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WHITE HOUSE COMMISSION
on
COMPLEMENTARY and ALTERNATIVE MEDICINE POLICY

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Volume I

+ + +

Thursday, October 5, 2000

8:30 a.m.

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

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National Black Women's Health Project

Commission Members Not Present:

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CEO/President
American Specialty Health Plans

Buford L. Rolin
Poarch Band of Creek Indians

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P R O C E E D I N G S

DR. GORDON: Good morning everybody. I am Jim Gordon, and I am the chair of the White House Commission on Complementary and Alternative Medicine Policy. On behalf of our commission and our staff, I want to welcome all of you.

I want to welcome our commissioners as well. We have a group that comes from all over the United States, and they are here today. I want to welcome a new commissioner, particularly. Tieraona Low Dog, who is from New Mexico, and a physician and herbalist who will be here with us.

Both George DeVries and Buford Rolin will not be here today. They are unable to come. Otherwise, I believe all the other commissioners will be here, and are here. That's great.

The way that we are going to be organizing these sessions is we are going to have panels of people who are going to come and testify to us. Michele Chang, who is the executive secretary on my left, will be calling up the panels. The panels of people will testify. Each one will testify, and then we will all

1 have a chance to ask them questions, and we will keep on
2 going through the day with that format.

3 Now, as you can see when you look at the
4 schedule, and I think everybody in the audience, as well
5 as here, has a schedule. For us, it is under Tab 1, the
6 schedule. It is a very busy schedule. So we are going
7 to set time limits strictly. I even brought a little
8 clock to make sure it is at the very forefront of my
9 consciousness throughout these meetings.

10 So we will be setting time limits strictly, and
11 we want you speakers to know what your time limit is. It
12 is generally 10 minutes with a very few exceptions.

13 They have the lights on the table, right,
14 Michele?

15 So you have the lights, and when the red light
16 goes on, that means it is over. Not to put too fine a
17 point on it.

18 We welcome written testimony from all of you.
19 We welcome communications after this meeting. Many of
20 you may be communicating with us, interacting with us, as
21 we move ahead. Remember, the Commission continues
22 through March 2002. We have an interim report due next

1 July, and we will welcome all of your feedback, not just
2 the people who are coming to sit at the front table to
3 speak with us, but all of you who are here with us today.

4 There is a time for public comment, both today
5 and tomorrow, right after lunch. If you would like to
6 sign up, you can sign up outside at the table. Public
7 comment, we are asking people to limit their time to 3
8 minutes, so we have some time interact with you, ask you
9 questions, have a dialogue.

10 There is going to be a press briefing here at
11 12:30, and any of you who would like to stay and see the
12 press briefing are welcome to be part of it. When you
13 speak, there is an on/off microphone for all of us up
14 here and for those who are sitting at this front table,
15 so turn it on when you are speaking, and turn it off when
16 you are not.

17 This is for the commissioners. When people
18 come and speak, give their testimony, we have a chance
19 for questions. I am going to ask all of you to ask brief
20 questions. We have a lot of time for discussion among
21 ourselves. We will have a lot of time when we are
22 formulating the interim report and the final report to

1 discuss the issues, to discuss the philosophical
2 implications or the practical implications.

3 So I want to remind all of us, including
4 myself, to ask questions, not make statements. Our work
5 here is to help these people, the experts who have come
6 to us from all over the country, and we hope from all
7 over the world, to answer the questions that we need to
8 have answered, to give us the information that we need in
9 order to formulate our recommendations to the President
10 and to Congress.

11 There is a schedule which is available to
12 everyone. Does everyone in the audience have a schedule
13 of our Town Meetings and future Commission Meetings?

14 MS. CHANG: It still hasn't been finalized.

15 DR. GORDON: It hasn't been finalized, but the
16 next Commission Meeting will be on access to services and
17 on issues related to services. CAM will be here December
18 4th and 5th. There will also be a Town Hall Meeting in
19 Seattle on October 30th and 31st. Those will be the
20 meetings that we will be having between now and December,
21 and we welcome communication from you in the interim. If
22 anyone would like to communicate with us. The best way

1 to communicate is through e-mail, probably, and the
2 e-mail is?

3 MS. CHANG: WHCCAMP@od.nih.gov. Our web site
4 is www.whccamp.hhs.gov. All that information is in the
5 materials in the back of the room.

6 DR. GORDON: Great. Thank you, Michele.

7 Now, before we move into a brief introduction
8 to today's session, I would like for everyone to just sit
9 quietly for a minute so we kind of collect ourselves.

10 [Moment of silence observed.]

11 DR. GORDON: Thank you very much.

12 Today we are going to explore issues related to
13 research and complementary and alternative medicine, and
14 we are going to be hearing from a wide range of people
15 who are going to discuss a number of different topics,
16 present a number of different programs that have been
17 undertaken at the federal level, at the private level,
18 programs of funding, of philanthropy.

19 People from the CAM community and the
20 conventional medical community who have been doing
21 research in the field will be telling us how that
22 research is going, what the challenges are, the progress

1 that they have made, and what some of the vehicles for
2 improving our approach to research might be. All of
3 these hearings are done in the spirit of collaboration.

4 Just as this commission is composed of people
5 from a number of different disciplines and a number of
6 different perspectives, so our work is a collaborative
7 work. We are bringing people together to put our heads
8 together, to open our minds, open our hearts, to work
9 collaboratively to develop an agenda that will best serve
10 the needs of the American people. That is our task here.

11 This particular session is the first of two
12 that we have planned on research initiatives. There will
13 be another one after we have had the sessions on access
14 to services, on education for health professionals, and
15 on information to the public. We have had a committee
16 that has worked on this, that has been instrumental in
17 helping to put together the program. The committee
18 includes Dean Ornish, and Wayne Jonas, and Bill Fair, and
19 Effie Chow, and Buford Rolin. I have worked with that
20 committee.

21 We have put together a lot of the ideas. What
22 has made this session happen is the work of Steve Graft,

1 the executive director, Michele Chang, the executive
2 secretary, and the staff that have been in touch with
3 people who are sitting here who will be talking with us
4 today, and who have helped to coordinate and pull
5 together a vast number of people and a tremendous amount
6 of information to make it possible for us to have these
7 hearings.

8 So without any further ado, let's begin with
9 the first panel on Research Priorities and Public Input.
10 We have asked Dr. Leon Rosenberg, the chair of the
11 Institute of Medicine Committee on the NIH Priority-
12 Setting Process to talk with us about some of the issues
13 in involving the public in setting priorities for CAM
14 research, and indeed, involving the public in setting
15 priorities for all research at NIH.

16 So, Dr. Rosenberg.

17 **Session I: Research Priorities and Public Input**

18 DR. ROSENBERG: Thank you very much, Dr.
19 Gordon. I am pleased to testify before this commission
20 and your very important task.

