

THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE
MEDICINE POLICY

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RE: PLANNING MEETING :
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LOCATION: Hubert H. Humphrey Building,
Ninth Floor Meeting Room
200 Independence Avenue, S.W.
Washington D.C. 20201

DATE: Thursday, July 13, 2000

APPEARANCES:MEMBERS:

JAMES GORDON, M.D., CHAIR, Director, The Center for Mind-Body Medicine, Washington D.C.
GEORGE M. BERNIER, JR. M.D., V.P. for Education, University of Texas Medical Branch, Galveston, Texas
THOMAS CHAPPELL, Co-Founder and President, Tom's of Maine, Kennebunk, Maine
EFFIE CHOW, President and Founder of East-West Academy for the Healing Arts, San Francisco, California
GEORGE T. DEVRIES, III, Chair, President and CEO, American Specialty Health Plans, Sand Diego, California
WILLIAM R. FAIR, M.D., Director Prostate Diagnostic Center, Memorial Sloan-Kettering Cancer Center, New York, N.Y.
JOSEPH J. FINS, M.D., F.A.C.P., Assoc. Professor of Medicine, Weill Medical College of Cornell University, New York Presbyterian Hospital, New York, N.Y.
CHARLOTTE R. KERR, R.S.M., Traditional Acupuncture Institute, Inc., Columbia, Maryland
DEAN ORNISH, M.D., President and Director, Preventive Medicine Research Institute, University of California, San Francisco
CONCHITA M. PAZ, M.D., Las Cruces, New Mexico
BUFORD L. ROLIN, Poarch Band of Creek Indians, Atmore, Alabama
JULIA SCOTT, President, National Black Women's Health Project, Washington D.C.

OTHER APPEARANCES:

PETER REINECKE, Legislative Director for Senator Harkin
KAREN SANTORO, Ethics Counsel, National Institutes of Health

EXECUTIVE STAFF:

STEPHEN C. GROFT, Pharm.D., Exec. Director
MICHELE M. CHANG, M.P.H., Exec. Secretary
STEVEN OTTENSTEIN, Liaison from the Department of Health and Human Services to the White House Commission on CAM

P R O C E E D I N G S

(2:15 p.m.)

DR. GORDON: Good afternoon, I'm Jim Gordon and I'm the chair of this Commission. I thought before we begin we might take a moment to sit quietly and take a deep breath.

(Pause for moment of silence.)

DR. GORDON: We're going to go around and introduce ourselves. And the purpose of taking a deep breath is to remind ourselves to relax. We have a lot of work to do together, but that work needs to be done in a spirit of openness, and of collaboration, and calm, as well as with enthusiasm.

So what I'd like each of the commissioners to do is to begin to go around and introduce yourself, and say a little bit about who you are, and little a bit about some of your hopes for participating on this Commission. Would you begin then, Buford?

INTRODUCTIONS

MR. ROLIN: Thank you, Jim. My name is Buford Rolin. I am health administrator for the Poarch Band of Creek Indians, in Atmore, Alabama. I am presently serving on the board of the National Indian Health Board, which is for the 12 areas in the Indian Health Service. The board members are appointed. And I most recently, in

1 December, completed a term as chairperson, well, two terms
2 actually.

3 And, basically I've been in health care as an
4 administrator for the last 16 years. I've had an
5 administration background all my life, through the military
6 forward, and I have not been active in health until 16 years
7 ago. And I'm really looking forward to this Commission and
8 working with it and with you.

9 I've had an opportunity to meet various of
10 the members on the Commission and certainly am really
11 interested in knowing more about what our roles and
12 responsibilities are. I'm here to represent our Indian
13 community. And as a lot of people have heard, Commission
14 members that I have talked to, are familiar with the
15 traditional medicine and practices of the Indian community.

16 So I look forward to bearing critical
17 information to this Commission. And I certainly want to
18 involve the Indian community in this whole process, making
19 sure the final report reflects our concerns as well. Thank
20 you.

21 DR. GORDON: Thank you.

22 MS. CHOW: I'm just very delighted to be a
23 part of this prestigious group in answering some of our
24 mission, which I think will be very important. I am Effie
25 Chow. And I came from a long background in complementary

1 and alternative medicine.

2 In the late 1960s when we held the first
3 training program for acupuncture for physicians at Stanford,
4 I worked from then on and was faced with helping our masters
5 get out of jail. Back in those days, there were a lot of
6 people being jailed, homeopaths being jailed, and the
7 acupuncturists, and so forth. And so I go back a long ways
8 and I have fond memories of us struggling.

9 This is a wonderful status right now. I
10 specialize in Chinese medicine and try to integrate in the
11 last 30 years Chinese medicine and Western medicine. I am
12 president and founder of East-West Academy for the Healing
13 Arts, with a base in San Francisco, with our international
14 bases having different liaison aspects on different parts of
15 the world. We are now specializing in the area of Qi Gong,
16 as part of the Chinese medicine. It is a self-help program.
17 And so we're very excited about it, everything that is
18 happening.

19 I had the pleasure of being part of the first
20 Office of Alternative Medicine Panel, too, so this
21 development is kind of another step. And I look forward to
22 being a part of the great plan for the Nation. I think we
23 can really touch people a great deal. Thank you.

24 DR. GORDON: Thank you.

25 DR. FINS: Good afternoon. I'm Joe Fins and

1 I'm delighted, as well, to be a part of this Commission and
2 to have so many colleagues. I'm a general internist and
3 medical ethicist, and I teach and practice medicine at New
4 York Presbyterian Hospital Weill Cornell Medical Center in
5 Manhattan.

6 I have a special interest in ethics and
7 consultation and care of the dying in palliative care. And
8 my hope is really to better integrate complementary and
9 alternative medicine into the medical mainstream and into
10 medical curriculum at the undergraduate and post-graduate
11 medical training levels, so I'm really delighted to be here.

12 MR. CHAPPELL: I'm Tom Chappell and I'm the
13 founder of Tom's of Maine. We are makers and marketers of
14 natural personal care products and natural wellness
15 products. I've been part of the consumer movement for 30
16 years, interested in natural and alternative nutritional
17 products, alternative health practices. And I have come to
18 know the concerns and orientation and interests of that
19 consumer group which is, obviously, growing considerably.

20 I am delighted to be a part of this
21 Commission. And my hopes are that the Commission will
22 contribute to the ultimate raising of standards of products,
23 the efficacy of what's marketed in the marketplace of
24 products, but, most importantly, access of the alternative
25 services and products to consumers.

urologist

Not

Neurologist

1 DR. BERNIER: My name is George Bernier.
2 I've Vice president for Education at University of Texas
3 Medical Branch, at Galveston, Texas. I was born in Maine
4 and raised in New England. I am a physician trained in
5 hematology and oncology. And my biggest interest has been
6 that of medical education.

