



Performance Reporting

Voice: (301) 871.0010 Fax: (301) 871.0020
Toll Free: (877) 871.0010

PHOTOCOPY
PRESERVATION

WHITE HOUSE COMMISSION
on
COMPLEMENTARY and ALTERNATIVE MEDICINE POLICY

+ + +

Volume II

+ + +

Friday, October 6, 2000

8:40 a.m.

Hubert H. Humphrey Building, Room 800
200 Independence Avenue, SW
Washington, D.C.

PARTICIPANTS:

Chairperson:

James S. Gordon, M.D., Director
The Center for Mind-Body Medicine

Commission Members:

George M. Bernier, Jr., M.D.
Vice President for Education
University of Texas Medical Branch

Thomas Chappell
Co-Founder and President
Tom's of Maine, Inc.

Effie Poy Yew Chow, Ph.D., R.N., DiplAc (NCCA)
Qigong Grandmaster
President, East-West Academy of Healing Arts

William R. Fair, M.D.
Attending Surgeon, Urology (Emeritus)
Memorial Sloan-Kettering Cancer Center
Chairman, Clinical Advisory Board for Health, LLC

Joseph J. Fins, M.D., F.A.C.P.
Associate Professor of Medicine
Weill Medical College of Cornell University
Director of Medical Ethics
New York Presbyterian Hospital-Cornell Campus

Wayne B. Jonas, M.D.
Department of Family Medicine
Uniformed Services University of the Health Sciences

Tieraona Low Dog, M.D., A.H.G.
(Private Practice)

Charlotte Kerr, R.S.M.
Traditional Acupuncture Institute, Inc.

PERFORMANCE REPORTING

Silver Spring, Maryland
Phone: 301.871.0010 Fax: 301.871.0020

PARTICIPANTS (continued):

Dean Ornish, M.D.
President/Director
Preventative Medicine Research Institute
Clinical Professor of Medicine
University of California, San Francisco

Conchita M. Paz, M.D.
(Private Practice)

Julia R. Scott
President
National Black Women's Health Project

Commission Members Not Present:

George T. DeVries, III
CEO/President
American Specialty Health Plans

Buford L. Rolin
Poarch Band of Creek Indians

Executive Staff:

Stephen C. Groft, Pharm.D.
Executive Director

Michele M. Chang, C.M.F., M.P.H.
Executive Secretary

Joseph M. Kaczmarczyk, D.O., M.P.H.
Senior Medical Advisor

Doris A. Kingsbury
Program Assistant

Geraldine B. Pollen, M.A.
Senior Program Analyst

C O N T E N T S

Page No.

Session VIII: Guiding Principles of CAM Perspectives and Practice	
Commission Discussion	4
Session IX: Not-for-Profit Sector Support for CAM Research	
Dr. John Templeton, Jr., Templeton Foundation	48
Ms. Dyanne M. Hayes, Conrad N. Hilton Foundation ..	56
Dr. Daniel Callahan, Hastings Center	66
Ms. Teri Ades, American Cancer Society	74
Panel Discussion	81
Session X: Private Sector Support for CAM Research	
Mr. Randy Burkholder, Advanced Medical Technology Association	106
Dr. Raymond Ruddon, Johnson and Johnson	116
Dr. Frank C. Sciavolino	~~125~~ 126
Mr. Mark Blumenthal, American Botanical Council ..	131
Dr. Annette Dickenson, Council for Responsible Nutrition	142
Panel Discussion	149
Public Comment	
Dr. Richard Levy	191
Ms. Ingrid Lucis	196
Ms. Diana Chambers	201
Ms. Monica Lenz	209
Mr. Ned Hartfield	214
Mr. Boyd Landry	218
Mr. Richard Pavek	230
Session XI: Outcomes Research Part II - CAM Research and Experimental Study Design	
Dr. Leanna Standish, Bastyr University	239
Dr. Lydia Segal, Kaiser Permanente	248, 273
Dr. Elaine Cramer, Medical Epidemiology, CDC	250
Dr. Douglas Lloyd, Association of Schools of Public Health	281
Panel Discussion	287

PERFORMANCE REPORTING

Silver Spring, Maryland
Phone: 301.871.0010 Fax: 301.871.0020

CONTENTS (continued):

Session XII: Federal Agency Support for CAM Research	
Mr. John Demakis, Veterans Affairs	306
Dr. Craig Vanderwagen, Indian Health Service	311
Panel Discussion	317

PERFORMANCE REPORTING

Silver Spring, Maryland
Phone: 301.871.0010 Fax: 301.871.0020

P R O C E E D I N G S

[Opening remarks by Dr. Gordon.]

[Moment of silence observed.]

Session VIII: Guiding Principles of CAM

Perspectives and Practice

DR. JONAS: I think there are a number of core issues for CAM research, and instead of me giving a world view, which I think is preposterous, I decided I would just lay out what are some of the themes that affect research especially in these areas.

We talked many if not all of these already, but I would just like to list them for you and talk a little about some of the wording that might be important in terms of that.

I think some of the core issues include, first, public impact, not only the impact of the public's interest in these areas, but what research does in terms of actually providing public impact. Paul Starr wrote a book, a magnificent book, on the social transformation of medicine, and I think this involves, really, the social transformation of science.

We are in the process of the democratization of

1 science. Figuring out how the public and the
2 practitioners, as we saw yesterday, can have a place at
3 the table of scientific agenda, scientific methodology,
4 and the type of information we want to see science
5 produce is a key issue.

6 I think the second core issue for CAM is
7 multiculturalism, seeing different world views. I think
8 we have to be able to travel around the circle. We need
9 to have a circle in which individuals can say, this is
10 what I see from this part of the circle. Like the blind
11 man and the elephant, we all have a little bit of a part,
12 but if we don't communicate, if we don't have the skills
13 to go around and communicate the aspect that we see, then
14 in fact we will never have, really, the whole truth.

15 I think the third issue is the issue of chronic
16 illness. I think there is no question that modern
17 medicine, and it is acknowledged all of the world, has
18 found an extremely powerful method of managing acute
19 illness, infectious disease, trauma, drug therapy,
20 surgery, et cetera. There is no question that all over
21 the world, the modern Western medical system is the envy
22 of this.

1 The result of that is it has been very
2 successful in the Western world, and we are no longer
3 dying at young ages anymore because it is so successful.
4 That has created another problem, and that is the problem
5 of us aging, if that is a problem, and therefore an
6 increase in the prevalence of chronic illness. Chronic
7 illness is different than acute illness. It is complex.
8 It requires a multifactorial and a holistic approach.
9 Very few magic bullets are likely to be found in the area
10 of chronic illness.

11 The fourth area, I think which is at the heart
12 of how we should prioritize, certainly, our research in
13 these areas, is health promotion. The term that I use
14 for this, the scientific term, is salutogenesis. That is
15 the opposite of pathogenesis, which is the process by
16 which disease occurs. Salutogenesis is studying the
17 process by which health occurs. So how, in fact, on a
18 fundamental, biological mechanism, but in terms of
19 biological research, can we understand this process and
20 therefore facilitate it.

21 I think the fourth critical issue is that we
22 are no longer in the modern materialistic age. We are

1 now in the post-modern information age. So managing
2 information is crucial. We shouldn't call it information
3 management, we should call it knowledge management
4 because there is data, there is information, there is
5 knowledge, and there is wisdom.

6 What we hope, eventually, all to get to is to
7 be able to exchange wisdom, but before we do that, we
8 have to be able to create the data into information, and
9 then create it into knowledge. Knowledge means we all at
10 least understand what the other person is talking about.

11 So it is not sufficient to say, here is the
12 data, show me the facts. We have to know in fact, what
13 is the knowledge that that imparts, what is the meaning
14 and what is the importance of it.

15 What does all this mean for research? I think
16 what it means is that we need to make sure that our
17 research agenda is balancing rigor and relevance. There
18 is a playoff between rigor and relevance. We have heard
19 a lot talking about the importance of science and the
20 importance of rigor, and there is no question about this,
21 the type of research you do has to be rigorous. You have
22 to use good methods in these areas.

1 However, the more focused you become in terms
2 of what is currently acknowledged as the gold standard or
3 the rigorous science, often the less relevant it becomes.
4 There are many examples of this. P-6 acupuncture is the
5 only proven acupuncture treatment that, I think everyone
6 agrees, works for a single condition, and yet P-6
7 acupuncture is rarely used and is relatively irrelevant
8 for your average acupuncture practice, and there are
9 numerous kinds of examples of that.

10 So I think as we are doing and going forward in
11 research in these areas, we need to change the research
12 hierarchy so that rigor and relevance become balanced
13 rather one dominating the other.

14 MS. KERR: I was hoping to have a little more
15 time to wake up, but I will go.

16 When I reflect on the values and principles
17 that inform, or could inform, our reflections on CAM, I
18 have two paths I thought I might begin. One is that I
19 wanted to reflect on the founding documents of our
20 country that essentially are saying that we are all of
21 equal value, endowed by our creator and with certain
22 inalienable rights. I think it would do us well to

1 reflect on these. It certainly would inform our works
2 here.

3 The other is values that I found to be
4 reflected in some work from the United Kingdom. During
5 the Sir James Watts presidency in the United Kingdom of
6 the Royal Society of Medicine, he initiated a series of
7 colloquia on medicine and complementary therapies. One
8 of the presenters was a Dr. Patrick Patroni at St. Mary's
9 Hospital in London.

10 He, like many of us here, felt that the current
11 biomedical model of today was, and we have all been
12 talking about this for years, based on the
13 Cartesian/Newtonian view of the universe. It was
14 essentially dualistic, mechanistic, and reductionistic.
15 You thought that, of course, which I agree with, that it
16 served us in many wonderful ways, but in about the last
17 50 or 70 years, there has been a growing change in
18 scientific thinking, and it really hasn't been integrated
19 into the biomedical model of health and disease.

20 In fact, and I still think this is true, we
21 really need to inform ourselves better on the discoveries
22 that are challenging the philosophical underpinnings of

1 our medical model.

2 He goes on to quote some of the innovators of
3 this new thinking, and some of those people who you are
4 well familiar with, are people like Einstein. Einstein,
5 of course, said that, "We may therefore regard matter as
6 being constituted by the regions of space in which the
7 field is extremely intense. There is no place in this
8 new physics -- for field and matter, for field is the
9 only reality."

10 He quotes Heisenberg, David Bowen. Then for
11 those who not only like to hear from the Nobel Prize
12 winners, but visionaries such as Lao-tsu and Plato, and
13 others, he is calling us to apply some of the new
14 scientific thinking to the revitalization of our medical
15 system.

16 What I agree with and what he concludes with is
17 some of the concepts that he feels comes out of the new
18 scientific thinking. I wanted to submit this today, and
19 I want to read just a few of these. These are only
20 eight.

21 The first is that the human organism is a
22 multi-dimensional being, and at one level we are

1 bioenergetic organisms.

2 Second, is matter and energy are
3 interchangeable in the primary ordering factors are not
4 biochemical, molecular, or genetic, but field forces.

5 Third, is that there is an interconnectiveness
6 between all living beings, non-living, microscopic,
7 macroscopic. The whole is greater than the sum of the
8 parts, and the part contains the whole.

9 Fourth, is the linear model of cause, and
10 effect is only partly applicable to disease and health.

11 Fifth, is consciousness plays a role in the
12 physical universe. We each possess a powerful innate
13 capacity for altering both our internal and external
14 environments.