21 Two and a half years ago, Ken Schein, the
22 president of the Institute of Medicine, called me and

1 asked me to chair a congressionally mandated committee of
2 the IOM on the processes by which NIH sets research
3 priorities. I blithely accepted, as I usually do when
4 the IOM asks me to do something, and that set in motion
5 the most challenging committee assignment that I have
6 ever done.

7 It was a fast-track study. We were given
8 exactly six month from start to finish. We met the
9 deadline, but some of us paid the price for having done
10 so. It was rather exciting.

11 The booklet that you have all received,
12 "Scientific Opportunities and Public Needs," is the
13 output of that committee, and the overheads that I asked
14 that you all receive is really the distillate of the
15 committee's report, which I would like to take a few
16 minutes to discuss with you now. Some of my comments
17 will be general about research, and some of them will be
18 very specific about public input to NIH, which I judge to
19 be the thing that you are most interested in here.

20 As Dr. Gordon alluded to, the United States is
21 the preeminent medical research establishment in the
22 world. It is a source of great pride in the country, and

1 it is the envy of the world. The federal government is
2 the largest single sponsor of that research, spending
3 close to \$20 billion this year, the lion's share of which
4 is budgeted through the National Institutes of Health,
5 whose budget in this fiscal year is \$17.9 billion and may
6 be over \$20 billion, depending on congressional actions
7 in the next couple of weeks.

8 Given the size of this public investment and
9 the likelihood that it will continue to grow, it is not
10 surprising that there is intense interest at NIH,
11 particularly when one looks at the NIH mission statement,
12 which is: "To uncover new knowledge that will lead to
13 better health for everyone."

14 So the question is, why this intense interest,
15 and I think it is an easy answer. Every one of us wants
16 to live a long and healthy life. Every sick person,
17 woman, man, or child, wants researchers to find new ways
18 to make him or her well, or to improve the quality of
19 life for those who are disabled, without regard to
20 whether the ailment is common or rare, acute or chronic,
21 life-threatening, or self-limiting.

22 So the NIH has an enormous task, and an

1 exciting one, to be sure. It has done its job, in my
2 view and in the view of the committee, very well. It is
3 the leading federal agency supporting research related to
4 improving the nation's health.

5 The quality and quantity of excellent science
6 NIH has supported, and the outstanding basic and clinical
7 researchers it has trained for many, many years, have
8 advanced both fundamental knowledge of human biology and
9 better ways to treat or prevent disease and promote
10 health, but the NIH budget, however large it is, will
11 never be large enough to meet every need or fund every
12 promising opportunity. Choices will be made, and
13 therefore, priorities have to be set.

14 When NIH writes about and talks about its
15 priority-setting process, it starts with its objectives,
16 to identify the public's health needs, reducing the
17 burdens of disability and disease by developing better
18 means of prevention, diagnosis, treatment, and
19 rehabilitation. A second objective, to extend the basic
20 knowledge base to lead to even better methods in the
21 future. The third, to communicate to the public and to
22 health providers the current state of scientific

1 knowledge.

2 So this is where NIH starts in its priority-
3 setting processes. In order to define its priorities,
4 NIH takes into account its many constituencies, and you
5 and I know how many it really has. Research scientists,
6 on the one hand; clinicians who apply research results as
7 a second; organized voluntary groups and individuals
8 active as advocates as a third; organizations and
9 individuals who represent population groups with special
10 health problems as a fourth; Congress as a fifth, and a
11 rather important fifth; and of course, the media.

12 So I don't think any of us would doubt that
13 setting priorities at the NIH is an awesome task. Not
14 only must the leadership of NIH answer to the Executive
15 Branch and the U.S. Congress, but it must work with all
16 of those constituencies that I mentioned before, making
17 its fateful decisions, and it must also adapt to a
18 changing policy environment in which scientific
19 opportunities have grown more rapidly than the budget.
20 Health problems have changed as the population's
21 demographics have shifted, and globalization has exposed
22 the U.S. population to new problems, such as emerging, or

1 reemerging, infectious diseases.

2 The study whose committee I chaired was set in
3 motion because of sources of concern registered by many,
4 in the second half of the 1990s, about how NIH sets
5 priorities and how it was doing as it set them. Some
6 members of Congress believed that there should be more of
7 a correlation between the allocation of research funds
8 and the magnitude of disease burden in the population.
9 An increasing number of disease-specific interest groups
10 campaigned for increases in NIH funding related to
11 particular diseases: AIDS, breast cancer, Parkinson's
12 Disease, diabetes, and so on.

13 Some of these groups always feel that NIH
14 doesn't listen well enough or doesn't respond to their
15 input. The leadership of the health committees in
16 Congress, on the other side, such as John Porter, have
17 become increasingly uncomfortable with intervening in
18 research priority-setting by NIH by using mandates or
19 set-asides.

20 And so, this was the background under which our
21 committee was called into session. Our committee was
22 charged very clearly by Congress, and I would like to

1 read the charge to you:

2 "The IOM will review the research priority-
3 setting process of the NIH and make
4 recommendations for possible improvement. The
5 study will consider (1) the factors and
6 criteria used to make funding allocations; (2)
7 the process by which the funding decisions are
8 made; (3) the mechanisms for public input; and
9 (4) the impact of congressional statutory
10 directives."

11 That is what the committee was asked to do, and
12 set out our proposal and our recommendations in a very
13 short period of time.

14 So we set to work in March of 1998, and we
15 entered into a series of activities, panel discussions
16 with the director of the National Institutes of Health,
17 with a number of institute and center directors. We
18 conducted a full-day session, a town meeting with
19 interest groups at the National Academy of Sciences. We
20 collected written statements from organizations and
21 individuals, and had several hundred of those. We
22 surveyed NIH constituents, researchers, clinicians, and

1111
Rosenberg

1 advocates. We interviewed congressional staff, and we
2 reviewed published reports and other information provided
3 by NIH, insofar as we could.

4 Let me address the four charges to the
5 committee in turn. First, the one about NIH's criteria.
6 What are the criteria that NIH uses in prioritizing its
7 budget. NIH has published on this, and I hope that the
8 Commission has access to their book on how NIH sets
9 research priorities. Their criteria are very
10 straightforward. There are five in number: public health
11 needs; scientific quality of the research; potential for
12 scientific progress; portfolio diversification along the
13 broad and expanding frontiers of research; and adequate
14 support of the infrastructure, that is, human capital,
15 equipment and instrumentation, and facilities.

16 Those are the criteria. Are they rocket
17 science that can be quantitated to the fourth decimal
18 point? Of course, not. They require a great deal of
19 expertise and judgement, and that is why we attract as
20 outstanding a group of people to the leadership positions
21 of the NIH, starting with the director, as we possibly
22 can.