7 My own background is that I went to Boston
8 College and Harvard Medical School, served on the faculties
9 and Case Western Reserve University in Cleveland, at
10 Dartmouth Hitchcock Medical Center, in Hanover, New
11 Hampshire, then spent nine years as dean of Medicine at
12 University of Pittsburgh, and prior to this as dean of
13 Medicine at the University of Texas.

14 My hope is that by participating in this
15 Commission that I'll be able to play some role in
16 heightening the interest in medical education in
17 complementary and alternative health care.

18 DR. FAIR: Hi. I'm Bill Fair. I was
19 trained as a neurologist. My background is at Stanford,
20 Washington University, and Memorial Sloan-Kettering Cancer
21 Center. I would like to say that none of those institutions
22 are known as bastions of complementary and alternative
23 medicine.

24 My interest in CAM was stimulated from my own
25 experience five years ago I was diagnosed with colon cancer.

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25 experience five years ago I was diagnosed with colon cancer.

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Commonwealth?

1 And going through a year of chemotherapy and a total of four
2 surgeries, I came back with another recurrence and at that
3 time was told I had more or less expended all of the known
4 curative options in allopathic medicine.

5 At that time I was looking around for things
6 to do and some advice. And my good friend, Dean Ornish, was
7 instrumental in suggesting I go out and see Michael Ernst's
8 program at Commonweal. Many of you may know that. The
9 mantra of the institution is almost "expand life even if you
10 can't extend life."

11 And that struck a very responsive cord and I
12 came home and talked to my family and said, "This is what I
13 want to do, is not to take the therapies." They had offered
14 me an experimental therapy. But I wasn't going to just sit
15 there and wait for the other shoe to drop, so I began
16 looking at what could be done in the area of complementary
17 and alternative medicine. And I was really delighted and
18 surprised to know there was as much science out there as
19 there was.

20 And as a result of that, I became extremely
21 interested in this. I left Memorial Sloan-Kettering, in
22 April, and was involved in a venture of establishing a
23 complementary medical center in Manhattan, which was opened
24 by the end of the year.

25 And my hope for this committee, this sounds a

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1 bit grandiose, but I honestly think we need to change
2 medicine. I think that complementary medicine should not be
3 looked upon as another specialty that the patient has to go
4 to.

5 From a patient's viewpoint, and I speak from
6 that primarily, it's a bewildering array of choices out
7 there and I think we need to bring these complementary and
8 alternative medicine techniques into the practice of every
9 doctor. And I think, hopefully, that this committee will
10 set the first stage and we can accomplish that.

11 DR. GORDON: Let me introduce myself a little
12 bit at the end, but I want to introduce a couple of people
13 now. First, the two on my left and my right, will you say a
14 couple of words? And then I also want to introduce another
15 one of our Commission members who can't be here today.

16 MR. GROFT: Thank you very much, Jim. I'm
17 Steve Groft, and I've been given the opportunity to serve as
18 the executive director of this Commission. By training I'm
19 a pharmacist. And the last 18 years of my life has really
20 been devoted to orphan and rare diseases, except for the
21 period of 1991 to 1992, where I had the opportunity to
22 establish the Office of Alternative Medicine at NIH.

23 And I must say that year has turned my life
24 around tremendously. Energy that I never thought existed
25 continued to flow into me, and I don't know how I got here,

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23 And I must say that year has turned my life
24 around tremendously. Energy that I never thought existed
25 continued to flow into me, and I don't know how I got here,

1 to be honest. But I am here, and I'm really pleased with
2 the Commission.

3 The task in front of us is tremendous. We
4 have a year's period to get it done, but I think the
5 opportunities are great and we do have a growing group. If,
6 you the audience, knew what we went through to get the
7 people here and what they went through to get here, I think
8 you'd be very proud of them. So it's my thanks to them for
9 agreeing to serve with the Commission and giving up so much
10 of their lives and their schedules next year or year and a
11 half to get this report done.

12 You'll hear from me later on but not too
13 much. This is their Commission and we are here to work with
14 them and to listen to you, the public, to give us direction
15 as well, for what has to be done. So I thank whoever it was
16 that gave me the opportunity to do this, thank you.

17 MS. CHANG: My name is Michele Chang, and I'm
18 serving as the executive secretary for the Commission. I
19 spent the last 10 years in Federal government with the
20 Centers for Disease Control in prevention, working on
21 tobacco issues. And I spent a year with Senator Harkin's
22 office, during which time I had a great opportunity to help
23 with the conception of this Commission. And I'm really
24 pleased to now be serving the Commission itself more
25 directly.

1 I am trained in public health policy and
2 management and I am also a certified massage therapist, so I
3 am really looking forward to what we will be learning over
4 the next two years together.

5 DR. GORDON: Peter Reinecke will be
6 introducing himself a bit later, and bringing some words of
7 welcome to us. I'm very glad to be flanked by Steve and
8 Michele. They are a wonderful core of this staff that's
9 going to be working with us and serving all of us as we move
10 a head with the Commission.

11 I want to introduce now Wayne Jonas, who
12 cannot be here this afternoon. And from time to time I may
13 bring up some points. Wayne left some papers with me about
14 some of his concerns.

15 Wayne was formerly director of the Office of
16 Alternative Medicine, and is an associate professor of the
17 Uniformed Services University of Health Sciences. He is a
18 family physician who, for a number of years, has been
19 working with complementary and alternative therapies and has
20 a particular interest in homeopathy.

21 And he has a wonderful grasp of the field
22 and of some of the issues that will come up as we try to
23 bring recommendations to fruition and try to take a look at
24 what's happening in the Federal Government around the
25 Country. Wayne will be with us at the next meeting and

1 sends his regrets.

2 DR. PAZ: I am Conchita Paz. I'm a family
3 practitioner from Las Cruces, New Mexico. I have lived
4 there for about 10 years. I did my medical school in the
5 University of New Mexico and my residency over at Creighton
6 University in Nebraska. When I got on this Commission, over
7 the last year, actually, I have been helping with developing
8 some policy for a Hispanic population.

9 And part of my interest in this is to make
10 sure that some of the older cultural kinds of folks in these
11 United States are also looked at as far as the complementary
12 medicine. Because, for instance, in the Mexican culture,
13 they have the curandismo, that is also very strong,
14 especially in New Mexico where we have a large population.
15 So some of the other issues involved with alternative
16 medicine, I'd like to see, you know, to be a part of from
17 the very beginning. Thank you.