15 Sixth, is health and disease lie along the
16 continuum and represent the organism's intrinsic state of
17 health with the universe.

18 Seventh, is one of the primary tasks of someone
19 entrusted to heal, be it a doctor, priest, or
20 acupuncturist, is to the encourage the innate capacity of
21 the individual in distress and help restore state of
22 balance and harmony.

1 I think these are some good places to start as
2 we reflect on the new science affecting medicine and
3 disease. Thank you.

4 DR. GORDON: Thank you, Charlotte.

5 We are actually giving everybody 3 minutes, it
6 seems like.

7 MS. KERR: I thought we had a minute after the
8 first buzz.

9 DR. GORDON: We have expanded time.

10 [Laughter.]

11 DR. LOW DOG: I started out, really, in the
12 other direction with herbal medicine. Certainly,
13 beginning in my childhood believed that spirit permeated
14 all of our life, and that illness was very much a
15 reflection of an imbalance within ourselves or within the
16 world around us.

17 When I grew up and went on in my life, and
18 later on, went to medical school, that never changed.
19 Medical school, when we got down into anatomy and
20 cellular physiology, I remember coming home and feeling,
21 after I had learned about the nucleus and the cytoplasm
22 and the mitochondria, the cell membrane, G-proteins, I

1 thought, my god, there is a god. This is phenomenal. I
2 am awed and humbled by all that we know of life and
3 science.

4 At the same time, I felt very much that science
5 and spirit were not mutually exclusive, that we could
6 embrace both willingly. In my time as a practitioner, I
7 won't separate Western medicine. It is medicine. It is
8 just all medicine. It is an artificial label that we
9 have given, also to keep our battles and to keep us
10 separate. It is the language of separatism, not bringing
11 us together.

12 What patients really want from us, or want from
13 me -- I can only speak for myself -- is really my time,
14 my hands, my heart, my compassion. They want me to be
15 good at what I know. They don't, at the end of the day,
16 really care if I give them an ace inhibitor or if I give
17 them Hawthorne. They really don't. What they want from
18 me is just to know that for the time we spent together I
19 was completely there for them and I made a safe place.

20 As George and I were talking earlier, I think
21 what is going to come out of all of this is that
22 hopefully we are all going to be better practitioners, we

1 are all going to take a little more time with our
2 patients, do a little bit more exploration of ourselves,
3 think a little bit more about what healing means versus
4 curing, and that that is the medicine, not so much if we
5 are using acupuncture or chiropractic or surgery.

6 They all have value. They all have a place.
7 Science can help get us there, but I just hope that we
8 don't forget that there are some things about healing
9 that can't be reduced to the double-blind RCT.

10 DR. GORDON: Great. Thank you, Tieraona.

11 DR. ORNISH: It is a very simple idea, but it
12 is a very radical one in the sense that even the word
13 "radical" means to get to the root of something, as
14 opposed to literally or figuratively bypassing the
15 problem.

16 As part of that context, is the presumption
17 that the body has a remarkable capacity to begin healing
18 itself if we give it a chance to by addressing whatever
19 the causes are that are causing the illness in the first
20 place.

21 Now, in some places that is going to be diet or
22 exercise or genetic factors, which are often invoked but

1 less often really a causal factor, but it also includes
2 the psychosocial, the emotional, and the spiritual
3 dimensions of health and healing. That is not only on an
4 individual level, but also on a social level.

5 So, for me, there is an opportunity, when we
6 look at suffering or illness, to not just treat those
7 symptoms, not only just the physical symptoms but also
8 the other kinds of symptoms that are often medicated --
9 certainly, Jim, in your field in psychiatry, we see that
10 a lot. Antidepressants is one very common example -- but
11 to say, what is really going on here, and what can we do
12 to address those issues. Those issues are far-reaching.

13 If we can integrate the best of these
14 traditional and non-traditional approaches, but not
15 simply in the context of what some of the people
16 yesterday were talking about in terms of ginkgo instead
17 of another Alzheimer's drug, or St. John's wort instead
18 of imipramine.

19 In a way, it keeps us in that same mechanistic,
20 mechanical model, and this is the larger picture of how
21 it all fits together.

22 DR. GORDON: Thank you.

1 DR. PAZ: Our psyche has a very big play as far
2 as our physical status. If I just treat what I feel is a
3 medical problem, frequently I lose out on quite a bit
4 because one's emotional state plays such a big role in
5 whether one will improve or not.

6 Some of the therapies that modern medicine
7 addresses doesn't always address that part. I think some
8 of the alternative, actually most of the alternative,
9 therapies treat that as a complete model, and I think we
10 need to really look at that more, facilitate that more
11 with our cultural differences.

12 I think we need to encourage the research and
13 how that works, and support the practitioners that are
14 already doing those kinds of therapies. Some of the
15 examples that we saw yesterday were pretty touching. I
16 think we need to try and be more supportive in folks who
17 are not always doing traditional therapy. I think we
18 need to facilitate the research in that. That is pretty
19 much where I am coming from.

20 DR. GORDON: Great.

21 MS. SCOTT: I agree. I don't know if I can
22 improve upon it. To me, values and principles are very

1 important as a foundation for how you look at the world,
2 and how you act in the world, and how you are in the
3 world.

4 For me, CAM, I think, offers an opportunity for
5 a perspective of wellness as opposed to illness.

6 Holistic in its approach is the integration of physical,
7 mental, emotional, spiritual, and economic, because all
8 of those things are at play when you are dealing with
9 one's wellness.

10 I think we are all in agreement that we want
11 rigorous science. We are all in agreement that we want
12 to have devices and drugs and botanicals, whatever, that
13 is safe and effective. I do get concerned that sometimes
14 suggesting that there needs to be a different way to do
15 something is seen as not wanting to have good science.

16 I think we have to keep making the point that
17 this research paradigm does not always work and that
18 there has to be an openness to change and to doing things
19 differently. We do have to change the paradigm. That
20 doesn't mean we have to throw out everything that has
21 worked, but we have to be willing to look at some
22 different ways of measuring for the safety and the

1 effectiveness.

2 I think it is very important that what CAM
3 brings to the whole field of wellness and health care is
4 validating the person's experience and the practitioner's
5 experience. I think this is what has been missing from
6 medicine. We have been trained to walk into the
7 practitioner's office and give up all of our reality, or
8 be swayed from our reality, to the practitioner's way of
9 looking at it. I think that that is a very core and key
10 part to the partnership in the quest for wellness.

11 The one caution I have is that I think we need
12 to celebrate the things we have in common in being human,
13 but also, and something I think that CAM does, is
14 acknowledge and pay attention to the differences among
15 us, without seeing that as a division. I think that is
16 key.

17 So, safety, effectiveness, availability,
18 equity.

19 DR. GORDON: Great. Thanks, Julia.

20 DR. BERNIER: It is really important to be able
21 to identify agents that are really, really helpful, and
22 distinguish those from agents that aren't helpful.

1 To me, the single most important message that
2 the whole CAM movement has made, and this is really
3 reinforced by reading your elegant book -- no plug -- was
4 that that has really shifted the focus to the patient and
5 away from systems, and away from the health care provider
6 to a substantial degree.

7 I have worked as an oncologist for a
8 substantial part of my life, and I always tried anytime I
9 got a new cancer patient to work with that I made a house
10 call. I did this for two reasons, one of which was
11 probably self-promoting, and that was that I felt that if
12 I could interact with the patient in his or her home,
13 that they would know that I would come if they needed me.
14 They rarely ever called upon me to come. So it was a way
15 of ensuring some privacy, but it also, to me, was a
16 really important bonding that one could witness.

17 To get back to the President's charge, I think
18 that how much of modern-day CAM becomes part of the
19 mainstream of American medicine, American health care, is
20 going to depend, to a significant degree, on how careful
21 the research that is carried out is going to be, and how
22 critical that research is.

1 The better that is, I think the greater the
2 likelihood that we will have sharing of the entire field
3 by a whole host of health care workers. I think this is
4 too good an opportunity to establish the efficacy of a
5 lot of the agents that research is going to be critical
6 for what happens. Thank you.

7 DR. GORDON: Thank you, George.

8 MR. CHAPPELL: I apologize for missing the
9 opening.

10 I see CAM as an opportunity to be part of that
11 world view in which everything is related to each other.
12 Interrelationships versus distinct and separate and
13 isolated realities, which the hierarchical model
14 promotes. In interrelatedness it is webs, it is
15 networks, it is cooperative, collaborative, and it
16 celebrates the gifts of each person, the different gifts
17 of each person.

18 So I see this movement as an opportunity to be
19 part of that way of looking at the world. I think some
20 of the principles are openness, collaboration,
21 particularly openness, open to the new idea, the
22 imagination of the new attempt so that discovery can

1 happen without being stifled by the halls of, just, day-
2 to-day management of different functions.

3 That is how this movement has gotten as far as
4 it has. That is why the term "alternative," I believe,
5 but I also like the term "complementary" because I think
6 it needs to be a complement to the good work that has
7 been gained to date by Western medicine.

8 Other than that, I think safety and efficacy
9 should still be the guiding principles that we need to
10 discover new protocols of understanding effectiveness.
11 Trying to fit this other world view into the protocols
12 and models of the old world view will only frustrate us.
13 So I think we have to be prepared to research and find
14 new ways of establishing effectiveness.

15 DR. GORDON: Great. Thank you, Tom.
16 Effie?

17 DR. CHOW: This is really an opportunity of a
18 lifetime I see. We must make the most of this
19 opportunity, as many of you have spoken about. We must
20 take a look at a new paradigm, perhaps, not discarding
21 the old paradigm. Improving the old paradigm of medicine
22 and health as we have it here.

1 I think we should be creative and be brave,
2 courageous about recommending new things. Even that
3 which seems ridiculous, I think we should look at with
4 open eyes. I am just really thrilled with my fellow
5 commissioners because I sense that is what we have here,
6 people with really openness.

7 Chardin says we are born perfect. In Buddhism,
8 it says we are created perfect, but in harmony with
9 nature. Khayyam says, "We cannot study life and look at
10 cadavers." It is true. The energy is all gone, the Chi
11 is all gone, so how do you study life. Einstein says,
12 "We have our own physician inside each of us," and this
13 is every patient.

14 This is sort of a few of the philosophies, my
15 vision, my world vision, I would like to see followed.

16 We have to look at our past to talk about the
17 future. In 1969 we had the first acupuncture training
18 for physicians at Stanford. Since then, there has been
19 arrests for people using acupuncture. They were arrested
20 for practicing medicine without a license. The lawyer
21 was smart. He said, no one was claiming they were
22 practicing medicine, they were practicing acupuncture.

1 It got thrown out of court.

2 So just a few of my own examples: Hope, she is
3 20 years cancer-free now, and she is in my book. She was
4 supposed to die in three months. Jane, 10 years in a
5 wheelchair. She is a Grade 1 school teacher. Last
6 September, after three treatments, she taught standing,
7 and she has had her first summer standing.

8 Dorianne, twelve and a half years my senior.
9 The Mayo Clinic, Harvard, Johns Hopkins, said tape your
10 eyes shut. She couldn't close her eyes. She had a
11 stomach-tube feeding. In five days, I got her drinking,
12 and also her eyes closing for the first time, and she is
13 eating. Andre, in Germany, was scheduled for his fifth
14 operation, brain operation, and they called me and said,
15 can you come over. Thursday they called me. Tuesday he
16 was supposed to have an operation. So I said no, I will
17 send energy for you, and they canceled his brain
18 operation. Three MRIs showed that his brain tumor had
19 gone to nothing.