*NIH
Rosenberg*

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19 expertise and judgement, and that is why we attract as
20 outstanding a group of people to the leadership positions
21 of the NIH, starting with the director, as we possibly
22 can.

1 After its deliberations, our committee
2 concluded that NIH's criteria, as explicitly laid down in
3 their book "Setting Research Priorities," are generally
4 reasonable and useful, both for allocating research
5 resources and for enabling organized interest groups and
6 Congress and members of the public to understand and
7 evaluate NIH's program. The book "Setting Research
8 Priorities" is not for evening, bedtime reading. It is a
9 tough read, but it is a very important read if you really
10 want to understand how NIH does its job.

11 We had several recommendations concerning this
12 issue of criteria, but I think basically what we said
13 was, the Committee thinks your criteria are fine, but we
14 think you should make them clearer, and we think you
15 should pay more attention to how the public understands
16 the criteria that you are using, and we think you should
17 strengthen your analysis of health data and burden of
18 illness as it relates to the criteria.

19 The second thing we were asked to look at were
20 the processes for setting the research priorities. These
21 are decentralized through all of the more than 20
22 institutes and have to be decentralized because that is

1 the way the NIH is structured. We felt that, in general,
2 the Office of the Director of the NIH requires an
3 increased capacity to analyze cross-cutting needs and
4 opportunities. This means a more central role for the
5 NIH director in priority-setting, which is a very
6 controversial matter, as I am sure you know.

7 We suggested that if the director was going to
8 have this increased role, than he needed, or she needed,
9 to receive, regularly, strategic plans that indicated
10 what the various centers and institutes of the NIH were
11 going to do with their budgets.

12 Let me get to the heart of the matter here,
13 NIH's mechanisms for public input. This is where, I
14 believe, our committee made its most important
15 contribution. We felt that NIH's interactions with
16 various publics is weak compared with NIH's interaction
17 with the research community. We suggested that there
18 ought to be something done to make that better.

19 So we had three specific recommendations: One,
20 the NIH should establish an Office of Public Liaison in
21 the Office of the Director, and where offices performing
22 such a function are not already in place, in every

1 institute and center. Second, we said that there should
2 be established a Director's Council of Public
3 Representatives chaired by the NIH director to facilitate
4 interaction between NIH and the general public.

5 Third, we suggested that the public membership
6 of NIH policy and program advisory groups should be
7 selected to represent a broader range of public
8 constituencies than was the case in 1998. We also made
9 some recommendations to Congress, but I think those are
10 really not the heart of this discussion.

11 I would say that, for this group particularly
12 interested in the questions that I was asked to look at,
13 what role should the public have in setting research
14 priorities for complementary and alternative medical
15 research, and how can public input regarding such
16 research be increased, I think the heart there is in the
17 recommendations about the public liaison offices and
18 about the committee of public representatives, and about
19 the broader constituencies.

20 My own feeling is that your role, or the role
21 of advocates for complementary and alternative medicine
22 should be to inform, to advocate, to challenge, to

1 discuss, and then to respect the authority and
2 responsibility that goes along with the lead people in
3 the NCCAM or in the other institutes concerned about
4 broadening the research base.

5 As far as the second question, how can public
6 input regarding complementary and alternative medicine
7 research be increased, I would simply say you must use
8 all the mechanisms that NCCAM and the other institutes
9 have now established. That means be sure that your
10 voices are heard through the Office of Public Liaison,
11 through the Committee of Public Representatives, through
12 town meetings.

13 Will that stop individuals or groups from going
14 directly to Congress? No. Do I think that is the best
15 way to move the priority-setting process forward? No,
16 because in the final analysis, I think the system
17 generally works. I think it is working better. I think
18 NIH is really trying hard to hear more voices and to
19 think more broadly.

20 I am now more than willing to answer some
21 questions.

22 DR. GORDON: Thank you very much, Dr.

1 Rosenberg. One of the reasons that we asked you to come
2 is because you spent, albeit a brief, an extremely
3 intense time looking at these issues.

4 Our subgroup that was working on research
5 decided that this was a wonderful way for us to begin to
6 frame the whole discussion about research, since the
7 movement to create a new medicine which includes
8 complementary and alternative therapies is very much one
9 that is a very large, popular movement. So the issue of
10 public involvement is one that is crucial to our
11 thinking, and, of course, we, as a White House
12 Commission, represent the public and their interests.

13 So what I would like to do is to ask the
14 commissioners who would like to ask questions to please
15 feel free to ask Dr. Rosenberg questions, or ask for his
16 guidance and what he has learned in this process.

17 Dean first.

18 DR. ORNISH: Well, first, I appreciate your
19 report and all the effort you put into the Institute of
20 Medicine, which I found fascinating. I didn't find it
21 too dense. I thought it was actually very eloquent.

22 One of the issues that wasn't addressed in

1 there was, in doing research that is innovative as
2 opposed to incremental, it is sometimes more difficult to
3 get NIH funding for it because there is a bit of a catch-
4 22, that, without the funding one can't show that
5 something is feasible if it has never been shown before,
6 but if it has never been shown before, they are less
7 likely to fund it.

8 I am wondering, many of the complementary and
9 alternative medicine approaches often fall into that
10 category. Do you have any thoughts about that particular
11 dilemma?

12 DR. ROSENBERG: Well, I think the point you
13 make is valid, but, as someone who has spent my life
14 doing medical research, clinical and basic, I believe in
15 the process. I value the need to ask a question and try
16 to get an answer, and to get that answer through the
17 collection of unbiased data. So when you ask me, how
18 does one get your foot in the door with innovative ideas,
19 I say by crafting a good proposal and by proposing a good
20 study with which to answer it.

21 There are all kinds of ways in which
22 information about health and medicine are obtained:

1 anecdotal; case studies; small, uncontrolled studies; all
2 the way up to the rigorous, blinded, randomized studies
3 that are the gold standard for improving a medicine or a
4 new technology. The more work that is done at the top of
5 that scale, the more likely one will have of convincing
6 other people of one's ideas.

7 I do not doubt that many of the things that are
8 now called complementary and alternative will be tested
9 properly, and find their way into their rightful place in
10 medicine. I am really quite excited by the agenda of
11 NCCAM and the work that I have read about under the
12 leadership of Steve Straus. The studies that are ongoing
13 about ginkgo, about St. John's wort, about glucosamine
14 and chondroitin sulfate, I think these are all exactly
15 where that organization should be going, and I think they
16 indicate an openness and a desire for good science to be
17 done about important things in the world of CAM.

