Yes, so those three places it would
10 be.

11 DR. GORDON: Thank you.

12 Joe and then Effie.

13 DR. FINS: Wayne anticipated my question to Dr.
14 Segal, and I was going to ask you more specifically about
15 CQI, which is continuous quality improvement, a way of
16 marrying data collection and recordkeeping, so that you
17 actually have a record that is usable perhaps for
18 assessment of quality, but also collection of
19 standardized data, and how it might fit in with NCQA,
20 which is the accrediting body that assesses whether or
21 not managed care is up to snuff, and whether or not it
22 will be productive to engage in dialogue with them, so

1 that plans would collect the requisite data to assess the
2 dollars that they are spending in the care that their
3 patients are receiving.

4 DR. SEGAL: I am not exactly sure if there is a
5 question there, and so if my response is not what you are
6 going after, please ask me again.

7 I will give one small example. NCQA likes
8 functional status data, so you can look at an FS-36, but
9 they actually like an FS-12 even though it is not as
10 strong an instrument. So, we will in a pain program that
11 I run, that is a mindful meditation, cognitive
12 behavioral, a little yoga movement stuff program -- we
13 don't use all those words when we publicize it -- but we
14 do pre- and post-treatment FS-12's to look at just that,
15 because we are expecting NCQA, I am just waiting for NCQA
16 to come and say, so, does your program make a difference
17 in functional status, and I can say yes, it does, and I
18 have got the numbers.

19 So, we are just starting to roll out those
20 kinds of instruments where it is appropriate.

21 Does that address your question or not?

22 DR. FINS: Well, I guess one thing that we

1 could recommend is that for accreditation and Medicare
2 eligibility and federal entitlements, that there is
3 adequate assessment of functional status.

4 DR. SEGAL: Actually, NCQA is in the process of
5 doing that, as I understand.

6 DR. FINS: And maybe it shouldn't be an FS-36,
7 it should be 50, so we get into mindfulness, you know, as
8 an extra indicator.

9 DR. SEGAL: I think it is a wonderful idea,
10 absolutely a wonderful idea. I support it entirely.

11 DR. GORDON: Effie.

12 DR. CHOW: Wayne and Joe have taken care of
13 some of the questions, so I am left with one question,
14 but I really appreciate this panel and giving such
15 clarity and the obstacles, and you have given a variety
16 or the variation in your case you gave about acupuncture,
17 about how the diagnosis is different when they go to the
18 practitioner and then each person with the same diagnosis
19 could be treated differently.

20 That, I think pinpoints some of our concern,
21 much expressed concern elsewhere, too, about the
22 individuality of treatment and that we can't treat

1 everybody the same.

2 Do you have further comments about that or
3 recommendations about that?

4 DR. SEGAL: I actually do because if you come
5 to me and you need a hernia surgery --

6 DR. CHOW: There are over 100 different
7 diagnoses for hernia in China --

8 DR. SEGAL: No, I was actually coming back to
9 Western medicine. You come to me and you need hernia
10 surgery, there is multiple ways to go after repair of
11 that hernia surgery, and within one surgeon may choose a
12 different way with you or your twin sister. So, I don't
13 know that we actually have to say the acupuncturist must
14 put the needle in, in exactly the same spot on the next
15 thousand patients for your back pain. I don't know that
16 it has to be done.

17 We would have to sit down with the Elaine
18 Cramers of the world and work that out, but I think it is
19 workable out. I don't think it's actually rocket
20 science, I think we can do it. Maybe that didn't answer
21 your question.

22 DR. CHOW: And then what about addition of

1 counseling and things like that, the emotional, the mind,
2 and spiritual along with the actual needle implantation?

3 DR. SEGAL: For me, that is very easy. The
4 field of psychoneuroimmunology is 20, 30 years old. The
5 work of Adler and Engel, I guess, from Rochester is well
6 established. There are ways to go about that research,
7 and I think you can take that as an arm or take that as
8 part of a piece as you say doing acupuncture, and you can
9 look at it. It's a piece I strongly support.

10 I don't know if that answers your question.
11 That doesn't answer your question? I think there is
12 research out there, and there can be more research. You
13 can look at the work at Ohio State of Kendicott Glazer
14 [ph] that says what are the hormones and
15 neurotransmitters that change when you do mind-body
16 studies, and it is there.

17 DR. STANDISH: Jim, could I just respond to
18 that? Is that okay?

19 DR. GORDON: Sure, please.

20 DR. STANDISH: This issue about individualized
21 treatment is so important, and one of the potential
22 solutions is taking a whole system and looking at it as

1 an algorithm.

2 I think each one of us who does complicated
3 therapies, as most CAM therapies are, if you really sit
4 down -- it is not rocket science -- you can just say that
5 it is an "if then," and you have flow charts of how you
6 end up giving a particular set of therapies for a
7 patient.

8 I think if we were to ask practitioners in a
9 study to develop those algorithms and sort of formalize
10 them, that we can do individualized therapy inside of a
11 clinical study, I think that is possible.

12 DR. LOW DOG: I would like to just continue on
13 that theme a bit. One of the things that has always been
14 interesting and also challenging for me with this type of
15 therapy, well, with any therapy -- I am going to include
16 Western medicine -- is that most of our studies have
17 worked very hard to remove the role of the healer.

18 I mean that is why we do double-blind and
19 randomized trials is so that nobody knows who is getting
20 what patient or practitioner, where, in reality, my own
21 belief is that the role of the healer is extremely
22 important in the relationship and that in complementary