20 There are others, MS, quadriplegics that in two
21 sessions we have got walking. Now, this will blow a lot
22 of people's minds out, but this is happening every day.

1 Miracles like this are happening. Do we call it
2 miracles? I think we need to look at these things, CAM,
3 as miracles.

4 So I end with saying that I believe in the
5 rigors of research, and as Julia said, we need to look at
6 other paradigms and, I think many of you have said, at
7 other paradigms of establishing rigor. My recommendation
8 to the patient -- I don't call them patients, I call them
9 clients because they have the right to choose to live or
10 die. We help them to die, and they die so well that they
11 want to live. This is really a phenomena.

12 They come for their eight hugs a day. My
13 theory is at least eight hugs a day and three bellyaching
14 laughs a day. Most of my clients say, I really come in
15 here just for my eight hugs because I can't get hugs at
16 home. Now, that is a shame.

17 So, anyway, thank you very much. I hope that
18 we will be courageous and really look at a really new
19 world model integrating, as Wayne says, the
20 multicultural, the ethnicity, because systems has helped
21 cultures survive for thousands of years. I think we
22 should use some of those things and not only wait until

1 it undergoes rigorous scientific review.

2 Thank you very much.

3 DR. FAIR: Well, my view of CAM has been
4 shaped, both professionally and personally,
5 professionally since my introduction to this field. I
6 almost have the feeling that I have had blinders on for
7 most of my professional career.

8 While there is no denying the advances of
9 modern medicine, it caused me to reflect on some of the
10 things that I thought were truths. I look back with
11 concern about some of the things we have done. When I
12 was a resident, it was standard operating procedure to
13 give 100 percent oxygen to premature babies. It has been
14 estimated there are 10- or 15,000 children that were
15 blinded by that approach, and yet that was standard
16 therapy at that time.

17 We mentioned yesterday, the autologous bone
18 marrow in women with breast cancer. It is still being
19 done, by the way, and recognizing that despite the cost
20 and toxicity, there is no effect whatsoever. This was
21 also standard therapy.

22 Then on the other side of it, these mind-body

1 therapies that I, like many people, thought was really
2 far out and more or less to be ignored, I am just
3 astonished by some of the observations. We were talking
4 yesterday, some of us, about the recent study in London
5 taxicab drivers showing at the posterior hippocampus, the
6 part of the brain that controls spacial orientation, is
7 larger in taxicab drivers than control -- this is in
8 London, not New York, now.

9 [Laughter.]

10 DR. FAIR: Where it is a real profession. The
11 longer the person drove the taxi, the bigger the
12 posterior hippocampus got. It is the first observation
13 that cognitive functions can actually influence anatomy,
14 which just is phenomenal.

15 So I think that this has been disturbing to my
16 professional balance, if you will, or what I thought
17 about the truths that were taught to me and what I
18 thought I had learned over the years. Now I begin to
19 wonder if we really know what questions to ask to
20 evaluate this.

21 Personally, my introduction to CAM was
22 uninvited. Five years ago, I was diagnosed with colon

1 cancer, and despite four surgeries and a year of
2 chemotherapy, I had a recurrence and at that time began
3 seeking out other options. Thanks to Dean Ornish, and
4 subsequently and Michael Lerner, going out of the common
5 wheel, I really learned a different approach.

6 I always prided myself on being an empathetic
7 physician and truly liked taking care of patients, but I
8 came to learn, through my friends, the distinction
9 between healing and curing, and particularly, almost the
10 mantra of common wheel, the idea of expanding life, even
11 if you can't extend life. As Tieraona mentioned, I think
12 I found there a safe place, which was something I could
13 carry with me in my daily activities.

14 These approaches have added so much to my life
15 that my personal goal now, and I think also the goal of
16 this commission, is to try to bring these approaches,
17 again, as a complement to standard therapy. I don't view
18 this as a replacement.

19 Unlike some of my colleagues, as a patient, I
20 don't think we need a new specialty of CAM physicians. I
21 think what we need to do is to enlighten physicians to
22 the benefits and to bring it into the practice of every

1 physician, you might say getting back to old-fashioned
2 medicine. We can't expect everyone that graduates from
3 medical school to be accomplished in all these areas, so
4 it involves the coordination and cooperation between
5 physicians and CAM practitioners in a way that I think
6 has not been done yet.

7 So that is my personal goal. I have changed my
8 career pattern. I hope, and I really believe, that
9 through the workings of this commission, that we can go a
10 long way toward establishing that new medicine, to quote
11 Jim.

12 DR. FINS: I, too, came from a traditional
13 background in medicine as an internist. In participating
14 with all of us here, I am seeing, increasingly, that
15 there really are two parallel universes, and that both of
16 these universes are motivated by a very strong healing
17 ethos across the continuum.

18 With this in mind, I think what we need to do
19 is to try to promote and develop a new synergism and
20 reciprocity between these two universes and have a sort
21 of reunified field theory, as it were, between these two
22 parts of the continuum to serve the health needs of the

1 American public, because I don't think our patients
2 really are distinguishing where they are receiving care.
3 They know they are receiving care, it is just that we
4 have distinguished where they are receiving care.

5 So I think what we should try to do in our
6 world view as a commission, should be to try to create
7 enduring structures that allow for the promotion and the
8 sustaining of the kind of the dialogue that we are
9 engaging in here, I think, so collaboratively, as Effie
10 suggests, even though we do all have very different
11 backgrounds.

12 Also, I think, secondly, appreciate that these
13 enduring structures really allow and foster the
14 application of the scientific method to evaluate and to
15 assess new and novel therapies.

16 I think that, given the massive biomedical
17 establishment, the scientific method is going to be the
18 coin of the realm, and I think it really needs to be
19 addressed and worked with, but I also would say that we
20 need to look to the social sciences to assist in the
21 assessment of border issues or outcomes and health
22 promotion. Not just science alone but the social

1 sciences together will help promote discovery and
2 knowledge.

3 Fourthly, I think we need to look and
4 understand better those parts of the health universe
5 where there have been successful integration of these two
6 universes and overcome the false dichotomy between these
7 two cultures. I think we heard a little bit about that
8 in the Best Practices that we heard about yesterday.
9 Also, I think, in the world of palliative care and
10 hospice medicine, where people have overcome that
11 dichotomy and there has been successful integration.

12 I think if we do all this, it is obvious that
13 CAM will change, and traditional medicine will change,
14 but the healing arts together will be fostered. I think
15 that should be our legacy, and that should be what we are
16 trying to do. I think that will create not only the
17 articulation of a new world view, but also a tremendous
18 amount of health promotion.

19 So thank you for the opportunity to share that.

20 DR. GORDON: Thank you, Joe.

21 It is wonderful to listen to everybody, and to
22 hear, see, feel everybody's commitment to this mission we

1 have in common.

2 There were a few things I said at the end of
3 our talk with Dr. Straus that are some of the principles,
4 it seems to me, important. They have been pretty well
5 articulated around the table. One has to do with
6 focusing on the uniqueness of each individual and his or
7 her journey through life.

8 The work that we do is not just about healing,
9 treating diseases, promoting health, dealing with
10 illness. Our work is the work of helping people become
11 themselves, be themselves. To me, that is the deepest
12 part of the work we do, the highest form of being a
13 healer.

14 The second point has to do with integration and
15 integrating whatever works. Buddha said, "Truth is what
16 works." In my own life and in my own practice I
17 integrate many healing traditions. I have learned from
18 Chinese medicine, I have learned from Ihrveda [ph], I
19 have learned from Western medicine, I have learned from
20 shamanic healing, I have learned from indigenous
21 practices in the United States. They are all part of
22 what happens when I am in the room with somebody.

1 Whether I am in my office, or in their home, or in an
2 intensive care unit, that is all part of what I am doing.

3 The third perspective is a focus on wellness,
4 health, and especially on education. I think it is
5 really so important to help people help themselves. This
6 seems to me fundamental to what I do. Whether someone
7 has a life-threatening illness, or whether I am working
8 with children in a primary school, I am helping to show
9 them the possibilities for healing themselves, for
10 helping themselves, for being happy, for celebrating
11 life, as well as treating whatever problems they may
12 have.

13 The fourth principle is one of outreach, of
14 connection to other people, whether it is in a practical
15 way of helping young investigators, or people from CAM
16 professions that have been outside the mainstream, or
17 physicians who are trying to enlarge what they are doing
18 and trying to study what they are doing.

19 I think we need not only to reach out
20 ourselves, as we are with this commission, but to
21 encourage all of the government agencies, all of the
22 medical schools, all of the establishment, to really

1 reach out and embrace those who have been left outside
2 and to bring them in, and to share with them our
3 privilege, the benefits that we have accrued and what we
4 know.

5 The other thing that is fundamental to me that
6 is really where I started when I sat down here, is I
7 realize that at our Center for Mind-Body Medicine we have
8 a mission, and our mission is both to create a healing
9 community and a community of healers. I see us here on
10 the Commission as a healing community helping to heal
11 what ails medicine and health care in this country, and
12 also, and it was just brought home to me by listening to
13 everyone as we went around the table, a community of
14 healers working together.

15 So my hope is that, as we work with all the
16 people who come before us, as we ask for their testimony,
17 and as we ask them questions, and as we formulate
18 recommendations for the President and for Congress, and I
19 felt this very strongly yesterday, we are also welcoming
20 them into this circle of healers, and that we understand
21 that we are all engaged, coming from very different
22 points on this circle, which is wonderful to see and

1 hear. We are all engaged in the same work.

2 So it is great to be here. It is great to hear
3 you, great to feel you, see you. Thank you, everybody.
4 We will continue this discussion.

5 Yes, Effie.

6 DR. CHOW: Can we hear from Steve, our
7 executive director?

8 DR. GORDON: I asked Steve, and Steve demurred,
9 but we can certainly hear from him.

10 DR. GROFT: I am really here to provide you
11 with what your needs are. I think the audience and the
12 public needs to hear from you more than it does from me.

13 Okay, just a few thoughts, I guess. I know I
14 haven't given it a lot of thought because of the
15 intricacies of what we have been involved with in just
16 getting the meeting together.

17 I guess my philosophy of life, in dealing with
18 the issues, are, we come into the world and we don't have
19 any control when we come into the world. We are all
20 given different tasks to do. In the last nine years
21 since I have been involved in CAM directly, I think I
22 have tried to create a safe environment, an environment

1 that people could come and present their views in a
2 totally non-confrontational manner, that they could be
3 absorbed into the system and just to be able to talk and
4 to listen and to move ahead, and we are moving ahead.

5 I think we all strive for an inner peace, that
6 we work with our family, our friends, different people at
7 work. We are getting there. It is a struggle when you
8 go against so many organizations or individuals who are
9 threatened by what you would like to see, and what we
10 know is right, and what we know brings us peace. That is
11 very important.

12 I think wellness is so much a part of our own
13 being. Sometimes it is not because of external factors,
14 family and friends and the world around us, but I think
15 we all have to strive for that. I think that is what we
16 are trying to do. That has been, again, the religion,
17 the spirituality part, has been a big part of my life,
18 and I try to stay with it.

19 DR. GORDON: Thank you, Steve.

20 I am also going to ask Michele and Geri and Joe
21 and Doris, if they are here, just to say a couple words
22 as well, because they are part of our team. So thank

1 you, Effie, for asking again after he refused once.