18 DR. GORDON: Thank you. Wayne?

19 DR. JONAS: This, I think, is such an important
20 theme, and I hope we don't shortchange this. This entire
21 topic is right at the heart of the whole decision-making
22 process, or recommendation-making process, that this

1 panel is going to make around science and scientific
2 research.

3 I want to commend Dr. Rosenberg for this
4 report. When this came out and I was at the NIH, I
5 thought, this is fabulous; this is absolutely fabulous,
6 because we were in an office that was started largely
7 because many people felt that the NIH had not done its
8 task around certain topics. The difference, however,
9 between alternative medicine and what a lot of the
10 disease advocacy groups were is that it wasn't about a
11 particular disease. It was actually about a different
12 world view, or about expanding our view to encompass more
13 of the world.

14 For example, focusing on disease, per se, a
15 specific diagnosis, which is the way we go about doing
16 research in the western world, was something that often
17 caused a lot of confusion and, in many cases, false
18 information, inability to do reviews, inability to set
19 priorities in these particular areas, because many of the
20 traditional systems that we were charged with looking at
21 did not take these same kind of world views, did not have
22 the same kind of disease classifications or interventions

1 and this type of thing.

2 You could extend that to the public, and I
3 thought bringing the public into the decision-making
4 process was key. So I was extremely happy to see this
5 report.

6 I guess my question is, in your view, how good
7 has the follow-up on this report been? Has the process
8 for improving this communication between the public and
9 the NIH developed? Has it improved? Is it moving
10 forward? Is there a way in which the Commission can say,
11 this is working and in the area of complementary and
12 alternative medicine, we should move into those areas,
13 especially in the area of knowledge management? Because
14 I think this is key.

15 It is one thing to exchange data, which
16 currently we are doing right here. It is another thing
17 to exchange information in which you begin to understand
18 and talk about the synthesis of data. It is another
19 thing to begin to exchange knowledge in which you
20 understand what someone's perspective is. That almost
21 requires some kind of training program, if you will,
22 cross-disciplines.

1 I know this is going on in a lot of areas, and
2 business, and this type of thing. I am just wondering if
3 you could comment, what has the progress been in terms of
4 moving some of this integration of the public and the NIH
5 forward?

6 DR. ROSENBERG: Wayne, I feel very upbeat about
7 the recommendations that we made concerning public input.
8 They have been the recommendations that have received the
9 greatest attention at NIH. They were the recommendations
10 that caused the greatest consternation when they were
11 originally made, but sometimes that is the good news part
12 of it, because the three recommendations that we made
13 concerning Offices of Public Liaison, the Director's
14 Committee on Public Representative, and a broader
15 inclusion in institute boards and high-level committees,
16 all of those have really been done in a very significant
17 way in two years. I have been very impressed, both at
18 the level of the Director's Office and at the institute
19 and center offices.

20 Is there unevenness still in that? Of course,
21 but I believe there has been a really a major, good-faith
22 effort to be more inclusive, to have more voices be heard

1 in order that the people ultimately charged with making
2 the decisions will have more information and will not be
3 second-guessed as much when they do make their decisions.
4 For, after all, the decisions still have to be made by
5 the people who are entrusted with the responsibilities to
6 be the best stewards of these public monies.

7 The recommendations concerning the priority-
8 setting process at NIH, strategic planning at the
9 institute level, I think, has been well received, and it
10 has been put into motion. The NIH's efforts to be more
11 concerned about disease burden and the cost of illness
12 has begun, but I wouldn't say it has gone as far as some
13 of the other recommendations.

14 So I think the score card is pretty good. It
15 is not an A-plus, but it is pretty good, and I think it
16 will still get better.

17 DR. JONAS: One of the things that might be
18 useful, just to follow up on that, and you don't have to
19 do it here, but I think what would be useful for the
20 committee is that, if there are some institutes that have
21 kind of really moved forward in this area that we could
22 look at, perhaps, as examples. I think this would be

1 extremely useful, and perhaps we can talk about that
2 after the meeting or sometime.

3 DR. GORDON: Thank you. Joe.

4 DR. FINS: Dr. Rosenberg, thank you very much
5 for your comments.

6 Your last criteria was the adequacy of the
7 infrastructure, and I was wondering if you could comment
8 on the adequacy of the infrastructure, that is, for
9 funding and criteria related to CAM, and specifically the
10 relationship between the social sciences and the more
11 clinical and basic sciences.

12 A lot of the outcome assessment issues will
13 pertain to quality-of-life indicators, and I am wondering
14 about the false divide between the social sciences and
15 the more traditional and clinical sciences.

16 DR. ROSENBERG: I think that the social
17 sciences and the behavioral sciences are increasingly
18 being recognized as important players in the NIH world,
19 but I really think it would be wrong of me to try to tell
20 you that I know the state of the infrastructure having to
21 do with CAM. I do not.

22 All I know, really, about CAM as it relates to

1 the NIH, is that I have followed pretty carefully the
2 affairs of, first the office, and now the center, and I
3 have read pretty carefully the strategic plan of NCCAM,
4 and the statements that I have seen from Steve Straus.

5 As a standard bearer for the name, I think he
6 is off to a wonderful start, and I think that the broad
7 agenda that now is framed for NCCAM augers very well for
8 infrastructure in terms of training, in terms of looking
9 for centers around the country, in terms of broadening
10 the horizon for expertise in CAM, and for visibility of
11 the area. I think that is in a good direction.

12 DR. GORDON: Are there other questions? Others
13 who have not asked a question? Yes, Effie.

14 DR. CHOW: Again, thank you for the great talk.

15 You know, research for the general practitioner
16 and the public is seen as this prodigal son, way up here,
17 and sometimes the practitioners, particularly with CAM,
18 are sort of afraid of research.

19 Is there a program within NIH that would
20 introduce research at a gentler level to reach the people
21 so that they will become more amenable to research?

22 There are a lot of practitioners out there that

1 are getting terrific results, but when you talk about
2 research, they feel, well, I don't know anything about
3 that. And they are scared off. I think this public
4 representation is wonderful, but I do wonder where the
5 outreach is.

6 Is it strictly to the universities or those
7 that are well established? Or, is there a method to
8 reach the community-based groups?

9 DR. ROSENBERG: That is a very, very hard
10 question to answer. When you say that practitioners are
11 frightened about research methodology because they don't
12 understand it, I am sure that what you say is true, but
13 research has its metier. It has a beginning and it has
14 an end. It has a process and it has a way of doing
15 things.

16 I think that clinical research, which is, after
17 all, I think, the heart of CAM research, at least for
18 now, also has a way of being done. I think there is a
19 great deal of effort being made around the country now to
20 educate young professionals into the methodology, into
21 the statistical evaluation, into the epidemiologic
22 precepts of what clinical research is, so that when a

1 study is planned, it has a reasonable likelihood of
2 producing significant results, so that people will
3 understand the difference between an anecdote and a bona
4 fide result.