18 MS. SCOTT: Good afternoon. My name is Julia
19 Scott. I am president of the National Black Women's Health
20 Project. We are a national membership organization that
21 focuses on wellness self-help and health advocacy. And I
22 figure I got on this Commission representing a constituency.
23 And I think that most people in the room would agree that
24 the person who ends up doing most of the negotiating and
25 obtaining of health care falls to women. And so it's a

1 fairly large constituency.

2 Our organization focuses on African American
3 women, but we also participate in the broader women's health
4 community, so that's part of the reason why I'm here. In
5 addition to that, I think a large number of our constituency
6 uses complementary and alternative medicine and they are
7 looking for ways to discuss this with their practitioners,
8 and who use it, to a large degree along with medicine as
9 practiced in the United States, and are finding a lot of
10 resistance.

11 So I just think this Commission is a
12 wonderful opportunity to really put this issue, that so many
13 people want, on the front burner. So I am very happy that
14 this Commission was put together. My hopes and my interests
15 for being on the Commission is that I hope that we can be
16 helpful in moving acceptance of CAM by buyers and especially
17 the payers of the health care system.

18 I think it's a wonderful opportunity to raise
19 the consciousness of the Country about how an important this
20 is for people in their daily lives. I also think it's
21 important to develop a policy that will broaden access into
22 new areas.

23 I'm very concerned for, especially, people of
24 color and people living on low incomes, to make sure that
25 this doesn't become one of those things that you can only

1 obtain if you are of an economic base or a social class.

2 And most important, I guess, is that we all want
3 to be sure that these alternative and complementary methods
4 are safe and effective. This Commission has a great
5 opportunity to move all of this forward and I look forward
6 to being a part of that.

7 MR. DEVRIES: I am George Devries. And I'm
8 the chair, president, and CEO of American Specialty Health.
9 And that was a company, and I helped co-found that in 1987.
10 We are one of the largest health service organizations for
11 complementary and alternative health care nationally.

12 We, specifically, have created specialty
13 health plans and networks and administrative systems for
14 complementary health care. And then we go and we work with
15 health plans across the Country to help them offer
16 complementary and alternative medicine benefits and other
17 types of programs for their base of members.

18 In many ways we function a lot like a vision
19 or a dental plan, except we focus on complementary health
20 care and we work specifically with chiropractic and
21 acupuncture, massage therapy, dietetics, naturopathy, and
22 other areas of complementary and alternative health care. I
23 think the White House Commission has some tremendous
24 opportunities.

25 And among those that I'm most excited about

1 are really the focus on safety and efficacy of service and
2 products, and helping to increase the credibility of
3 complementary and alternative health care, as well as focus
4 on research and education. And all of these areas, as they
5 are enhanced and improved, will certainly lead, I believe,
6 to better coverage for all Americans through complementary
7 and alternative health care.

8 We really have seen, I believe, probably even
9 just a very modest beginning, the tip of an ice berg, so to
10 speak, of actual coverage of complementary and alternative
11 health care among governmental payers as well as private
12 payers, employers' health plans, insurance companies and
13 others, so there is tremendous opportunities as we look to
14 the future.

15 SISTER KERR: My name is Sister Charlotte
16 Kerr. I'm a Sister of Mercy, I'm a nurse, I'm an
17 acupuncturist, and also a woman, the ground upon which I
18 stand. Since 1977, I have been a practitioner of
19 traditional acupuncture and a faculty member of the
20 Traditional Acupuncture Institute in Columbia, Maryland.
21 Before that I was an assistant professor of nursing at the
22 University of Maryland. And I have served with some of the
23 distinguished panel here on the National Institute of Health
24 Advisory Council.

25 My hope, as a Commission, is that we will

1 continue to heal and to serve the citizens of the United
2 States through complementary and alternative medicine. And
3 my continued hope is that we will be able to offer
4 complementary and alternative medicine to the citizens in
5 ways that forwards individual and cultural healing and does
6 not just add on techniques to our present health care
7 system. I'm sure I have many more hopes and I will leave it
8 with those two for today. Thank you.

9 DR. ORNISH: My name is Dean Ornish. I'm an
10 internist and a member of the faculty, a professor of
11 medicine, at UCSF, and founder and president of the non-
12 profit Preventive Medicine Research Institute. And I feel
13 very privileged to be with such a distinguished group of
14 people. I'm particularly delighted to have Jim Gordon as
15 the chair.

16 And for me this Commission represents a real
17 dream manifesting, I think that's probably true for many of
18 us who have been in this field for a while. For the past 23
19 years, my colleagues and I, including Dr. Sandra McLanahan,
20 who is here, and several others, have conducted a series of
21 scientific studies demonstrating that the progression of
22 even severe heart disease often can begin to reversal when
23 people make much more intensive changes in diet and
24 lifestyle.

25 And it really integrates traditional and non-

1 traditional approaches than had been thought possible
2 before, without bypass surgery, angioplasty, a lifetime of
3 lipid-lowering and other drugs, and so on. And we have
4 published our findings in a number of journals and presented
5 at scientific meetings, and so on.

6 And I think our work is a model of a
7 scientifically-based approach that may be helpful to others
8 in building bridges between the so-called conventional or
9 allopathic and alternative medical communities. The idea
10 that heart disease might be reversible was a radical concept
11 23 years ago when we first started doing this work, and now
12 it's become pretty mainstream.

13 Since looking at the medical effectiveness,
14 for the last seven years or so, we've been looking at the
15 cost effectiveness of these kinds of approaches. We are a
16 non-profit institute. We train hospitals and other sites
17 around the Country. And we've been able to demonstrate that
18 most people who are eligible for bypass surgery,
19 angioplasty, were able to safely avoid it by this integrated
20 medicine approach. And the insurance companies found they
21 save an average of almost \$30,000 a patient by doing that.

22 And recently, after six years of going back
23 and forth with HCFA, which has become very familiar to me,
24 they agreed to do a demonstration project to look at 1,800
25 people, at the various sites that we train, to see if we can

1 show this in the Medicare population. And I have come to
2 learn that the primary determinant of medical practices is
3 less science and more reimbursement. And if we can change
4 reimbursement, we can ultimately change medical practice and
5 medical education.

6 And we're also finally doing a study-in-
7 progress with Dr. Fair and his colleagues at Sloan-
8 Kettering, to see whether the prevention of prostate cancer
9 might be affected with similar kind of intervention. We
10 began that three years ago and our preliminary data there
11 are encouraging.