2 Michele?

3 MS. CHANG: Let me time myself here.

4 DR. GORDON: Michele is setting her own timer.

5 MS. CHANG: I think my philosophy and the
6 guiding principles for working with this commission are
7 the same that I have for living life, which is, I believe
8 that we are here to learn, and by learn, to teach, and
9 hopefully, that we will have a lot of fun in doing both.
10 That is what I am here to do.

11 DR. GORDON: That is beautiful. Does somebody
12 want to ask Joe and Doris to come up here, too.

13 MS. POLLEN: I would like to share with
14 everyone the fact that I had a very special father. He
15 was a physician and a biomedical scientist, but he was
16 also a very beloved physician, beloved by his patients.
17 I learned early from him the art of medicine as well as
18 the science. He practiced the art of medicine.

19 I think, as I have been listening to everyone
20 speak, that we lost the art of medicine. That is the
21 really special part of healing, is to be cared for and
22 feel that you are being cared for by your caretakers, by

1 your physician. That was something that my father gave
2 to his patients and always expressed. He also, in the
3 '50s, coauthored a book, probably one of the first, on
4 prevention in medicine.

5 DR. GORDON: Great. Joe, I see you in the
6 back. Would you say a couple of words?

7 MR. KACZMARCZYK: [Off mike.]

8 DR. GORDON: No? Okay. He is our silent
9 partner.

10 Doris, come up, not to put you on the spot at
11 9:30 in the morning. We have just been going around the
12 room, and everybody has been talking about their vision
13 of CAM and of our work. After Steve first didn't want to
14 say anything, Effie asked him again, and he said okay.
15 So he and Michele and Geri have each said a few words.

16 So to complete this team, I thought that maybe
17 you -- and Joe is here -- that Joe and you could each say
18 a couple of words as well.

19 MS. KINGSBURY: Well, first of all, it is a
20 great pleasure to be on the team working with the
21 commissioners. It is really great. I am learning a lot,
22 good experience. That is it.

1 DR. GORDON: Okay, great. Thank you.

2 MR. KACZMARCZYK: First of all, I don't speak
3 without slides.

4 [Laughter.]

5 MR. KACZMARCZYK: That is an internal joke.

6 I have never really had to articulate my own
7 views about complementary and alternative medicine
8 because I have been, for the last several years, the
9 voice for the nameless, faceless, voiceless people who do
10 not have access. I come from the Bureau of Primary
11 Health Care, the Health Resources and Services
12 Administration, where access is not a buzzword or a
13 mantra.

14 I can tell you that I related to everything
15 that everybody said around the table, but most especially
16 when Julia equity because I think we are at the unique
17 and wonderful intersection of many opportunities. Chief
18 amongst those is to have the opportunity to create an
19 environment that allows access to complementary and
20 alternative therapies for everybody and to have access to
21 a new and better kind of health care delivery system.

22 In addition to that, we are also at the

1 intersection of the opportunity to not only reform health
2 care, but also education. By education, I mean not only
3 medical education, all education. When we talk about
4 education, it should include health care professionals,
5 but also students starting at the youngest possible age.

6 Did I make it, Michele, within the time
7 constraints?

8 DR. GROFT: Next slide, please.

9 [Laughter.]

10 DR. GORDON: One thing I want to just say is
11 that these five people are representatives into the
12 world. They communicate not only the substance of what
13 we want people to come to talk to us about, but the
14 spirit of what this commission is about. So they are us,
15 and we are them. It is great to work with them.

16 DR. JONAS: We couldn't have gotten a better
17 group if we had handpicked them from the world.

18 [Applause.]

19 DR. GORDON: Let's take about a 2-minute break
20 while the first panel comes forward.

21 MS. KERR: Jim?

22 DR. GORDON: Sure, go ahead, Charlotte.

1 MS. KERR: First of all, thank you all for
2 serving us so well. I did want to say this, even in the
3 spirit of our joy as we have shared in this last few
4 minutes. I heard some challenges and some opportunities
5 in the speaking as we spoke, and I wanted to say this. I
6 mentioned a couple of conclusions of possible principles
7 that would be underpinnings, philosophical underpinnings
8 for our work.

9 For example, and this is very important to me,
10 one was that the linear model of cause and effect is only
11 partly applicable to disease and health. When several
12 people spoke around the table, they talked about the need
13 to find the cause for certain problems. To me, I saw a
14 little flashing light. I thought, is it necessary for us
15 to be congruent, perhaps, in our philosophical thinking
16 in order to have a cohesive outcome in CAM?

17 So that was one thing, because that is not
18 exactly how I am thinking, that there is just cause and
19 effect when we do research. The other was, just to
20 mention, as the physicists say, we are probability
21 patterns of interconnectedness. I understand and believe
22 that. If you are hungry in Bosnia, I believe we cannot

1 be full and nourished in Baltimore or in the inner city
2 in Washington. We are connected.

3 When one thinks this way, you immediately, at
4 least in my opinion, are then driven to look at public
5 health issues. If this is a principle we believe in,
6 then this is informing us in the work we must do in CAM.

7 Do you understand what I am saying? I am
8 speaking to my partners here.

9 So I think it is important that we really spend
10 some time in seeing, what are the principles we agree
11 with, because I, frankly, don't know if I do feel we were
12 congruent in our foundation here today, and I think it is
13 pretty important. I understand maybe we are beginning,
14 but I don't have the knowledge to know we are beginning.

15 DR. GORDON: Let me say that I am not looking
16 for congruence. I am just looking for each person right
17 now to express themselves.

18 MS. KERR: Okay.

19 DR. GORDON: We will work. We are going to
20 work and see how we come and where we come.

21 MS. KERR: So this is just the beginning.

22 DR. GORDON: This is just the beginning. We

1 are going to continue this process.

2 DR. JONAS: I think what Charlotte is
3 expressing, and also I have this sense, too, is I do not
4 see, in the process that has been laid out for us, time
5 for us to really fundamentally deal with some of these
6 issues. I would just like to express that.

7 DR. GORDON: You would like to have some more
8 time.

9 DR. JONAS: Yes, absolutely.

10 DR. GORDON: Fine. Actually, that was what Tom
11 proposed. This is the beginning. This is just the
12 introduction. We wanted, in the first time, not to set
13 aside too much time but just to have each person have an
14 opportunity to express him- or herself. We can talk
15 about how much time everyone would like to set aside.
16 That is very much an open question.

17 MS. KERR: Thank you for that. I think that is
18 one need. Then the other is, how do we get on board with
19 one another? One is time, but how are we educating
20 ourselves, perhaps, as a group to see. I mean, we are
21 all doing the best we can, but we also come with
22 different backgrounds.

1 So, Mr. Chairman, I request that we think about
2 that, how we will do it.

3 DR. GORDON: Yes. I think we should think
4 about it.

5 MS. KERR: Thank you.

6 DR. GORDON: Steve?

7 DR. GROFT: I think as we are preparing the
8 future agendas for the meetings, we will factor in some
9 additional time just for thinking and discussing, and
10 open mikes to us, or to you as the Commission members, to
11 be able to talk about things.

12 These initial meetings, I think we felt an
13 urgency to get things moving, that there were so many
14 things to cover. I guess the agenda for these two days
15 was tremendously, probably overly ambitious, to really
16 give you an opportunity to even question the individuals
17 appropriately, but I think that opportunity will come in
18 the future. I think we will have the opportunity for you
19 to talk among each other and just hash things out, where
20 are we.

21 This is all part of the process as we begin to
22 think about the report, and think about the issues. You

1 come together as a group, and I think as you come
2 together and bring all of your differences and
3 similarities, you become one voice, and it does happen in
4 the process of a commission or a committee. You do
5 arrive at that. You don't see that right now, and we
6 don't want you at that point right now. We do want the
7 variability in the statements. Things will start to
8 happen as the second meeting occurs, the third meeting,
9 the fourth meeting, and you spend more time together.

10 It does evolve. I think by the end of the
11 time, we are going to feel that we really don't want to
12 break apart, that you are going to miss the interactions,
13 you are going to miss the individuals. That is when I
14 think we have accomplished the purpose. I think that
15 harmony will come within the group. We may not agree
16 with each other, but I think there will be an acceptance
17 and a harmony that will follow.

18 DR. GORDON: I think it is very important that
19 part of our work is to come together among ourselves, but
20 we are coming together among ourselves with all the
21 people who are coming before us. We don't want to have
22 what is a premature closure of our accounts with reality.

1 So, as a kind of sense of welcoming in the people who are
2 coming, and us evolving our process as well at the time.

3 So we can set aside more time. What we need
4 from you, and maybe we can talk about this a bit later,
5 but that is also going to require more time for
6 participation from everybody here. If there is a
7 willingness to do that, then we can set aside more time.

8 Yes, Effie?

9 DR. CHOW: Just to affirm, I really feel
10 strongly on that, too. I think we should know where we
11 agree, and then respect where we disagree or have
12 different ideas. I think that is what we are chosen for,
13 not everybody thinking the same way, but the diversity
14 that we can come to respect.

15 DR. GORDON: Exactly. Exactly.

16 DR. CHOW: This is how we are going to deal
17 with the bigger vision, too. Thank you.

18 DR. GORDON: Great. Joe, did you want to say
19 something?

20 DR. FINS: I think the agreements and
21 disagreements can be about ends and means. So I think
22 that we probably have a comparable sense of where we want

1 to go and what the end point is, but how we get there and
2 the balance we put on the various opportunities, is, I
3 think, what we will probably have to negotiate and talk
4 about. I think you are absolutely right in bringing this
5 up now.

6 I wrote Steve a note that you need a little bit
7 of dissonance to have a good sense of harmony, otherwise
8 it becomes a Gregorian chant, and we are all singing the
9 same tune, but it is a good tune.

10 DR. JONAS: I think, also, one thing in terms
11 of the means is that we may find as we go around, that we
12 don't have all the skills necessary, sitting around this
13 table, to properly understand or move forward with the
14 means, so we might want to bring individuals, especially
15 in policy-setting, since that is our purpose here, to
16 help with that process.

17 DR. GORDON: Anyone else before we close for
18 now?

19 [No response.]

20 DR. GORDON: Okay, thank you all for this. We
21 will take a couple minutes and then we will come back for
22 the next panel.

1 [Recess.]

2 DR. GORDON: This is Session IX. It is the
3 representatives of the Not-for-Profit Sector. They are
4 going to be talking about support for CAM research.

5 So I want to welcome the four of you here, and
6 thank you very much for responding.

7 One of the things I wanted to say to the
8 commissioners is that the people who have come here, who
9 are coming here, are coming, of necessity, on rather
10 short notice. For this first panel, we only had six or
11 so weeks from the time we planned to the time to ask
12 people. So a lot of people who are here have really made
13 time in their schedules for us.

14 So we appreciate that extra effort you have
15 made as well.

16 So let's begin with Dr. John Templeton from the
17 Templeton Foundation.

18 **Session IX: Not-for-Profit Sector Support**
19 **for CAM Research**

20 DR. TEMPLETON: Good morning. I am very
21 grateful for the opportunity to share with the Commission
22 some of the work of the John Templeton Foundation. In

1 particular, I am very pleased to share with you our
2 interest in science-based complementary medicine
3 research, and the application of that research in
4 clinical practice.

5 The foundation is very supportive of the use of
6 the scientific method in the evaluation of spiritual
7 topics. In the case of health and healing in medicine,
8 we are especially supportive of spiritually related
9 approaches to assuring and maintaining good health, as
10 well as contributing to more effective healing when
11 illness occurs.