5 I think that in the world of CAM, just as in
6 the world of traditional medicine, though I really don't
7 like any of these words very much, I think that is not
8 different. There is good science, and there is not-so-
9 good science, and then there is non-science. I think
10 that insofar as we can, we should want to foster good
11 science, because that is what will lead to good health.

12 DR. GORDON: I have a question or two. I am
13 wondering, when you looked over the work that is being
14 done at NIH, was there questioning of the balance that
15 you describe here between basic, applied, and
16 developmental research, and whether or not that meets the
17 needs of the public, and whether the public input is
18 continuing to justify that kind of balance?

19 DR. ROSENBERG: Yes. We looked hard at the
20 various divisions. We asked about the NIH's estimates of
21 what fraction of its budget was for basic research, what
22 for clinical research, and so on.

1 I think we ended up saying we didn't think that
2 that was Congress had really asked us to do. It didn't
3 ask us to say whether there was too much clinical
4 research or too much basic research. We felt that if you
5 take a look at the overall improvement in health that has
6 occurred through the NIH system over the past 50 years,
7 the investments in basic research have been enormously
8 important, as have the investments in clinical research.

9 So I do not think the Committee ended up
10 feeling that it needed to send a message that there was
11 too much of this or too little of that as a fundamental
12 issue for the NIH, and my own opinion is concurrent with
13 that.

14 DR. GORDON: One other issue that is related to
15 that. A couple of the examples that you give in the
16 report, which I enjoyed, and actually it was bedtime
17 reading for me. I really was very glad to have a chance
18 to read through it. A couple of the examples you gave
19 were of some very important basic research projects that
20 were government funded that then lead to the development
21 of patentable drugs by private industry.

22 What are the issues that we face here? I think

1 one of the tasks of this commission, especially in the
2 area of research is that many of the approaches and
3 interventions of CAM or of an integrated approach to
4 medicine are not patentable.

5 I am wondering if you dealt with the issue of,
6 given that these are public funds that are being spent on
7 research, whether there should be a shift in the
8 direction of those approaches that may not be patentable,
9 whereas much of the basic research now leads to
10 interventions that are patentable.

11 DR. ROSENBERG: Well, Dr. Gordon, I think it is
12 precisely on this point that many people, and I am one of
13 them, feel that NIH should have a larger portfolio of
14 clinical research directed at answering questions
15 concerning modalities that are not going to be patentable
16 and that will not have their research paid for by biotech
17 or pharmaceutical or drug device industries.

18 I think that that is why we can point to the
19 enormous importance of the NIH study on aspirin years ago
20 with regard to preventing coronary disease, and why I
21 think the studies on St. John's wort and glucosamine and
22 chondroitin sulfate are exactly in that same zone. There

1 are certain things that will not be sponsored by the for-
2 profit world, and they should be an important product of
3 publicly supported funds.

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

5 Wayne, you had another question?

6 DR. JONAS: I just had one other thing. It
7 sounded like the Committee was fairly universal, but I am
8 wondering if there were some minority opinions about the
9 wisdom of further centralizing and recommending further
10 centralization of the prioritization and funding process,
11 first in the NIH, and second, even more so in the
12 responsibility of the director of the NIH.

13 This is, I know, a very difficult thing because
14 you always want to bet a winning horse, and I think
15 everybody said, well, NIH is doing good, so we ought to
16 give it some more. I have used and actually loved the
17 prioritization document that was used, and used it for
18 developing our own priority plan.

19 So I think it is very good, but there is a risk
20 in that, and I am wondering if that was discussed at all
21 with the committee in terms of getting too unbalanced in,
22 not only research directions, but types of research and

1 domains of research. NIH is extremely focused, for
2 example, on basic science research. Not in the area of
3 complementary medicine, however, but in general, and
4 providing more input from other agencies that also do
5 important research for the public health.

6 I mean, was this something that was discussed,
7 the risks of that type of thing?

8 DR. ROSENBERG: Wayne, it was discussed, not in
9 great detail, but certainly in passing. It was why the
10 Committee felt uniform in wanting to start out our report
11 by saying NIH has been a remarkably successful federal
12 agency, and when you have a remarkably successful federal
13 agency, you take care of it, because not all of them are.

14 So that was the bottom-line view of the
15 Committee. There were many people who were concerned
16 about what would happen to NIH as its budget goes up even
17 more. We had the view, I think, that the only way you
18 can tell anything about what is going to happen in the
19 future is how an individual or an institution has done in
20 the recent past, and we had the feeling that NIH in any
21 way has fallen apart as its budget has grown.

22 That doesn't mean it doesn't have plenty of

1 problems, because of course it does, but we felt that on
2 balance it can be an effective steward of these larger
3 budgets.

4 On the other hand, and now I will just
5 editorialize here, I do not think that it is in the best
6 interest of the American public that such an enormous
7 fraction of the federal commitment to health research be
8 at the NIH. That isn't to take money away from the NIH.
9 It is to see to it that there are larger budgets for the
10 Agency for Health Care Research and Quality, for the CDC,
11 and for other named entities in the federal
12 establishment.

13 DR. JONAS: Just a very short question.

14 DR. GORDON: Sure.

15 DR. JONAS: Was there a discussion in the panel
16 about complementary medicine and its role in this
17 prioritization process? Did the topic come up during the
18 discussion?

19 DR. ROSENBERG: Yes, it did. If you look at
20 the composition of the Committee, I think you could see
21 the people who would almost be the voices for bio-
22 behavioral, for sociologic, and for alternative medical

1 approaches. We heard about it, and I think we paid
2 attention, but we did not view CAM as a thing apart.

3 DR. GORDON: Thank you very much. Effie, and
4 then Tom.

5 DR. CHOW: I agree that NIH has been doing a
6 terrific job, and also, it needs more money in the
7 research area.

8 My comment is that, as shown up in the Town
9 Hall Meeting, our first and only yet, in San Francisco,
10 was that there was a lot of concern, and voices my own
11 concern, too, is that the research protocols are
12 inadequate to measure CAM, not only the practice, because
13 it is theoretical as well, and as George said, it is
14 behavioral.

15 So perhaps there needs to be additional budget
16 to really explore research protocols and instrumentation.
17 We have instruments such as thermography and biofeedback
18 and Kirlian photography, et cetera, right now, but that
19 is also questionable, whether that is picking up the
20 proper subtle energies that is being utilized in healing
21 right now, or Chi, or Qi, or bioenergy.

22 So I just want to throw out, perhaps NIH could

1 take a look at, strongly into other than just biomedical
2 research. What about field research? There was a strong
3 research, emphasizing that part, and strengthening the
4 protocols for that, and ground research and all.