12 And I think his own story is an example of
13 how these approaches -- again, we focused on heart disease
14 as a model but the implications go far beyond that. So I'm
15 thrilled to be here and very much looking forward to working
16 with such a distinguished group.

17 DR. GORDON: I'm Jim Gordon. And I am so
18 pleased, as I listen to all of us go around the room this
19 morning, as you say who you are and why you're here, and it
20 feels like an extraordinary opportunity for all of us to
21 work together and to work for everyone in this Country and,
22 indeed, around the world. Because it's important to
23 remember that in many ways the United States is still the
24 leader. And as we go here in this room, as we go in this
25 Country, many other countries will pay serious attention.

1 I'm "trained", that's an interesting word,
2 trained as a psychiatrist. I went to Harvard Medical School
3 and did my psychiatric residency, and then spent 10 years as
4 a researcher at the National Institute of Mental Health,
5 where I created the first national program for runaway and
6 homeless children, and worked on a preceptorship program for
7 medical students in complementary, holistic, integrated
8 medicine.

9 And I spent a great deal of time beginning to
10 get to know many people in this field, partly working for a
11 special study on alternative services for President Carter's
12 -- remember President Carter? -- Commission on Mental
13 Health. So it's wonderful to be back with the Commission.

14 I have founded and directed a non-profit here
15 in Washington D.C., called the Center for Mind-Body
16 Medicine. And our work is really helping to transform
17 medicine in this Country and helping to revive the spirit of
18 healing in all of health care. And that's the work that I
19 see that we are going to be doing here, in a variety of
20 ways, on the Commission.

21 I've been interested in this area for 35
22 years. I began my studies with an interest in Chinese
23 medicine in the mid-1960s and I've spent time with healers
24 all over the world. And I hope that one of the things that
25 we do here is bring some of the wisdom of all of those

1 healing traditions in a kind of wonderful celebratory
2 marriage with the best of our science. And then the fruits
3 of what we learn here together, we'll then be able to make
4 available to everyone in this Country. And that's my hope
5 for our work together.

6 And now I 'd like to introduce Peter
7 Reinecke, who is going to say a few words. I'll let Peter
8 just say it for himself. One question first, is there
9 anyone who needs assistance with sign language, we have
10 interpreters?

11 (No response.)

12 DR. GORDON: Okay, thank you.

13 WELCOMING REMARKS

14 MR. REINECKE: I'm Peter Reinecke. I'm
15 Senator Harkin's legislative director. And I have worked
16 with him for over 10 years, and also worked in the health
17 care area on Capitol Hill for almost 20 years now. But
18 Senator Harkin was very thankful for the opportunity to talk
19 to you all this morning and give you his rationale and
20 feelings of why this Commission is so important.

21 He has obviously been very active at the
22 national level in trying to promote better attention to
23 complementary medicine, and primarily in the area of
24 additional research. But his thought for this Commission
25 was really to catch up public policy to the people and the

1 use of complementary and alternative medicine therapies.

2 So, first, just to say again, thank you from
3 Senator Harkin to the Commission for taking time out of your
4 busy schedules to participate in this. And, second, to say
5 how great of an opportunity you have to have an impact on
6 public policy and, hopefully, on health care delivery to all
7 Americans.

8 Third, to say that there is a broad interest
9 in what you do and what you are going to come up with on
10 Capitol Hill, both amongst Democrats and Republicans. It is
11 not at all a partisan issue, there is strong interest in all
12 quarters of the political spectrum. And I think that you
13 will be received in that light, that this is not a political
14 effort, this is a public policy health care effort.

15 And, fourth, to make the point that it's so
16 important for the Commission to have public input. And so
17 I'd urge you in your meeting today, from Senator Harkin, to
18 develop a comprehensive plan to seek public input. Because
19 how this Commission Report will be received, in large part,
20 will be determined by the extent that people feel that they
21 have a stake in the process. I can't underscore that
22 enough.

23 And, finally, just to go over a few of the
24 questions, and I know that some are outlined in the paper
25 that you already have, some of the questions that Senator

1 Harkin had in mind that you might consider making
2 recommendations on in your work. And they are not in any
3 particular order but they are relative to training.

4 Should those being trained in CAM practices
5 be eligible for Federal assistance in terms of loans,
6 grants? What can be done through Federal mechanisms and
7 otherwise to encourage continuing education of CAM therapies
8 among practicing physicians and other conventional health
9 care providers? What can be done through Medicare's support
10 of graduate medical education to encourage integration?

11 And the second area of research, as Senator
12 Harkin made clear in the morning, that it's his belief that
13 that Commission is not, and that you have enough to do, that
14 it's not necessary for the Commission to get actively
15 involved in commenting on the research agenda for NIH; that
16 there is a separate advisory council for that, and that that
17 was not his intention in establishing this Commission.

18 He was and is hopeful that you all will take
19 a look at what can be done to encourage greater public
20 investment in research on CAM. As you know, a lot of the
21 treatments and therapies are not patentable, and so we don't
22 have that incentive built into Federal law. And there has
23 been some discussion amongst different experts about how to
24 better encourage the private sector. And if you all could
25 help with recommendations in that area, I know that would be

1 very well received on Capitol Hill.

2 Third, on the delivery of integrated health
3 care, that's been mentioned, I'm very interested to get the
4 Commission's recommendations on what kind of criteria the
5 Federal government should use for the inclusion of CAM
6 therapies into Federal health programs and federally
7 supported health programs.

8 And, finally, in the area of oversight in
9 coordination. As some of you may know, there are many
10 departments, including the Department of Health and Human
11 Services, within the Federal government that have an
12 interest and active agenda in the area of complementary and
13 alternative medicine, whether it's the Defense Department,
14 whether it's the Department of Veterans' Affairs, the
15 Department of Health and Human Services and their entities,
16 there is a great deal of activity going on.

17 The question is, is that activity at an
18 appropriate level and is that appropriately coordinated?
19 Again, that's something I think the Congress would be very
20 interested in getting your input on. Those are just a few
21 of the questions.

22 I think one of the big challenges that you
23 face is going to be trying to limit what you look at because
24 there is so much you could do. But you are obviously very
25 well qualified, and Senator Harkin is very pleased to see

1 that diversity of experience and backgrounds of people on
2 the Commission, because this, in particular, needs to have
3 input from a very broad array of expertise and personal
4 background.

5 And so, again, to say thank you. Senator
6 Harkin is very excited about this and he is committed to
7 making sure that, in working with his colleagues, you all
8 have the resources you need to finish the job. And, again,
9 to make sure that your report, when it does come out, gets
10 the attention it deserves on Capitol Hill. So thank you,
11 Jim, and members of the Commission.