12 As part of this, we are very interested in the
13 ability of spiritually related complementary medicine to
14 contribute to better health outcomes with significantly
15 greater cost effectiveness.

16 In the last 10 years, there has been a sea
17 change in the growing acceptance of working with the
18 patient's inherent spirituality in the delivery of
19 traditional medical care. When I was in medical school
20 in the 1960s, the two hot issues were honesty and
21 sexuality. The honesty issue concerned the growing
22 recognition of the need to include the patient as an

PERFORMANCE REPORTING

Silver Spring, Maryland
Phone: 301.871.0010 Fax: 301.871.0020

1 equal member of the patient care team.

2 For example, when dealing with a patient with
3 cancer, the new thesis was that the patient should know
4 his or her diagnosis and as much as possible about that
5 diagnosis, and thereby participate better in choices
6 regarding therapy.

7 In the case of sexuality, it was felt that
8 physicians should be more forthright in discussing
9 sexuality with their patients, especially when these
10 discussions had a bearing on the patient's health and
11 well being. However, at that time, if one ever broached
12 the topic of spirituality, such discussions would have
13 been considered by one's peers as being intrusive and
14 even unprofessional.

15 Since that time, especially in the last 10
16 years, surveys by Gallup and other groups have given us a
17 new perspective. We have learned from these studies that
18 70 percent or more patients want their doctors to know
19 about their spirituality perspectives regarding their
20 health. Amazingly, 40 percent or more patients would
21 like their doctors to pray with them.

22 Also, at the same time that we learned of this

1 new level of permission on the part of our own patients,
2 we began to recognize hundreds of scientific studies
3 which showed the positive benefits of spirituality in a
4 patient's life, both in regard to health preservation and
5 recovery from illness.

6 Presently, most of the science-based studies in
7 spirituality and healing are in their infancy, in that
8 most of these studies are correlational, namely that
9 there is a correlation between religious practice and
10 belief and health outcomes.

11 Currently, there are only a few studies that
12 address the issue of the mechanism of action whereby
13 religious practices and belief can affect health
14 outcomes. This is similar to the example of many
15 advances in the history of medicine in which valid
16 correlations were made prior to understanding the
17 underlying mechanisms.

18 For example, the scientific studies that
19 demonstrated that the use of citrus juices could prevent
20 scurvy in sailors were a valid correlational study that
21 preceded the later understanding that the mechanism of
22 action of ascorbic acid.

1 When there is a solid scientific basis for some
2 component that has beneficial impacts, we feel that these
3 components pass into the realm of complementary medicine
4 in which the approach in question can serve as a
5 complement to traditional medicine and surgical
6 therapies.

7 For example, working with a patient's intrinsic
8 religiosity and belief would not replace the beneficial
9 use of medications and/or surgery. Instead, spirituality
10 and/or religion can serve as a positive complement to
11 traditional medicine.

12 Consider these examples of scientific studies
13 in this area. In the 16-year follow-up study in Israel,
14 members of orthodox kibbutzim had 50 percent lower
15 mortality rates than did members of secular kibbutzim for
16 a variety of disease categories, including cardiovascular
17 disease, neoplasm, and external causes.

18 In another study, patients undergoing
19 orthopedic surgery were randomized to receive chaplain
20 intervention visits of 15 minutes per day per patient in
21 the test group. When they were compared with the control
22 group of patients, they had reduced length of stay by 29

1 percent, and one-third the number of patient-initiated
2 nursing calls, and one-third the use of PRM pain
3 medications.

4 In another study of 248 men addicted to opiate
5 drugs, long-term religiously based therapy produced a 45
6 percent long-term success rate in abstinence, compared to
7 a 5 percent success rate in the secular-based program.

8 In the area of research-based mechanism of
9 action, there are some early studies which examine
10 psychoneural immunology as a possible explanation for how
11 religion might contribute to good health outcomes.

12 In the study at Duke, frequent religious
13 attendance predicted lower plasma interleukin-6 levels in
14 a variety of serious medical conditions. These findings
15 suggest that persons who attend a church frequently have
16 stronger immune systems than less frequent attenders.

17 In order to stimulate high-quality scientific
18 research studies on the impact of spirituality and
19 healing in medicine, the John Templeton Foundation has
20 funded two carefully designed research studies on the
21 efficacy of prayer.

22 The first study assessed the effect of

1 personal, one-on-one, face-to-face prayer therapy in
2 patients with moderate to severe rheumatoid arthritis.
3 Those who were prayed for had a statistically significant
4 decrease in the number of tender and inflamed joints, and
5 a significant increase in joint range of motion and
6 physical mobility.

7 Another study currently underway involves a
8 controlled and randomized multi-institutional evaluation
9 of the efficacy of remote intercessory prayer in 1,800
10 patients undergoing standard coronary bypass surgery.
11 This study, centered at Harvard Medical School, is due to
12 be completed within the next year.

13 The first question we were asked to consider
14 is, how can the not-for-profit sector stimulate CAM
15 research. There are several possibilities: No. 1,
16 providing seed money to obtain pilot data for larger
17 research grants; No. 2, to support the publishing of
18 research results through book prizes or awards for the
19 best research papers in CAM therapies; No. 3, financial
20 rewards for exemplary courses or research programs in
21 medical schools, or maybe more importantly, during
22 residency, in regard to how to integrate complementary

1 medical practices into traditional medical approaches.

2 Finally, support the convening of consensus
3 conferences to bring together both insiders and
4 outsiders, or skeptics, to discuss existing CAM research
5 and to propose new productive lines of research.

6 Second, we were asked to address some barriers
7 to accomplishing this goal. Number one, we need to
8 address the lack of awareness of the research which
9 already exists or the perception that CAM research is on
10 the fringe. The solution to this problem is the
11 publishing of research results in peer review journals
12 which might normally be skeptical of such studies.

13 A recent example was the publishing of a study
14 in the New England Journal of Medicine showing the
15 efficacy of acupuncture. A second obstacle is a general
16 lack of traditional funding for CAM research. The
17 solution to this problem is improving the methodological
18 rigor of proposed studies. This will help in finding
19 partners in the public and the private sphere.

20 The third obstacle is the need to encourage new
21 researchers in CAM therapies. A solution to this problem
22 is to provide mentors who are well trained in scientific

1 research to guide junior investigators in the designing
2 and conducting of their research.

3 The final question is, how can not-for-profit
4 CAM research be better coordinated with federally
5 supported CAM research. My suggestion in this area is to
6 develop new types of collaborative relationships. This
7 can be done very effectively by convening a jointly
8 funded consensus conference to review in depth the
9 strengths and weaknesses of existing research, and to
10 propose new, well-designed studies to advance the science
11 behind specific CAM therapies.

12 New studies, for example, might seek to
13 elucidate both correlation results and mechanism of
14 action. In addition, they might focus on cost-
15 effectiveness as a means of lowering the overall cost of
16 therapy for the patient. If such research proposals are
17 well designed, they would then lend themselves to
18 increased government grant support.

19 Thank you very much.

20 DR. GORDON: Thank you very much. Next is
21 Dyanne Hayes of the Conrad N. Hilton Foundation.

22 MS. HAYES: Good morning. We at the Hilton

1 Foundation are very honored to be invited to appear
2 before the Commission today, and commend each of you for
3 taking time out of your busy professional lives to serve
4 on this commission.

5 Dr. Chow, before I leave today, I want a hug
6 from you.

7 [Laughter.]

8 MS. HAYES: We come together, hopefully, to
9 create a climate in which CAM research is more appealing
10 in both the public and private sectors. Hopefully, you
11 have had an opportunity to read the brief profile of our
12 recent cocaine alternative treatment study. I know it
13 came in late, but I am going to be referring to it
14 several times in my remarks.

15 I am a foundation executive with more than two
16 decades of experience. I work closely with organizations
17 throughout the world, each seeking to alleviate human
18 suffering. Thus, I understand very clearly the
19 challenges in competition for grant dollars, and the
20 tension that often occurs when grant awards are
21 determined.

22 If our diligence proves that all things are

1 equal, who is to say a substance abuse program deserves
2 funding rather than a project to eliminate preventable
3 blindness.

4 I believe the federal government faces similar
5 challenges, and that is what brings us together today.
6 How do we step up to the plate and increase our attention
7 on CAM research which hopefully translates to increased
8 support?

9 As a non-scientific person, I will share with
10 you some perceptions that help guide me in my response to
11 the three questions the Commission has posed to us.
12 First, CAM research seems to be the stepchild of the
13 National Institutes of Health. Perhaps, I am being very
14 impolite to my host when I wonder whether the NIH is
15 attempting to pass on the bulk of this very important
16 responsibility to the private sector.

17 Second, as complementary and alternative
18 products and practices continue to increasingly become
19 more acceptable throughout mainstream America, coupled
20 together with our improvement in attitudes among
21 individuals, health care professionals, and reimbursement
22 entities regarding wellness and prevention, many of us

1 incorporate one or more of what are called complementary
2 and alternative into our lives, whether it is
3 acupuncture, nutritional and vitamin supplements,
4 herbalists, natural products that range from soap,
5 dietary products and beverages to pet food, and even
6 landscaping materials.

7 Speaking for myself, frankly, I have been more
8 influenced in my choices by family and friends than
9 scientific data. Perhaps, I thereby increase a risk to
10 my wellness. Who knows? I suppose that is why we must
11 have more data disseminated.

12 I am certain most of you have read this week's
13 article in Time Magazine regarding the supposed dangers
14 of mixing herbal supplements and anesthesiology. Just
15 how are we going to make these informed choices? Which
16 begs the question, is the amount of research currently
17 devoted to CAM, at a minimum, in reasonable proportion to
18 its widespread use?

19 My last perception, correct or not, deal with
20 what it must be like working with the federal government
21 and/or a private foundation. Some quarters believe that
22 government and philanthropy have very distinct, separate

1 roles and should always maintain a distance. There are
2 those that are quick to label foundations as standoffish
3 and arrogant, and probably in some instances, these
4 labels are correct.

5 Yet, I believe that if we generalize, continue
6 to unfairly generalize, that this will inhibit many
7 possible good partnerships. Among my foundation
8 colleagues I have heard that working with the government
9 can be messy, unpredictable, and responsiveness is hardly
10 a priority.

11 The first question, and I will incorporate what
12 I think a role for the government might be. First, for
13 the government, it is about communication. Believe me,
14 Dr. Templeton and I have never met before this panel this
15 morning, but I am going to echo many of his remarks.

16 First, begin with hosting introductory face-to-
17 face meetings and site visits among foundation people
18 with representatives of existing centers currently funded
19 by the NIH doing CAM research. This provides an
20 informative glimpse of what is on the cutting edge of CAM
21 research. We who are interested in and open to the idea
22 of CAM research then have an opportunity to learn,

1 discover what the needs are, and get ideas in which they
2 and we might work together.

3 At these meetings, use the opportunity to
4 inform foundation people how one actually navigates the
5 federal grant process. Second, be more aggressive in
6 seeking opportunities for foundation representatives to
7 participate on panels such as this to discuss their
8 experiences and perceptions regarding CAM and CAM
9 research.

10 Third, at a minimum, get these foundation
11 people on your mailing lists, publicize the heck out of
12 those grants that do or have had public/private funding
13 support. Let us not be shy about celebrating our
14 accomplishments or reluctant to discuss our challenges,
15 because both are going to frame how we are going to go
16 forward.