5 So CAM, I am afraid if we put it into the
6 medical science model of research, may eliminate some of
7 the benefits that CAM has proven, being able to practice.

8 DR. GORDON: Effie, excuse me. Do you have a
9 question?

10 DR. CHOW: Well, I guess I am making a comment
11 about focusing, perhaps, some of the direction in
12 exploring alternative research protocols.

13 DR. GORDON: Tom.

14 MR. CHAPPELL: Thank you, Dr. Rosenberg.

15 Do you think that the promotion of health
16 versus the prevention of disease, as is described in the
17 mission of NIH, can really hold its own in the
18 prioritization process, or is the make-up of the whole
19 NIH in its orientation, so disease-oriented, that we are
20 really asking for a elevation of a point of view that is
21 just altogether too difficult for the context to
22 consider?

1 I think you understand the fullness of my --

2 DR. ROSENBERG: I do. I do, and I wish to tell
3 the Commission that this matter was explicitly discussed
4 at our committee on more than one occasion, this
5 distinction between prevention and health promotion.

6 I think, though we had a very lively dialogue
7 on the question, we came to the view that if we had
8 turned the clock back 25 years and asked about NIH in
9 terms of its interest in prevention as opposed to cure,
10 we would have said the same things about prevention that
11 you are now saying about promotion.

12 That is not a criticism of what you said. It
13 is a statement that time has moved on, that medicine has
14 become much more oriented toward preventing disease than
15 it was a quarter of a century ago. I believe that
16 medicine will become, and health practitioners in
17 general, will take a greater view about promoting health
18 and all that goes on with that as time goes on, as we
19 move more and more toward living long lives without as
20 much focus on interspersed episodes of illness.

21 MR. CHAPPELL: I guess, then, I hear you saying
22 the benchmark is still disease. Even though prevention

1 is a point of view, the benchmark is still disease
2 because prevention is a point of view toward disease. It
3 is not necessarily a point of view toward wellness.

4 Wellness is the benchmark we are concerned with
5 as well as prevention of disease, and they can be
6 different metrics.

7 DR. ROSENBERG: It is probably a dialectic
8 discussion that we can't achieve in 1 minute and 35
9 seconds.

10 MR. CHAPPELL: Sure, but it is still worthy of
11 raising, I think.

12 DR. ROSENBERG: Yes.

13 DR. GORDON: We have time for one more
14 question. Charlotte.

15 MS. KERR: Doctor, thank you very much for your
16 presentation. I want to say, first of all, your study,
17 to me, and your report, was very clear, wonderfully
18 clear.

19 Just to restate the mission, as you said, that
20 the NIH was to uncover new knowledge for the better
21 health of everyone. I think it is true to say that at
22 least there were two offices that were created and have

1 moved on, the Women's Study Office and Alternative
2 Medicine Office, as a result of intervention of members
3 of Congress, predominately.

4 Now, in light of your major recommendation,
5 which I understand to be the creation of the Director's
6 Council of Public Representatives so that there would be
7 more input by the public, is it your assessment, or would
8 it be your assessment, that those two offices, for
9 example, of Women's Health and Complementary Medicine,
10 that they were not created out of NIH itself because
11 there was not enough input by the public?

12 My point is that your solution and your
13 assessment seems to be that the lack of public input
14 would not have allowed something like this to be created
15 on its own outside of NIH. How will this be such a major
16 solution to bring forth the new creations of what is
17 needed to improve the health of America?

18 DR. ROSENBERG: I think you are implying that
19 we thought that the COPR would solve all the problems,
20 and certainly, I do not think that is true. We put it
21 forward as an element of how the director of NIH, and how
22 the Institute directors couldn't get input, could hear

1 from more voices than they have up to now.

2 I believe that is happening, and I believe that
3 many people at leadership positions think it is a good
4 thing that it is happening, but does that mean that I
5 feel that it will replace the need, from time to time,
6 for new organizations to be established by whatever
7 means? I am not naive enough to think that Congress is
8 going to leave all of its prerogatives to COPR, or to the
9 offices of Public Liaison, or to anyone else, nor should
10 they.

11 I believe that the more opportunities there are
12 for people to have their voices heard at NIH, the better
13 it will be for the NIH, and ultimately for the health of
14 the public.

15 DR. GORDON: Thank you very much, Dr.
16 Rosenberg. We really appreciate your coming and sharing
17 your perspective, and the work that your committee, for
18 the IOM, has done. We hope we will be able to be in
19 touch with you and ask for your thoughts and advice as we
20 move ahead. Thanks again.

21 Do you want to call the next panel, Michele?

22 MS. CHANG: If Dr. Jeffrey White and Dr. Claude

1 Lenfant, Dr. Marvin Cassman, Dr. Steven Hausman, and Dr.
2 Paul Coates could come to the speakers table, please.

3 DR. GORDON: Thank you very much, all of you,
4 for coming this morning. Each of the panelists will have
5 10 minutes, and then we will have about 40 minutes to ask
6 questions, so 20 minutes only to ask questions.

7 Is that right?

8 MS. CHANG: Yes.

9 DR. GORDON: All right, only 20 minutes to ask
10 questions. So please, when it comes time to ask
11 questions, would everybody please adhere to asking
12 questions on the Commission. You can frame it with a
13 couple of sentences, but we had a lot of time for Dr.
14 Rosenberg. We are not going to have as much time with
15 subsequent speakers to ask questions. So everybody be
16 concise and interrogatory.

17 The first speaker will be Dr. Jeffrey White --
18 welcome -- from the National Cancer Institute.

19 **Session II: Federal (NIH) Support for CAM Research**

20 DR. WHITE: Good morning, and thank you for the
21 opportunity to discuss the NCI's perspective on the
22 challenges and potential of complementary and alternative

1 medicine in cancer research. I also extend greetings
2 from the National Cancer Institute's director, Dr.
3 Klausner, and the deputy director of extramural science,
4 Dr. Robert Whittas [ph].

5 I am the director of the NCI's Office of Cancer
6 Complementary and Alternative Medicine. The office was
7 established in October of 1998, and has four main
8 functions: first, to coordinate the NCI's growing number
9 of CAM activities; second, to provide liaison to the
10 National Center for Complementary and Alternative
11 Medicine; third, to develop and implement an institute
12 agenda in CAM; and last, to provide the NCI an interface
13 with the general public in the CAM and conventional
14 practitioner and research communities on these issues.

15 As requested, I have provided a brief summary
16 of NCI's current and planned CAM projects. Given the
17 limited time, I will not be able to elaborate on them
18 during my presentation but will be glad to respond to
19 questions.

20 Prior to addressing the specific questions
21 posed in the invitation letter, I would like to state, up
22 front, some principles we applied to developing NCI CAM

1 initiatives, and then briefly, some challenges of CAM
2 research.