12 DR. GORDON: Thank you very much, Peter.
13 Senator Harkin has indeed been, as he would say of others,
14 he has been the torch bearer for this whole movement in
15 Congress, and Peter has been with him every step of the way.
16 And I just want to thank you publicly for your guidance and
17 support, and you are really making this all happen. Thanks
18 so much, we owe you a debt of gratitude.

19 MR. REINECKE: Thank you.

20 DR. GORDON: And I'll look forward to our
21 continuing debt of gratitude. We now have a presentation on
22 ethics from Karen Santoro and this is for Commission
23 members. Thank you, Karen.

24 ETHICS REVIEW FOR FEDERAL ADVISORY COMMITTEE MEMBERS

25 MS. SANTORO: Good afternoon. Welcome to

1 Government service. The purpose of this portion of the
2 meeting is to provide an overview of the ethics rules for
3 Government employees now that you are serving this
4 Commission. I'd like to start by showing a video tape.
5 It's about 20 minutes.

6 It was produced by the Office of Government
7 Ethics, which is an independent Federal agency that is
8 responsible for writing and interpreting the ethics rules
9 for Government employees. The video tape specifically
10 focuses on advisory committee members, such as yourselves.
11 And then after the tape, I'll wrap up by noting two
12 developments since the filming of the tape, and I'll answer
13 any questions you may have.

14 (Whereupon a video presentation is given.)

15 MS. SANTORO: Let me encourage you, if you
16 have questions about your individual circumstances, to
17 contact Steve after the meeting. Are there any more general
18 questions?

19 (No questions.)

20 MS. SANTORO: I know that's a lot to
21 comprehend, but let me just give you the additions since the
22 tape was filmed. In the section on resolving conflicts, you
23 heard about disqualification, waivers, and divestiture.
24 Well, the Office of Government Ethics now has some
25 regulatory exemptions. They have decided that some

1 financial interests are so insubstantial, they are not going
2 to present a conflict of interest. And I'm going to mention
3 two of them.

4 The first is diversified mutual funds. If
5 you hold these types of funds, they will not present a
6 conflict. "Diversified" means they are not concentrated in
7 any particular industry or sector. So, for example,
8 Fidelity Growth and Income Fund is a diversified mutual
9 fund. However, Fidelity Select Biotechnology Fund is not
10 and would not qualify for the exemption.

11 The last exemption I want to call your
12 attention to is an exemption that permits Commissioners,
13 advisory committee members, to work on general matters that
14 affect your primary non-federal employer. Let me give you
15 an example of this.

16 Let's say the Commission is working on a
17 policy for education of health care practitioners and the
18 commissioner is dean of a medical school. Well, of course,
19 medical schools as a class are going to be affected by that
20 policy. This exemption permits you to go ahead and work on
21 that policy.

22 I have left a brochure at your places. This
23 is a brochure from the Office of Government Ethics. It
24 gives more detail about conflicts of interest. And in
25 addition to Steve, your committee management officer is well

Again,
series of
Mr. Groff

— Not

Dr. Groff

1 acquainted with the ethics rules and can provide you
2 guidance. Thank you.

3 DR. GORDON: Okay. Any general questions?
4 (No questions.)

5 DR. GORDON: Please feel free to contact
6 Steve with any specific questions and he can arrange a
7 meeting or discussions with you. Steve?

8 MR. GROFT: Essentially, all of you have
9 indicated what potential conflicts may exist. And we do
10 have that, that was involved with your clearance. So, in
11 essence, you've been given a waiver to work on the issues
12 here, the policy issues that we will be discussing, without
13 any concern about conflict of interest, so you all are in
14 good shape.

15 DR. GORDON: Okay. Steve, do you want to
16 now, before we take a break, and we'll be taking a 20-minute
17 break in a few moments, to indicate to us what the
18 legislative charge is for the Commission?

19 MR. GROFT: I think if you read the Executive
20 Order that has been given out to you and is in the back of
21 the room, the goal and the charge for the Commission is to
22 provide a report to the President, through the Secretary, on
23 legislative and administrative recommendations to assure
24 that public policy maximizes the benefits of complementary
25 and alternative medicine to Americans.

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23 legislative and administrative recommendations to assure
24 that public policy maximizes the benefits of complementary
25 and alternative medicine to Americans.

1 It's a very broad directive, but it is one
2 that will take us quite a bit of time just looking at the
3 four major issues that were spelled out in the Executive
4 Order. And there is a time limit. We must be out of
5 business by March 7, 2002, two years after the Executive
6 Order was signed by the President.

7 And I would like to add that it is the intent
8 of the White House to expand this Commission to 20 members
9 from 15. We're hoping that this will all take place and
10 continue to grow, so there will most likely be six more
11 members who will be considered for appointment to the
12 Commission.

13 They are under consideration now, and
14 nominations and recommendations and has been put forth, and
15 the paperwork is still under review. So it is the intent of
16 the White House to expand the group and to give a little bit
17 broader expertise.

18 I think you all know that there are so many
19 different interventions involving complementary and
20 alternative medicine, and in order to give a good breadth of
21 experience, the decision was made that we would try to
22 expand the group.

23 DR. GORDON: What we're going to be doing
24 after the break is, I'm going to give a kind of general
25 overview of the tasks that we're going to undertake and some

1 of the ways that we are going to pursue those tasks. And
2 then, this afternoon, we're going to address the first item
3 on the agenda.

4 This was the first of our four charges which
5 is to develop a coordinated research to increase knowledge
6 about complementary and alternative medicine practices and
7 products. And I'll talk a little bit about the format when
8 we come back from the break. But I think it's time for us
9 now to break for about 20 minutes and then we will be back.
10 (Off the record for a brief recess.)

11 DR. GORDON: I just want to say a few words
12 about how we're going to be proceeding. First of all, we
13 are actually ahead of time, which is quite remarkable. I
14 don't know if it will happen again, but it's important to
15 note this occasion. We have until 5:30 today, and if we
16 finish a few minutes early, that's okay too. I know a
17 number of you have come from far away and we want to just
18 take it easy, but we may well go to 5:30.

19 Tomorrow morning, we'll begin at 8:30 and
20 we'll go to 5:00 tomorrow. That's our current plan. There
21 will be an hour of public comment tomorrow between 1:00 and
22 2:00, and you have that on your schedule. And I encourage
23 everybody here, who would like to make comment, to be in
24 touch with Michele Chang and let her know. And if there are
25 other people you know who you think might like to say

1 something, to this group at this point, please ask them to
2 come.