17 Ways in which the foundation world might
18 stimulate CAM research. First, I would like to see
19 foundations be more willing to fund small pilot projects.
20 I have been told that government dollars for CAM research
21 are becoming increasingly hard to get without pilot data.
22 Yet, the adequate funds -- and I am told this about

1 \$100,000 -- to do this are very scarce. \$100,000 grant
2 over two years seems very reasonable for a credible pilot
3 study. For the type of foundation that has an interest
4 in this, it should be doable.

5 Second, foundations interested in CAM research
6 might themselves create a pooled fund of monies and
7 announce the competition for projects up to so many
8 dollars. The collaborative would set up a scientific
9 advisory board of reputable scientists knowledgeable in
10 the area in which the proposals are being submitted.
11 This is done regularly among foundations. We do this
12 often when we are doing urban renewal projects.

13 This willingness to co-fund helps diminish the
14 risk factor of being the sole donor. Many foundation
15 trustees, including ours, and particularly those non-
16 corporate foundations, are more favorably impressed when
17 we can point to the fact that our resources can be
18 leveraged.

19 Additionally, when you have a mixed set of
20 funding partners involved, if a project falters as some
21 do, there is a safety net in place of smart, invested
22 persons poised to intervene and determined to succeed.

1 The second question deals with the obstacles
2 and barriers. I believe the fundamental obstacle we face
3 is the difference or sense of separation between two
4 cultures, Eastern and Western medicine. For example, the
5 idea of a blinded, randomized, placebo-controlled trial,
6 the gold standard in Western medicine, is often not
7 acceptable with practitioners of Eastern medicine. Our
8 colleague at the Lincoln Clinic at the Bronx, New York,
9 Dr. Michael Smith, and to whom I refer in the paper you
10 have describing our grant, refused Lincoln as a site for
11 our study because he and his staff feel, very
12 passionately, that it is irresponsible to allow a sham or
13 a placebo acupuncture condition for their client.

14 Three other obstacles are, and they address the
15 lack of information or knowledge-sharing that helps to
16 breed misinformation and mistrust between government and
17 foundation staff. First, is the dissemination of data.
18 It seems to take forever for NIH to digest data and have
19 it available for public consumption. Some responsibility
20 may lie with the researchers and report writers
21 themselves.

22 So I believe they need to apply some pressure

1 to mop up and finish their reports. This is a critical
2 part of the necessity to build bridges between those two
3 sectors, disseminating data. To expand further on the
4 information-sharing point, during the time when our study
5 was being designed, we and the site investigators learned
6 after the fact that there had been several very good
7 acupuncture symposia going on. These would have been
8 very helpful to us. Also, letting the foundation world
9 know what has already been funded.

10 Last but not least, foundations themselves need
11 to do a better job communicating its funding interests to
12 each other and to the government. Of course, sharing
13 whatever existing data we have regarding any CAM-related
14 research that we funded.

15 We, the foundations, should be a convener and
16 broker of information as well. This applies not only to
17 our external constituencies, but internally as well among
18 our own staff and trustees. We need to send the signal
19 that we are willing to deal with the largest funder of
20 health services there is, the federal government.

21 The last question, how can the two sectors
22 better coordinate CAM research. My answer to this in

1 some ways reflects my earlier response to the previous
2 questions. First, the subject of timing. If we really
3 are going to attempt an increased number of jointly
4 funded research projects, then both sectors have to
5 assess how to be more flexible regarding timing of
6 proposal submittals.

7 My experience with our study was that we gave
8 Dr. Klieber [ph] one year to match our grant or risk
9 losing it. He and I both scoured the foundation world
10 diligently to get this match. He gets the prize for the
11 most rejections, 15. By then, months had passed as well
12 as two of the three deadlines that year for submitting
13 grant proposals to the government.

14 Even if Dr. Klieber had met one of the
15 deadlines, I understand that an application review takes
16 four to five months, and then the investigator doesn't
17 learn what his priority score or comments are for another
18 two months. That is more than half a year. Plus, if
19 most applications aren't funded the first time around, it
20 takes nearly two years from the date of submission and
21 resubmission to get funded.

22 Perhaps for CAM research the review committees

1 will rethink the scoring system and make the process less
2 tedious and time-consuming. Thus, it really was very
3 unrealistic for the Hilton Foundation to expect a match
4 for our grant, especially for CAM research, that it could
5 happen in one year. No wonder scientists are less than
6 enthusiastic when offered private sector support with
7 this type of contingency.

8 In closing, I believe sincerely that both the
9 public and private sectors seek solutions that are
10 practical but effective, inexpensive, transferrable, and
11 reliable. We both want to demonstrate that we care about
12 protecting consumers against dubiously effective,
13 substandard or counterfeit practices, and thereby
14 minimizing health risks for populations worldwide.

15 Thank you.

16 DR. GORDON: Thank you very much.

17 Dr. Daniel Callahan from Hastings Center.

18 DR. CALLAHAN: I should say first, unlike my
19 distinguished colleagues, we are on the receiving end of
20 grants rather than providing grants. So I come with a
21 somewhat different perspective, but I would like to talk
22 about what I think the nonprofit sector can bring to this

1 general discussion.

2 I really got interested in the subject a few
3 years ago when I began noticing an uncommon degree of
4 hostility among a number of distinguished physicians
5 toward CAM, and I began asking myself, why is this
6 hostility there. It is obvious from surveys that a large
7 number of people use it, actually a large number of
8 educated people. Why is it?

9 I have come to think that probably the greatest
10 obstacle to getting more research and better research is
11 that remaining hostility. Not only has that discouraged
12 people from looking at the subject -- it has discouraged
13 many good researchers -- but there is a tendency, even
14 once the research is underway, not to take it very
15 seriously.

16 So I think one major problem is somehow finding
17 a way to work better with, I will call it, the medical
18 establishment, whether you call it the reductionistic
19 medical establishment, the dualistic medical
20 establishment, but yes, Virginia, there is a medical
21 establishment and it has its lay supporters.

22 Leon Jaroff [ph], a long-time writer for Time

1 Magazine, predicted recently in an issue of Time Magazine
2 -- it was an issue devoted to the future of medicine --
3 and one of his predictions was that within the next 30 or
4 40 years, alternative and complementary medicine will
5 have been thoroughly debunked and removed from the scene.
6 If you read the magazine reason, and there are few
7 others, you will find quite a great deal of hostility.

8 I think that, to me, is one of the major
9 obstacles, how to give it a higher status, give it a
10 stronger reputation, and bring in people from the middle
11 range of medicine, if you will, who could make a
12 contribution. Having said that, I would also add, I
13 think one of the difficulties created by this situation
14 is it has forced many researchers in CAM to play on
15 somebody else's turf, if you will.

16 I certainly believe it is important to look at
17 safety and efficacy issues, but I don't think that would
18 have become the most important issues if it were not the
19 main medical establishment saying, by god, if you want us
20 to accept you, here are our rules and you show you can
21 play by those rules. It seems to me, that is a kind of a
22 trap. The question is, while taking that view seriously,

1 not let that dominate it as the model of what counts as
2 good research.

3 Well, in any case, let me suggest four areas of
4 research I think are important. First, obviously, is
5 safety and efficacy. Enough has been said about that and
6 the need for good scientific research, so I will say it
7 no more.

8 I think it is important also to ask the
9 question, what does the public interest in CAM say about
10 the general attitude of Americans toward health care in
11 this country? What does it say about what they are not
12 getting, or what they feel they are not getting? What
13 they feel they need in addition to what they are getting,
14 and how can we better make sense of that?

15 Most of the people I know interested in CAM, it
16 is for them an alternative. They do both. They usually
17 turn to CAM when other things don't work, and typically
18 with chronic illness. But I don't think we really
19 understand the social dynamic, much less the medical
20 dynamic of chronic illness well enough.

21 It seems to me, research on why people are
22 drawn to it, what people who are drawn to it, what do

1 they mean by what we say works, or what do they find
2 satisfying about it that they don't find satisfying in
3 the rest of medicine. Here a good deal of social science
4 research would be very helpful, cultural research as to
5 what makes people think about it the way they do think
6 about it.

7 It is pretty clear for many people that the
8 fact that personal interaction is a key element. This is
9 constantly talked about in mainline medicines, the need
10 for better communication. We have a project at Hastings
11 on communication in cancer, but it is fairly clear that
12 it is a problem and perhaps exacerbated by managed care.
13 But even without managed care, it has always been a
14 problem.

15 We have to understand why that is the case.
16 Why is it that it is so difficult to get people simply
17 talking with each other in health care? CAM, it seems to
18 me, has some insights to offer in that respect.

19 Thirdly, I think the issue of medicine as art
20 and medicine as science, an ancient issue, remains an
21 important and fascinating one. It seems to me, when we
22 think about it, it is really interesting paradox or

1 puzzle that over the past 10, 15 years, not only has
2 evidenced-based medicine come to the fore, namely that we
3 need more and better scientific medicine, but at the same
4 time CAM has come to the fore. We have got these two
5 parallel things going on.

6 I have been increasingly impressed by the
7 limits of evidence-based medicine. First of all, very
8 expensive to do. An awful lot of conventional medicine
9 will never be properly tested. On occasion, of course,
10 when it is tested, it is tested, often, by pharmaceutical
11 companies who have got something to benefit. So there is
12 a certain suspicion, anyway. Surely, the federal
13 government is never going to put up the billions of
14 dollars necessary to really review everything. So it
15 can't be done in any very total fashion.

16 Secondly, the results you will get are
17 probabilistic results. It doesn't tell you what to do
18 with any individual patient. It tells what on the whole
19 might work some of the time with some of patients under
20 certain circumstances, which means that the relevance of
21 medicine as an art is still as much alive as ever.

22 If you get the evidence, you get the

1 probabilities, you have the ethical questions of, well,
2 should you spend the money doing something that may have
3 a low probability, might work with some people but not
4 for others; how should you think about individual
5 patients in the light of population statistics.

6 As far as I am concerned, the interaction
7 between science and the art of medicine is going to be a
8 persistent part of medicine in the future, regardless of
9 how much evidence-based medicine there will be, and there
10 will never be enough of it.

11 Finally, I think CAM is helpful in trying to
12 envision what we think of as the future of medicine. My
13 main work is in the area of health policy. I am
14 interested in the future of our health care system. This
15 is an excessively grandiose generalization, but I think
16 we face two large problems. One, the obvious aging of
17 societies, the larger and larger number of elderly
18 people, many of whom are going to have chronic illness.

19 On the other hand, we also have a great problem
20 of how to educate a younger generation to stay well so
21 that when they become elderly they will not become
22 chronically ill people, but they will get through a long

1 life in pretty good health.

2 Here, the idea of compression of morbidity, I
3 think, is alive and well, and worth pursuing. For this
4 reason, I think CAM not only offers the possibility of
5 dealing better with the aging population, but also of
6 enabling younger people to better take care of
7 themselves, better understand their own health, and thus,
8 reduce our, at present, I think, excessive dependence on
9 high technology medicine to bail us out and rescue us
10 after we have lived unhealthy lives, or one thing or
11 another has gone wrong. I don't think we can continue on
12 that route with an aging population.

13 So in my mind, a sustainable medicine is going
14 to require a CAM as a fundamental part of its future
15 because the present biomedical model, I don't think, is a
16 sustainable model for the future of medicine, either
17 economically, or for that matter in terms of improving
18 health.

19 So with that, I will stop. Thank you.

20 DR. GORDON: Thank you very much.

21 Next is Ms. Teri Ades from the American Cancer
22 Society.

1 MS. ADES: Thank you. I would like to thank
2 the Commission and Dr. Gordon for the invitation for the
3 American Cancer Society to speak to you today.