3 The determination of value for both
4 conventional and CAM modalities needs to be evidenced-
5 based. The same standards of evidence must be applied to
6 both to CAM and conventional cancer research. Also, the
7 principles for determining priorities should be the same
8 as in conventional research, that is, credible evidence,
9 testable hypotheses, quality of the science, availability
10 of the necessary resources and potential to advance the
11 field.

12 However, since CAM is already in the practice
13 arena, those methods that are more heavily used by U.S.
14 cancer patients may be somewhat of a higher priority, the
15 challenge of CAM research.

16 CAM practices a loose association of
17 modalities, many of which have few features in common.
18 Consequently, thinking of CAM as a single entity is at
19 times useful, and other situations may lead to
20 dysfunctional solutions.

21 For example, the same mechanism to support
22 research for a well standardized herbal product may not

1 be suitable for increasing research for a diet therapy
2 used by a single practitioner.

3 CAM regimens are often very complex and
4 individualized. Consequently, these approaches are
5 difficult to codify into protocols and transplant to
6 clinical research settings. Many approaches lack
7 uniformly accepted standards of practice, and therefore a
8 study of one approach may not resolve the issue of
9 efficacy.

10 It is difficult to obtain meaningful
11 preclinical information for certain CAM interventions,
12 for example, complex, multi-modal interventions. So
13 strategies to increase CAM cancer research will need to
14 address many of these challenges.

15 Some challenges common to CAM and conventional
16 cancer research. Conventional cancer research is
17 beginning to evaluate more therapies that are not
18 directly cytotoxic, but rather have potential for slowing
19 the growth of the malignancy or inhibiting its spread to
20 other sites.

21 Traditional clinical trials, designs that focus
22 on tumor regression, may be less informative about

1 potential efficacy of such therapies. Controlled studies
2 assessing survival and quality of life may be more
3 appropriate. These trials are more expensive and time-
4 consuming, and often require complex logistics. At the
5 same time, the percentage of adult cancer patients
6 entering clinical trials is low, in the range of less
7 than 5 percent.

8 Secondly, the dependence on survival as the
9 most significant end point of comparative cancer trials
10 lengthens the evaluation process. Validated intermediate
11 end points of clinical significance are needed to allow
12 more rapid screening of modalities for potential
13 efficacy. I mention these common challenges as areas of
14 potential investment to increase the rate of evaluation
15 of CAM therapies.

16 I will spend the remaining time addressing the
17 areas of particular interest described in the letter of
18 invitation. I hope my use of examples will help
19 illustrate certain points without implying the specific
20 case is applicable to all forms of cancer research. I
21 will be glad to expand on any of these points in the
22 response to questions in the discussion period.

1 It is important to note that the NCI's
2 approaches to promoting and supporting CAM cancer
3 research are being designed to attempt to capitalize on
4 some of the strengths of our programs, for example, the
5 NCI's designated P-30 cancer centers and cooperative
6 clinical trials groups, and therefore may not be
7 applicable to other disease types and other NIH
8 institutes and centers.

9 The question of potential contribution of CAM
10 perspectives and approaches to conventional biomedical
11 research. Some CAM approaches purport to promote the
12 general health of the patient, rather than to directly
13 impact the growth of cancer cells. Similarly, many
14 systems within CAM advocate caring for the whole patient.
15 This includes aspects of the patient's physical,
16 psychological, and spiritual health, and can even extend
17 to the patient's family and other support systems.

18 This broadening of the focus away from the
19 completely disease-focused approach is admirable, but
20 appears to be diminishing in conventional medical
21 practice. The potential for these approaches to improve
22 the patient's quality, and possibly, quantity of

1 remaining life should be more fully examined in cancer
2 research.

3 Other perspectives and approaches worthy of
4 being investigated may come from the CAM community. We
5 are endeavoring to open communications on these issues
6 with the CAM practice community via the Best Case Series
7 program, which is discussed in the materials I have
8 provided the Commission for review.

9 The question of overlap between CAM and
10 conventional research. Much of CAM cancer research is
11 closely related to conventional cancer research.
12 Consequently, every effort should be made to grow CAM
13 research in ways that access the resources of the larger
14 and more research-savvy conventional community. There
15 are several areas of overlap between CAM research and
16 conventional biomedical cancer research, and I will
17 briefly discuss five.

18 First, nutrition. There is a growing awareness
19 of the importance of nutrition in cancer prevention.
20 Also, the therapeutic use of diet modification in cancer
21 patients is slowly entering the conventional research
22 realm, for example, low fat diet interventions in breast

1 and prostrate cancer to prevent recurrence or
2 progression. Research is in progress to assess cancer
3 prevention potential for micronutrients, such as selenium
4 and Vitamin E.

5 Where does conventional diet research begin and
6 end? Certain types of dieting, cancer interventions
7 might be readily accepted as fitting the definition of
8 CAM, whereas others would engender more debate in order
9 to be uniformly designated as non-CAM. Reasonable people
10 could disagree on the dividing line between CAM and
11 conventional nutrition research.

12 The analysis of plant and animal products for
13 medicinal agents; what is CAM and what is conventional.
14 Much of the work with such products could be considered
15 CAM-related. Researchers doing conventional natural
16 products work would be appropriate collaborators with
17 herbal therapists to investigate the laboratory and
18 preclinical activity of herbal extracts, and then
19 providing quality control standards for clinical-grade
20 products.

21 Mind-body medicine. Behavioral research is
22 expanding at the NCI. Recently, it established a

1 behavioral research program in the Division of Cancer
2 Control in Population Sciences. Support group
3 interventions are components of the grant portfolio of
4 this and other NCI programs, and certain of these
5 interventions under investigation are CAM-related.

6 Immune modulation is another area, as is
7 symptom and side-effect management. These areas and
8 others represent potentials for a collaboration between
9 practitioners and researchers, as well as CAM academics
10 and conventional biomedical researchers. NCI CAM
11 programs are designed to encourage collaboration between
12 these communities.

13 However, we must recognize that there is a two-
14 culture problem, both between practitioners and
15 researchers, and between CAM and conventional paradigms.
16 Therefore, we need to provide opportunities and resources
17 that foster communication and collaboration, which
18 hopefully will lead to a greater degree of mutual
19 respect.

20 Expanding federal efforts to research CAM. The
21 NCI has implemented several programs to bring CAM
22 products and practices into mainstream biomedical

1 research. One example is the Best Case Series program
2 which provides an avenue for CAM practitioners to present
3 documentation of an effective CAM cancer therapy. We
4 have recently implemented an aggressive advertisement
5 program to increase the awareness of this opportunity
6 among CAM practitioners. The Best Case Series program
7 can expand if there is sufficient interest and commitment
8 by the CAM practitioner community.