3 We apologize for not having had more advance
4 notice. We didn't have much advance notice. And it's just
5 wonderful that all of you were here, to be here. And in the
6 future, there will be significant advance notice, there will
7 be a longer time for public comment, two hours for public
8 comment each time. And we are very eager to hear from the
9 public.

10 The form that we're going to take this
11 afternoon is we're going to begin with the first topic. And
12 the way we're going to work is this meeting is really an
13 organizational and a planning meeting. And we want each of
14 the Commissioners, and each and every one of you, to raise
15 issues that you think we want to consider when it comes to
16 research. And don't be afraid of being wide of the mark,
17 there is no such thing right now.

18 We're going to use everything that we
19 accumulate on these four topics and then with the staff,
20 I'll work with the staff, we'll distill it. We'll get it
21 back to you and we'll use that as a basis for planning
22 subsequent meetings, so feel free.

23 The other thing I want to tell everybody
24 here, that I've already mentioned to the Commission members
25 but I want to make everybody here knows, is that in addition

1 to the regular Commission meetings -- and we'll be coming at
2 the end of the day tomorrow to scheduling the next meeting
3 and perhaps even the next couple of meetings -- there will
4 also be a series of town meetings at different places around
5 United States.

6 And those meetings will not be for us,
7 Commissioners, to talk, but for us to simply listen and to
8 ask questions. And the plan would be for us to go out, and
9 I would go to those meetings, and work with different
10 Commissioners in different parts of the Country.

11 And I would ask the Commissioners, as well as
12 all of you, and all those who you know, and all those who
13 you represent, to bring in people in that geographical area,
14 or anywhere else for that matter, who would like to make
15 suggestions, inform the Commission about the kind of work
16 that they feel is important for us to consider.

17 And the reason we're doing it this way is
18 because we've initially thought of having different
19 Commission meetings at different places around the Country,
20 but we realized that by the time we got to do that, we'd be
21 very far down the road in our deliberations. So we want to
22 open things up as much as possible right in the beginning,
23 and have as much input as possible from all sectors of the
24 public.

25 And we welcome your comments in hearing the

1 public comment tomorrow. We welcome your comments on
2 particular places that you think we should be having some of
3 those town meetings.

4 And the other thing is, this process is going
5 to be open in an ongoing way to the public. Steve Groft
6 will talk a little bit about the Web site that we'll be
7 having up very soon. This is a process of continuing
8 interaction and dialogue among all of us and with everyone
9 who is interested in this field. And we welcome it and we
10 encourage it, and that's how this blueprint has developed,
11 and that's how it's going to continue to evolve.

12 This is, first and foremost, a popular
13 movement, a movement of people who are looking for better
14 health care, a movement of health professionals, on a large
15 scale, who are interested in improving their own health and
16 in being of service to the largest possible number of
17 people. And we're going to continue in this form.

18 We're going to continue this emphasis on
19 service to all, and at the same time making use of
20 scientific methodology to evaluate those approaches and
21 those techniques that should be included in those services
22 and should be included in professional education and public
23 education. So this is a process which we're all working on
24 together.

25 And as everyone heard earlier in the day, we

1 represent a number of different groups, a number of
2 different constituencies, a number of different points of
3 view. And our work is to come to understand not only our
4 perspectives but the perspectives of all those who have
5 something to contribute on these many issues.

6 So, without further ado, the first issue that
7 we're going to address is the issue of research. And if you
8 look at the agenda, it's under number one, "Coordinated
9 Research to Increase Knowledge about Complementary and
10 Alternative Medicine Practices and Products." So in this
11 discussion, we welcome your suggestions about ways that we
12 should approach this mandate of the Executive Order and of
13 the legislation that established this Commission.

14 How do we achieve coordinated research?
15 Perhaps how do we define "research"? How do we define
16 "coordination"? How do we define the domain that research
17 should be done in? And I know these are huge, if not
18 daunting areas. Our task is to begin to take a look at the
19 entire map and then to see what portion of it we can most
20 productively focus on.

21 Tomorrow we will have microphones for
22 everybody. Today Michele is going to perform the service of
23 moving the microphone around from speaker to speaker. So
24 anyone who would like to begin, please feel free. George?

25 DISCUSSION OF VISION, ISSUES AND CONCERNS

1 OF COMMISSION MEMBERS

2 Coordinated Research to Increase Knowledge about
3 Complementary and Alternative Medicine Practices
4 and Products.

5 MR. DEVRIES: Related to research, and I know
6 there has been discussion of legislation here in Washington,
7 and I want to support this particular legislation which is
8 potentially to, shall we say, incentivize or encourage the
9 private sector to move forward with research especially
10 related to efficacy and safety of botanical products. And
11 treating them almost like the drug law has, giving
12 opportunities to those companies, that step forward to do
13 research, to be able to market those particular products.
14 And, again, not only research that NIH can do but also
15 supporting outside research also.

16 DR. GORDON: Thank you. As people make
17 comment, I'm going to sort of ask some follow-up questions.
18 And if others of you have follow-up questions, please feel
19 free to do so as well. And one of the follow-ups for
20 everybody to be thinking about is what we should do to
21 consider the issue that you are raising.

22 So if you are talking about private sector
23 research of botanicals and other substances, what kind of
24 information do we as a Commission need, what kinds of
25 people, whether individuals or groups, should we be talking

1 to in order to get the information that we need to consider
2 this issue? Dean, go ahead.

3 DR. ORNISH: I'm a firm believer in research.
4 And I think that if we really want to integrate
5 complementary and alternative medicine into the mainstream
6 that research is a really good way to do that. And then
7 that gets it out of the realm of separate, to even stop
8 thinking about it as alternative and just say, "Does it work
9 or does it not work?"

10 And so I think that to the degree we can
11 focus on, to some degree, the kind of research that would be
12 of interest, but I also understand that is something of
13 consequence to focus on because that's an approved view of
14 the NIH National Center for Complementary and Alternative
15 Medicine, so to the extent that you can help me understand
16 it's in the purview of this committee to address those
17 issues, it would be helpful.

18 DR. GORDON: Okay, thank you. The way I see
19 it, and I have talked with Senator Harkin, among others,
20 about this, is that we are going to define the broadest
21 possible research agenda. The research that NIH is going is
22 one part of the research that's being done.

23 And one of the people who I would ask, and
24 I've already talked with him about this, I've asked Dr.
25 Steve Straus, to come and talk with and present NCCAM's

1 present research, future plans and issues. So that will be
2 very much a part of our discussion and a part of our
3 understanding very early on.