4 The American Cancer Society is the nationwide,
5 community-based, voluntary help organization dedicated to
6 eliminating cancer as a major health problem. Because we
7 are community-based organization, we touch millions of
8 people's lives everyday. My comments today, just to
9 share with you, will be related to cancer and
10 complementary and alternative medicine.

11 We realize that there are many definitions of
12 complementary and alternative medicine, and I would like
13 to share with you what our definitions are so that we can
14 realize that we may all have differences in how we define
15 these words.

16 "Alternative," to us, means a treatment that is
17 used in the place of a mainstream treatment. It may be a
18 disproved treatment or one that hasn't been proved to be
19 effective. Complementary methods are those that are
20 defined as used in addition to a mainstream treatment.
21 These do not replace mainstream treatment, and they are
22 not promoted to cure or treat cancer. Rather, they

1 control symptoms and improve the quality of life of the
2 person. This distinction separates the methods based on
3 how they are used. Any one therapy could fall into
4 either category, depending on how it is used.

5 I share this with you because the lack of
6 consistent definitions has created much confusion to the
7 public, and for professionals, studies published in
8 medical journals cannot be adequately analyzed, nor can
9 they be compared with other studies because of the
10 differences in our terminology. We do not believe that
11 alternative and complementary therapies are the same, and
12 should not be grouped as one.

13 I raise this because if the body of knowledge
14 is to grow, we must speak with one language. We are
15 sensitive to the growing public interest, in particular
16 those living with cancer with regard to alternative and
17 complementary medicine. We also acknowledge that more
18 research is needed regarding the safety and efficacy as
19 has been mentioned previously, and we advocate for peer-
20 reviewed scientific evidence.

21 We believe that all cancer interventions must
22 withstand the scrutiny of peer-reviewed scientific

1 evaluation before they can be recommended for the
2 prevention or treatment of cancer. We also realize the
3 need to balance access to alternative and complementary
4 medicine while protecting patients against those
5 therapies that might be harmful to them. We support
6 patient access, but strongly encourage more oversight and
7 accountability by governmental, public, and private
8 entities to protect the public.

9 We believe cancer is a little bit different
10 from some of the other chronic illnesses. The reason we
11 do is that many cancers today can be cured if the disease
12 is diagnosed early, and if the treatment is started, and
13 if the treatment is the treatment that is effective for
14 that cancer. If there is a delay in diagnosis or
15 treatment for whatever reason, then the chances of that
16 cure may be lost. The potential drug interactions in
17 people with cancer can occur, and they must be
18 recognized.

19 Now, to address the questions that I was asked
20 to address, the first one: How can the public/private
21 sector stimulate complementary and alternative medicine
22 research?

1 I think you have a handout from us that does
2 describe our current research in the area of
3 complementary and alternative medicine. I wasn't asked
4 to address that, but I do want to call your attention to
5 that.

6 I would like to revise the question that we
7 were asked and address: How can the public/private sector
8 facilitate professional participation in current funding
9 opportunities?

10 The American Cancer Society does support the
11 National Center for Complementary and Alternative
12 Medicine. The initial statements of Dr. Straus, we have
13 found, are very encouraging regarding the importance of
14 the systematic and scientific approach to studying
15 various medicines.

16 The Center has good funding, and we hope that
17 the Commission will support the Center's efforts. A
18 second important component of existing opportunities for
19 research is the NCI's Best Case Studies. I believe you
20 heard about that yesterday.

21 This gives clinicians who may not have the
22 research background an opportunity to learn how to

1 conduct their study using a scientific method. We
2 encourage this group and others to support this program,
3 to provide the necessary mentoring and coaching that
4 clinicians need to successfully complete their research
5 and to publish their findings.

6 We currently have in place the opportunities
7 for research funding for people with cancer through our
8 government agencies. More money may be needed to be able
9 to mentor and coach more of those who have therapies that
10 want further study, and if that is the case, that we ask
11 the Commission to recommend additional funding. We
12 believe that successful mentoring will be the impetus for
13 others to follow.

14 The second question: What are the obstacles,
15 barriers and possible solutions to accomplishing this
16 goal? For example, the use of incentives.

17 What we see as the primary barriers to more
18 research in this area are attitudes and perceptions.
19 Money may be an additional factor, as mentioned
20 previously. Obviously, good research costs money, and
21 money will attract those who are considering further
22 study.

1 We believe the major barriers lie in people's
2 attitudes, and perceptions had been mentioned previously.
3 For example, some believe that the randomized clinical
4 trial cannot be done with some of the complementary and
5 alternative therapies. My question is, is that fact? If
6 it is, then we do need to identify those types of
7 research that can be used.

8 We are beginning to see more research published
9 in some of the major medical journals, such as the New
10 England Journal of Medicine, the British Medical Journal,
11 and JAMA. We need to see more published research.

12 For others, the lack of scientific proof for
13 years in the past, and still today, causes trust issues,
14 which divide people into the "we" and "them." We must
15 move beyond this to a comfort level that allows everyone
16 to agree that safety and efficacy are essential.

17 Rather than considering incentives, we ask the
18 Commission to consider setting the expectation that all
19 therapies must be proved to be safe and effective so the
20 public does not have to question their therapy.

21 We also encourage an educational strategy, one
22 that will identify and teach the research methods that

1 are necessary to study this area, to offer mentoring, to
2 support the researchers through the process ending with a
3 publication, and to help in breaking down the barriers
4 that I have addressed previously.

5 No. 3: How can the public/private sector be
6 better coordinated with federally supported CAM research?

7 We have no really good model for this, but we
8 believe a model could be established with the National
9 Center for Complementary and Alternative Medicine as the
10 coordinator of the group. We would like to see the
11 public, private, and governmental agencies together
12 discussing how this might work.

13 We have also seen how quickly such cancer
14 centers as Fox-Chase, Memorial Sloan-Kettering, Dana-
15 Farber, and others, have developed their integrated
16 medicine programs to offer complementary therapies along
17 with their mainstream treatments.

18 These programs offer the patient the study
19 population needed, and the investigators clinicians to
20 conduct the studies in a coordinated approach to CAM
21 research.

22 So to summarize my comments, we do support

1 evidence-based scientific research to prove the safety
2 and efficacy of new promising therapies. We do support
3 the right of patients to expect that what they receive is
4 safe and effective. We do support the National Center
5 for Complementary and Alternative Medicine, and the NCI's
6 research agenda as well.

7 We support the Center's coordination of CAM
8 research involving all agencies, federal, private,
9 public. We ask that the cancer centers' integrated
10 medicine programs be considered a valuable resource. We
11 support existing federal funding opportunities, and
12 support an educational strategy, as I have mentioned
13 previously. Thank you.

14 DR. GORDON: Thank you very much.

15 Thank you all four for your complementary
16 perspectives.

17 Dean?

18 DR. ORNISH: First of all, I am sure that I am
19 speaking for everyone here to say how much we appreciate
20 your being here, and how fascinated I personally am by
21 what each of you had to say. As Jim was saying, it
22 really does complement. I have just one question for

1 each of you, if I can be brief.

2 For Dr. Templeton, in the pioneering work that
3 your foundation is funding, are you distinguishing
4 between what some would categorize as religion versus
5 spirituality, the idea that religion sometimes divides
6 and spirituality looks for commonality?

7 In many systems of healing, the very fact of
8 dividing itself, may predispose to suffering an illness,
9 and the very fact of finding common ground leads to
10 healing. I am just wondering if you make those
11 distinctions.

12 DR. TEMPLETON: The problem of designing good
13 studies is difficult when you have a harder time defining
14 an item that you are studying and be able to measure it
15 in particular. If you deal with religion or religious
16 practice, you could certainly assess people's attendance
17 or practices, whether those are prayers or devotions or
18 any kind of overt activity which you could quantify.

19 I think that has been the big weakness in
20 studying the broader issue of spirituality from a
21 scientific perspective because people seem to have
22 different perceptions of what their spirituality is,

1 compared to someone else.

2 DR. ORNISH: Right.

3 DR. TEMPLETON: So that why I say this kind of
4 research is very much in its infancy.

5 DR. ORNISH: Although, when you have relatively
6 crude measures, and yet find dramatic differences, then
7 you have to figure there is something going on there.

8 DR. TEMPLETON: Yes, I agree. That is, again,
9 why I say that I think much of the early assessments will
10 be correlational, and then you may, hopefully, in time,
11 be able to understand better why they have that effect.

12 But yes, I think it is important to try and
13 pick some aspect of spirituality that a group that
14 practices a certain type of spirituality approaches maybe
15 will say, this is what we are about when we say that, and
16 then study their intervention.

17 DR. ORNISH: Some orthodox groups, they may
18 distinguish themselves from other groups, but at least
19 within that group there is a greater sense of
20 cohesiveness. So it is even harder to tease those things
21 out.

22 DR. TEMPLETON: Right.

1 DR. ORNISH: Thank you.

2 And then, for the Hilton Foundation, I
3 understand you have no investigator-initiated grants. It
4 is all foundation-initiated. Are you doing anything in
5 CAM? I mean, you have talked about the cocaine study,
6 but in a broader sense, are you planning any initiatives
7 in CAM?

8 MS. HAYES: Nothing is in the works at this
9 time. This particular study, it really has been six
10 years. We expected a three-year time frame. Now, the
11 Hilton Foundation does like to commit its resources long-
12 term, but this took much longer than we had hoped.

13 However, our board is very eager to get the
14 results, and Dr. Klieber tells me they will be here next
15 month. Regardless of what the results are, I think for a
16 board as traditional and conservative as ours, it was a
17 giant step forward for them and we have been very pleased
18 with the organization that we funded, the Center for
19 Addiction and Substance Abuse, CASA, and Dr. Klieber, in
20 particular.

21 And so, I would hope that the board would
22 continue to be open if we bring something to it, because

1 we are a foundation where unsolicited proposals are not
2 funded. We look for niches that aren't being funded or
3 aren't particularly popular.

4 DR. ORNISH: Thank you.

5 Dr. Callahan, I was particularly fascinated
6 about what you were you saying about the limitations of
7 evidence-based medicine. I used to get the Hastings
8 Report when I was in medical school, and it was one of
9 the only things of its kind at the time. So I really
10 appreciate what you did then, too.

11 One of the things that we found in doing
12 randomized, controlled trials, is that there has to be a
13 certain narrow window in time. There has to be enough
14 evidence to justify doing it, but not so much that a
15 control group would be unethical.

16 If you have a new drug or a new device, that is
17 less of an issue, but in CAM, by nature of the fact that
18 so many therapies have been around for thousands of
19 years, they wouldn't be around for thousands of years if
20 there wasn't some evidence that they did some good.

21 How can you do randomized, controlled trials?
22 We find this all the time in our work. When someone gets

1 randomly assigned to the control group, they feel bad,
2 and we feel bad. We justify it by saying, well, it is
3 the higher purpose of, you really need to do this to get
4 that sense of rigor, and yet.

5 As an ethicist, what is your opinion? Is it
6 ethical to do randomized, controlled trials of CAM
7 therapies if there is enough evidence that there is some
8 benefit, that they have been around as long as they have
9 been?

10 DR. CALLAHAN: Whether it is ethical or not. I
11 guess the question is, there will be circumstances where
12 you really can't do randomized clinical trials. You are
13 going to have find some alternative method. It simply
14 won't even be practically possible.

15 Then I guess the question is, do you have
16 enough confidence in those other methods that you feel
17 reasonably certain that there will be no harm to the
18 patients, that you will really get good evidence, that
19 the results will allow you to say yes or no or maybe
20 about something.

21 So it seems to me, the question is really the
22 adequacy of the other methods of evaluation if you can't

1 use the randomized clinical trials. It seems to me, an
2 enormous need in this field is to find some better ways
3 of formalizing alternative means of investigation.

4 Interestingly, this issue came up in arguments
5 about doing AIDS research in Africa where many object to
6 doing placebo studies, which is a standard part of the
7 technique. It is just in certain circumstances, that
8 does not seem ethically appropriate. So the thing is,
9 what then is, if not equally good method, what is a very
10 good second-best method.

11 I gather CAM has really got a problem
12 articulating some, if you will, competitive research
13 models that seem to have the power of the randomized
14 clinical trials.

15 DR. ORNISH: Just as a follow-up, it even goes
16 beyond just adequate other methods, because we found, for
17 example, in our earlier studies with looking at CAM
18 approaches and reversing heart disease -- ideally, in a
19 randomized trial, you have to complete testing of
20 someone, and then you randomize, but in the process of
21 testing them, people develop such a positive expectation,
22 despite our best efforts, that if they were randomly

1 assigned to the control group, they would get angina.

2 One guy called me at 4:00 in the morning from
3 the coronary care unit saying, I got so disappointed when
4 I got the control group, I got unstable angina, and I am
5 up, and I want you to be up, too.

6 [Laughter.]

7 DR. ORNISH: Then, of course, it introduces all
8 kinds of confounding problems because then they are more
9 likely to change because you told them exactly what you
10 are doing. They are more likely to drop out because they
11 are angry they ended up in the control group, even though
12 you disclosed at the beginning exactly what the odds are.

13 So there are certain issues that are inherent,
14 almost, in many of the CAM studies that you don't find in
15 drug trials. I am wondering, as an ethicist, putting
16 aside, can you get good enough data, is it really ethical
17 to do these kind of designs?

18 What we ended up doing was modifying our design
19 to an invitational design where we would randomize people
20 before we conducted them. So we had less contamination,
21 cross-over, drop-out, people getting upset, and so on,
22 just to make myself more ethically comfortable, but I

1 think also it gives better science.

2 Do you address these issues at all in the
3 Hastings Center?

4 DR. CALLAHAN: We have not. We have actually
5 done a lot of work with human subject research generally,
6 but we haven't particularly looked at CAM research as a
7 special subcategory.

8 I guess my sense is that if you can't do what
9 is considered the gold standard, as they say, and
10 nonetheless it is important to test in some fashion, then
11 it is perfectly all right, I think, to pick some,
12 perhaps, less satisfactory method if it is the only one
13 available to use. It seems to me, this is sheer
14 necessity. Better something that you consider not quite
15 ideal than doing nothing at all and letting things just
16 continue wandering about, as they probably will, if you
17 don't do the test.

18 DR. ORNISH: Thanks.

19 My last question, which is brief, is, is the
20 American Cancer Society doing any CAM initiatives, any
21 CAM funding? I wasn't able to find it. In particular,
22 are you doing any kind of partnerships with the National

1 Center for CAM?

2 MS. ADES: In terms of our research, we have
3 three different areas of research, and we have activities
4 related to complementary and alternative medicine in all
5 three areas.

6 Our Behavioral Research Center, which, we
7 conduct our own research. Two previous studies that they
8 have done was the frequency of use of CAM among cancer
9 survivors.

10 Then the second one that was done was
11 professional perceptions of the use of CAM. The one that
12 is currently going on right now is the frequency and
13 impact of the quality of life of breast cancer survivors
14 who are using complementary and alternative medicine.

15 Our Epidemiology and Surveillance Department,
16 of course, has their ongoing cancer prevention studies 1
17 and 2, started in '59. They are following 100,000
18 people. A component of that is certainly nutrition,
19 their nutritional habits. That will include vitamins,
20 minerals, nutritional supplements, and so on.

21 In terms of our extramural grants program, I
22 looked quickly through to find some of the grants that we

1 currently are funding, and those include the use of
2 presurgery hypnosis, effect on post-surgery recovery of
3 breast cancer patients, the use of hypericin from St.
4 John's wort to treat tumors of the pancreas, the use of
5 Vitamins A and D for biologic modulation chemotherapy of
6 advanced breast and prostate cancers, and the
7 applications of acupuncture for pain management.

8 Those were, just quickly, four that I pulled
9 out.

10 DR. ORNISH: Thank you.

11 DR. GORDON: Wayne, Charlotte, Joe, and Tom.

12 Let me just say to everybody that we need a
13 little concision, too, because we are going to be running
14 way over time.

15 DR. JONAS: Thank you very much for the list
16 because that was my question, also, as to what was
17 actually being funded by the ACS in these areas. It
18 sounds like most of them are in complementary areas, and
19 so an important perspective.

20 I just wanted to follow a little bit up on the
21 methodological discussion that was had, and just point a
22 different dilemma, and we don't need to go into the

1 details, but I appreciate any kind of thoughts on that
2 perhaps you could deliver to us.

3 To me, I see almost an insolvable dilemma of
4 being able to address the need of new methodologies from
5 the perspective of complementary and alternative
6 medicine. It is almost like saying, well, I want to test
7 this untested area, and I am also going to use an
8 uncertain measurement technique. You don't combine both
9 of those.

10 It is very clear that the randomized,
11 controlled trial, as you have mentioned, is not adequate
12 for everything, but it is unclear as to what else can
13 provide you with equally valid information. So we don't
14 really have a substitute at this point. I am not sure
15 that complementary medicine can do that. It is the
16 responsibility, really, of the mainstream scientific
17 community to try to figure that out.

18 I am wondering if there are some ways in which
19 we can facilitate that, even though it is not directly on
20 complementary medicine. If there are ways in which some
21 of the work that you are doing, Daniel, could assist, or
22 if you perceive ways that the Commission itself could

1 facilitate them.

2 DR. CALLAHAN: Well, you may remember from our
3 project, I found one of the things in a project at the
4 Hastings Center was to bring in some people who were
5 experts in the philosophy of science. They weren't
6 experts in CAM.

7 DR. JONAS: Exactly.

8 DR. CALLAHAN: It seems to me, it would be a
9 valuable little project to find some people who were
10 interested in scientific methodologies who look at
11 different fields, because one thing is pretty clear,
12 there is no such thing as one single scientific method.
13 Biomedical fields use different methods of research to
14 bring together a group of scientists to talk about the
15 development of some alternatives which might be
16 appropriate.

17 If you can't use randomized clinical trials,
18 are there perhaps some models that research in other
19 fields that you could borrow from, or adapt, or modify
20 that might work here?

21 DR. JONAS: Should that be more of a foundation
22 or a think tank effort?

1 DR. CALLAHAN: No. I think it has to be a
2 think tank. It seems to me, a grant to bring together
3 some research methodologists to talk about this issue,
4 and to bring in not just people interested in CAM, but to
5 bring in someone who will find this a fascinating
6 methodological problem would be a valuable exercise and
7 very helpful, and probably not expensive. People like
8 that come rather inexpensive. No machines, no nothing,
9 just real cheap stuff.

10 DR. JONAS: Just brains, billions of years of
11 investment.

12 I had a couple questions, well, one question,
13 really, for the Foundation. I would love to get your
14 comments in writing, the succinct recommendations that
15 you had. I didn't see all of those in here. I think
16 they were excellent, both of you, in terms of some ways
17 to facilitate the private investment and the kinds of
18 things that you are looking for in these areas.

19 I had one question for Dr. Templeton. There
20 considerable interest in spirituality now, really, in all
21 sectors, both the government and the private. The NIH
22 currently has a working group that I help facilitate, and

1 it is ongoing now. It is cross-institutional, to look at
2 spirituality in health areas.

3 Rockefeller has funded now a project to pull
4 together the science in spirituality as well as energy
5 healing and distant things. Some of what you are doing
6 kind of overlaps that, the distant-healing study that you
7 mentioned looks at non-local issues in some regard. The
8 spirituality observational epidemiological studies are
9 looking more at the traditional religious and
10 spirituality practices.

11 I guess, from your perspective, I would be
12 interested to know, are there ways to kind of bring these
13 things together? Do we just allow them to spontaneously
14 come together? Is there a way that there can be a
15 bridging the Commission might help facilitate or suggest
16 in that area? What would be needed in that, from your
17 foundation's perspective?

18 DR. TEMPLETON: We are young foundation, and we
19 are very early in the area of supporting individual
20 research. We were impressed with the quality of the two
21 studies that I mentioned, which is why we supported them.

22 I think that we are great believers in the

1 importance, as has been suggested, of consensus effort to
2 bring together, whether it is on the ethical or
3 scientific design aspect, or on the feasibility of
4 addressing a structured study on any kind of
5 intervention. For us, it would be in the area of
6 spirituality.

7 We agree, going back to the earlier question,
8 that spirituality as a more general concept, is something
9 that needs to be addressed because most of the science
10 has been things that were more behavior-related in the
11 area of religion.

12 So I think a consensus conference could be very
13 helpful in suggesting the ways to study this.

14 DR. JONAS: Have you done things, for example,
15 with one of the NIH institutes in the past in some kind
16 of collaborative meeting or a conference? Has that been
17 something that has occurred?

18 DR. TEMPLETON: No, we haven't. So I think we
19 would be interested in some sort of collaborative effort
20 in our area of interest.

21 I thought these presentations were being
22 transcribed. Am I mistaken?

1 DR. GORDON: They are. They are being
2 transcribed.

3 DR. JONAS: Oh, okay. So we will get that,
4 then. Thank you.

5 DR. GORDON: Thank you very much.

6 Charlotte?

7 MS. KERR: Dr. Callahan, in your report here,
8 you speak of the conclusions of the research group. We
9 have already talked about it a bit, but the third one,
10 "There is no single, all-purpose, scientific methodology
11 suitable for CAM; and "The need to determine the
12 methodologies are most appropriate for evaluating CAM.

13 Wayne has already highlighted this. Also,
14 yesterday the founder of Bastyr suggested that we have a
15 consensus conference on research protocols. I wondered
16 what you thought about that. I think I have some
17 understanding from what you just said to Wayne.

18 I often feel when we are listening to people
19 and scientists speak to us, and even amongst ourselves on
20 the Commission, that we say, well, we need rigorous
21 scientific study, and it seems to be an ipso facto kind
22 of, we have got it all down and we know what we should be

1 doing.

2 To me, it is almost a fundamental starting
3 point. I have a question about that, which of course, is
4 what your research group is reporting. I am wondering,
5 in addition to anything further to say about the way to
6 pursue doing this, a consensus conference, a think tank,
7 what did you find in your research group? Did you find
8 that the world view, the new scientific thinking, is what
9 is creating the question in terms of research
10 methodologies to be used for CAM?

11 DR. CALLAHAN: Well, if I understand your
12 question, what seemed clearly evident is that there is a
13 view out there that there is a single type of scientific
14 methodology which is the scientific methodology. It
15 seemed pretty clear to us, first of all, that there
16 isn't. There are many scientific methodologies.

17 Secondly, that CAM, given the whole range of
18 things that are covered by that territory, I think to
19 evaluate spirituality is very different from evaluating
20 herbs. You can do a pretty clean study of efficacy, but
21 spirituality, even if you know that there is a
22 correlation, it is not clear what you would do with it