4 DR. ORNISH: So just to clarify as a follow-
5 up, so he'll say, "This is what we're currently doing." And
6 our agenda is to say "Okay, we can do things beyond that and
7 what are some of the areas that we should focus on"?
8 Because as you know, so many people are using alternative
9 approaches without really any studies at all being done on
10 whether they are effective or not.

11 DR. GORDON: Right. I think that what
12 Senator Harkin and Peter were saying is, the basic idea is
13 we're not going to micromanage the NCCAM research agenda.

14 DR. ORNISH: Okay.

15 DR. GORDON: But my hope is, and I think
16 Steve Straus's is as well, that we're going to have a
17 dialogue about research agendas. He values our input and he
18 values our thinking about the issues. And the question is,
19 ultimately, they can't do everything. And how are we going
20 to consider a whole variety of questions, some of which may
21 fall easily into their domain, some of which may fall
22 outside? And I think one of the things that we can do is
23 define what those different domains are.

24 DR. ORNISH: And also to determine whether we
25 would recommend an increase in funding for them, for

1 example, is that part of the scope --

2 DR. GORDON: That would certainly be a
3 possibility, increase in funding in particular areas that we
4 think need to be looked at in addition.

5 DR. ORNISH: Great, thank you.

6 DR. GORDON: Thank you for asking for that
7 clarification. But I wanted to follow up with George, if
8 there were any ideas that you had when you talk about
9 private sector research and private sector, how we should
10 make more sense of that?

11 Again, I apologize we only have the one
12 microphone. It's just a technical limitation. I do a lot
13 of work in Kosovo and one of the things that we have or
14 don't have there is power. So often the lights go off for
15 long periods of time. We're not only without microphones,
16 we do without slides, we do without lights, we do without
17 elevators. So these are just some of the vicissitudes of
18 modern life.

19 MR. DEVRIES: I'm sure there is a variety of
20 ways to approach it. But certainly if you look at the
21 orphan drug law legislation, and how that has worked, if you
22 potentially look at some of the major manufacturers of
23 botanicals and some of the research that they've already
24 done, for some are active in research, and then potentially
25 considering some of the needs for additional research, that

Mr. Graft

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Dr. Graft

1 might be a good place to start. And I'm sure through that
2 process we'd find out a lot more to look at.

3 MR. GROFT: For several of you who aren't
4 familiar with the Orphan Drug Act, there are several
5 incentives involved in the act that are given to
6 manufacturers. One is the seven-year marketing exclusivity
7 that is given to the company after the product has been
8 approved, after it's gone through the process of receiving
9 the Orphan Product Designation.

10 Another incentive would be tax credits that
11 are available to manufacturers. So they are a couple of the
12 incentives, and there are several others involving protocol
13 development and things working with the Food and Drug
14 Administration, so there are several options available. And
15 I think a broad subject like this is something that would be
16 appropriate to look at.

17 DR. GORDON: Tom, and then Conchita, and then
18 Bill.

19 MR. CHAPPELL: I'm going to build on the
20 question of how to improve the research for botanical
21 products by pointing out that in my experience we are not so
22 much currently set up in our Country to increase knowledge
23 as we are to fit the regulatory channels that govern the
24 claim.

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23 as we are to fit the regulatory channels that govern the
24 claim.

25 For instance, one kind of claim may put you

1 in the over-the-counter drug area, another claim might put
2 you in the DSHEA bill. Whatever, we're required to know as
3 much as we can about a single herb, a single ingredient, not
4 a blend.

5 My concern is that our present way of
6 marketing is dependent upon a regulatory system that is very
7 narrow and very structured, and it doesn't fit with the
8 consumer's mind. So that the whole industry of dietary
9 supplements, over-the-counter drugs, is driven by regulatory
10 norms, not consumer thinking.

11 The reason that we have a popular movement
12 today is because the consumer thinks naturally, logically,
13 and seeks to know more about ingredients. That's why the
14 term "self care" has evolved. So if we're going to increase
15 knowledge, we've got to connect that quest to a re-
16 examination of the regulatory norms to try to build some
17 flexibility into the category to which that research will
18 ultimately be accountable. Do you understand my point?

19 DR. GORDON: What, if anything in particular,
20 do you think we need to look at?

21 MR. CHAPPELL: Blends of herbs. I mean the
22 Eastern orientation is based on blends, the FDA is based on
23 single herbs. Single herb, single claim. So if our
24 research -- I know that NIH is granting money to provide
25 more knowledge about single herbs, but we also need to

1 venture into this realm of blends, as well as re-examining
2 the regulatory domain.

3 DR. GORDON: Thank you. One of the things I
4 also want to remind everybody is that as we develop next
5 Commission meetings, we will be asking all of you at the end
6 of this meeting tomorrow, to fill out which of the sort of
7 subcommittees you want to be on in terms of working on
8 research, or working on education, et cetera.

9 So as we pull together an agenda, we'll be
10 asking for input from all the people on those subcommittees
11 about the contents of the agenda. Let me go to Conchita,
12 who is next, and then Bill, and then Effie.

13 DR. PAZ: Well, getting back to how to
14 address some of these concerns. Part of what I think we
15 need to realize is that some of this, we don't need to
16 reinvent the wheel, so to speak. There has been actually
17 some research that has been published and we might need to
18 go back and relook at some of that literature that's already
19 been out.

20 However, there may be in other journals, like
21 some of the nursing journals, some of the psychiatric
22 journals, there may have already been some studies that have
23 been already done that we might need to pull together to
24 look at some of those data that is out there on some of
25 these alternative medicines.

1 DR. GORDON: Let me stop for a minute and ask
2 everyone to consider this question. What data do we need at
3 this point about the research that's already out there? We
4 have already said we're going to have Dr. Straus come to
5 talk about NCCAM research and perhaps some about NCCAM data.
6 But what data do we need here to make our decisions?
7 Anybody. I'm opening it now and then we'll go back to the
8 order. Bill?

9 DR. FAIR: I think when I start a research
10 project, we start by finding out what we know about a
11 subject. And I think that what -- and maybe I'm the only
12 one on the committee that is unaware of what the botanicals,
13 for instance, what the problems are. All you hear about is
14 the lay press, where they point out the difficulties with
15 the botanical problem.

16 And I think it would help the committee, and
17 I don't know who would do this, but for someone to present
18 the committee with where we stand right now. What is the
19 scope of the problem, or is there a problem, or is this
20 something that's a invention of the lay press primarily, to
21 pick on one particular incident and build it up?

22 Steve and I were talking before about my
23 undergraduate degree is in pharmacy. And I can well
24 remember the discussions that went on when generic drugs
25 came on the scene. And I well remember my professor saying,

1 "generic drugs, half the price twice the side effects." And
2 that was the concept.

3 And now we know that you can standardize
4 generic drugs and they are cheaper for the consumer. And so
5 I guess what I'm saying is, from reading the lay press, I
6 think there is a problem with the standardization and purity
7 of these botanicals. But I'd really like to hear from
8 someone who is knowledgeable to tell me really what the
9 scope of the problem is.

10 The second thing is what Tom mentioned. I
11 know my own institution -- which is trying to do a study on
12 a mixture of herbs for prostrate cancer, which is eventually
13 being done at U.C.-San Francisco -- but it was just because
14 it was a mixture and it wasn't a single ingredient. And as
15 you know, in standard oncology it's axiomatic that you only
16 use a drug in combination if it shows effect as a single
17 agent.

18 And not that I know much about Chinese
19 medicine, but it's more or less standard in Chinese medicine
20 that you use things in a mixture. And I also understand
21 that when a Chinese doctor would give a person an herbal
22 mixture, say, they may also be prescribing something in diet
23 and acupuncture, as a whole thing.

24 And I think that it's important that if we
25 look at these modalities, we ought to make some push that we

1 just shouldn't take any one of these thing out as an
2 individual aspect to be investigated without the whole
3 process.

4 We can test Chinese medicine against
5 allopathic medicine if we include all of Chinese medicine, I
6 mean, for treatment. If we just take acupuncture out for
7 Chinese medicine and test that against an allopathic
8 treatment for a specific condition, we may not get a valid
9 answer.

10 DR. GORDON: Great. Tom?

11 MR. CHAPPELL: Shall I answer his question
12 first or -- the problem, I think an industry problem right
13 now is the whole notion of standardization. Standardization
14 is based upon identifying a particular ingredient in order
15 to make a claim for that product. But that ingredient or
16 that active constituent, may not be the known, it may be a
17 marker rather than the known ingredient that has the effect.
18 So standardization is a shallow, illusory way of creating a
19 sense of efficacy.

20 DR. GORDON: So what are the things you are
21 suggesting, is it that we call into question the use of
22 standardization?

23 MR. CHAPPELL: It is.

24 DR. GORDON: I think it's kind of critical.

25 MR. CHAPPELL: It's going to beg the question

1 of what are the active constituents that are contributing to
2 the solution. Because that's part of the problem of
3 standardization, we don't know. Echinacea, we don't know
4 necessarily what is working, so the research could be
5 developed in that regard. What was your question that you
6 were asking earlier, because I wanted to respond to it and I
7 forgot it?

8 DR. GORDON: I was also asking what steps do
9 we need to take in this particular area, the area of
10 botanicals, for example. I want to go to Effie, first, and
11 then we'll come back. Because I think all of these
12 questions are -- incidently, and I see many of you are
13 taking notes, that's great. We're taking notes and we will
14 have transcripts, and we will be giving this information
15 back to all of you. And we will be posting it on the Web
16 site as we get the Web site up. So nothing is lost, it's
17 all a part of this mixture.

18 MS. CHOW: William mentioned considering
19 multi-disciplines in nutrition, and acupuncture, and maybe
20 Qi Gong, herbs, and so forth. Taken on its own, it may not
21 be effective research. And then moving down to isolate --

22 DR. GORDON: Effie can you speak a little
23 closer to the mic?

24 MS. CHOW: Moving into the isolated concept
25 that Tom just spoke about, is very real. Isolating the

1 compound from the herb may not work at all.

2 And now to go back. What do we know exists
3 in research? What research exists? We need to do a survey
4 of what we want to research, I think, first of all. And
5 then find what it isn't. We can't research everything, so
6 establish our priorities as to what area we should be
7 researching.

8 And then we need to do a survey on what has
9 been done. Again, falling back on Chinese medicine, I know
10 that there is lots of research that's been done in China.
11 It may not be as stringent perhaps, but some of it are very
12 stringent. And we need to get that. And I know there has
13 been some collection of this. And then take a look at what
14 is good, what isn't, and then decide what we need to
15 research.

16 And we need to question our protocol for
17 research because the energy concept in Chinese is "chi,"
18 just using Chinese medicine as an example. That the energy
19 there is constantly a question of whether our research
20 protocols can measure exactly what chi or the energy
21 component is.

22 But I think we need to look at our research
23 data. There was strong discussion about outcomes research
24 and ground research before isolating it into the double
25 blind studies and trying to isolate. So we need to do that,

1 explore ideas.

2 And botanicals is a big issue right now. But
3 there is a lot of spiritual healing, how do measure that, do
4 research into that? And also Qi Gong, and laying on of
5 hands, you know, acupuncture and all that. So I would say
6 an assessment of what is existing and then critiquing our
7 research methodology.

8 DR. GORDON: I'm going to go to Dean for a
9 minute. And then I want to come back to this issue and
10 return the question to you and to others, how do we suggest
11 any suggestions for looking at chi, any suggestions for
12 looking at spiritual healing methodologies that seem
13 appropriate, because I think we're looking to move as far
14 ahead as we can. We don't have to do it all today, but if
15 you have ideas -- Dean?

16 DR. ORNISH: Thanks. I just want to build on
17 what Effie was saying, and Tom, and Bill also. That besides
18 the data about research that's already out there, I think
19 there is some real challenges when doing research in areas
20 of what we call complementary medicine, behavioral medicine,
21 alternative medicine, where we don't want to give up the
22 rigors of good science but sometimes those methodologies
23 aren't appropriate, and to the degree that we can focus on
24 developing new research methodologies that maintain the
25 integrity of science and in some ways I think give better

1 data.

2 An example that we struggled with, for
3 example, is the most classically rigorous design, a
4 randomized control trial, double-blind intervention. Well,
5 you can't do a double blind intervention with most
6 alternative medicine interventions. And even the fact of
7 randomizing people after you tell people in great detail
8 what intervention you are going to do, and then they end up
9 in the control group.

10 And so then they also start to change. They
11 get disappointed because they feel like they didn't get
12 something that was helpful to them. That disappointment
13 itself confounds the intervention. You get cross-over
14 contamination, drop outs, all the kinds of things that out
15 weigh, in many respects, the very kinds of biases that you
16 are trying to avoid by doing randomized trials in the first
17 place.

18 Not to mention the ethics that come from
19 having negative mind-body effects of disappointing somebody
20 after you've told them that you think this intervention
21 could be really helpful for them and they end up in the
22 control group, which may have its own biases.

23 So I think what Effie mentioned, and Tom,
24 that this idea in science where you have isolated one
25 independent variable, one dependent variable, keep