9 Obstacles and possible solutions. The research
10 community needs to see consistent support for specific
11 fields of biomedical investigation. We must also
12 encourage excellent individual researchers in
13 institutions to enter the field. However, there is both
14 the perception and reality of a limited potential for
15 respected and vigorously supported CAM career in research
16 for a CAM topic. Time is needed, and resources, to
17 demonstrate a sustained growth potential for the field
18 and consistent opportunities for funding. Both CAM
19 investigators and CAM-knowledgeable conventional
20 investigators are needed.

21 I could cut my comments off at that point.

22 DR. GORDON: Thank you very much, Dr. White,

1 and thank you for your and NCI's leadership in this area.
2 We will have plenty of time. I am sure we will be coming
3 back to you for questions, to talk about some of the ways
4 you have made it possible for CAM to come more into the
5 NCI.

6 The next speaker will be Dr. Claude Lenfant.

7 DR. LENFANT: Thank you very much. I have
8 submitted to the Commission a number of examples of our
9 activities in complementary and alternative medicine. I
10 would like to focus my remarks in response to the
11 questions that were in your letter, although I have to
12 say that many of the things that I felt like saying have
13 actually been said by Dr. Rosenberg, and so I will
14 perhaps amplify some of the viewpoints and the issues
15 that he brought up.

16 The first question in your letter is quite an
17 interesting one, which is, what is needed to expand
18 current federal effort to bring CAM products and
19 practices into the mainstream of biomedical research.

20 To me, that is probably the most important
21 question that is before you and before us. When we look
22 at the evolution of medicine and the mainstream of

1 medicine, we have to go back where it starts. For
2 example, if you look at something which is part of
3 conventional medicine, such as nutrition, for years
4 nutrition was ignored and disregarded by so-called
5 conventional medicine, and it began to be in favor when
6 it became part of medical education.

7 Likewise, prevention, that was mentioned
8 earlier, the mainstream of medicine has ignored
9 prevention and preventive interventions for years, and
10 largely because it was not really taught in medical
11 school. My feeling is that one of the greatest hurdles
12 that is facing the introduction of what is called
13 complementary and alternative medicine, which,
14 incidentally, was pointed out to me earlier, is a bad
15 term, and I have to agree with that because it creates
16 something different. Therefore, it is more difficult to
17 fully use.

18 A fact, that as long as Medicare education will
19 not touch on the issue of what is today defined as
20 complementary and alternative medicine, will be terribly
21 difficult to bring it into the mainstream of practice. I
22 also think that it will be very difficult to bring it

1 into clinical research, because the questions just don't
2 come up as easily they should.

3 So it seems to me, that the issue of education
4 and the training of investigators are very important
5 issues to bring forth what is today called complementary
6 and alternative medicine.

7 The second point that I would like to make has
8 to do with how we set our priorities and where this
9 approach to medicine, complementary and alternative
10 medicine, fits into a priority-setting organization like
11 ours. I am sure I need not to tell this commission that
12 the public has problems that we are concerned with that
13 are enormous, involving a large number of patients,
14 individuals, likely to develop the conditions which are
15 of interest to us.

16 As was quite correctly pointed out by Dr.
17 Rosenberg, no matter what the extent of our resources,
18 they are never enough to do what everybody wants to do.
19 During the last few years we have seen a considerable
20 increase in our budget, but the demands for the budget
21 grows much faster than the budget itself.

22 So we have to set up priorities, and I think

1 that the input of the public is indeed very important,
2 and perhaps, I should say, very significant in our
3 activities. The work of Dr. Rosenberg has been, I think,
4 extremely important and useful to us, and we have since
5 adopted a practice to consult with the public and all the
6 interest groups which have interest in some of the
7 conditions that we have.

8 The public voice of alternative medicine is not
9 yet heard very well. I think that the various interest
10 groups which would like to foster more work in
11 alternative medicine, perhaps, should bring themselves to
12 -- so that we hear more from them.

13 It is interesting to me that once or twice a
14 year we invite to come to our institute, speaking to our
15 National Advisory Council, or representatives of our
16 Council, I should say, to come once or twice a year. No
17 one from this community has yet come forth to express
18 their views, and I think that is something that needs to
19 be done.

20 Now, the main role that I think that the
21 research enterprise can play with regard to complementary
22 and alternative medicine is to validate whatever comes

1 forth, the ideas, the suggestions. The validation of
2 such possible therapeutic interventions is very difficult
3 and requires some scientific rigor that as yet does not
4 exist in that field.

5 I think the reason is what I mentioned, that
6 basically there is no education about it, and the people
7 who are largely interested in these concepts, these ideas
8 and the possibilities, are not researchers, are not
9 people who are brought into that. I really think that is
10 the problem that needs to be solved if we want to be
11 successful in fostering more activities, and more
12 importantly, more applications.

13 That brings me to the last point that I want to
14 make. When we seek to validate something, an
15 intervention, because the demand exceeds what we can
16 really do, we set some criteria as to how we are going to
17 decide what needs to be done. There are basically, from
18 our viewpoint, three important criteria.

19 The first one is, that it is an issue of great
20 public health, public importance. The second is doing
21 what needs to be done, affordably. That may sound as a
22 strange criteria, but it is an important one in the real

1 world. The third one is, what will come from this
2 validation being applied, and can it be generalized.

3 These are very important questions. I have to
4 say that when we want to apply this criteria to a
5 question of complementary and alternative medicine, it is
6 very difficult to provide a positive answer to all three
7 criteria. So I will leave my comments here.

8 DR. GORDON: Thank you very much, and thank you
9 especially for addressing the questions that we posed.
10 We really appreciate that.

11 Dr. Marvin Cassman.

12 DR. CASSMAN: Thank you very much. Thank you
13 for inviting me.

14 When Dr. White says he is from the Cancer
15 Institute, and when Dr. Lenfant says he is from the
16 Heart, Lung, and Blood Institute, it is immediately
17 obvious what the broad goals of those institutes are.
18 When I say I am from General Medical Sciences, nobody
19 really knows.

20 That is quite understandable because it doesn't
21 really mean anything. The purpose of our institute is to
22 try and understand the fundamental properties of

1 biological systems, and that is usually using the tools
2 of chemistry, physics, mathematics, and generally
3 operating at either the molecular or the cellular level.

4 Now, with regard to the interest of this
5 meeting, that may put us a bit out of the range of your
6 primary interest. Dr. Rosenberg said, and I think I
7 agree with him, that at this point in time, clinical
8 research is the heart of CAM and we don't do any clinical
9 research, or, actually a very little amount, and I am not
10 sure I would even call it clinical.

11 So in fact, the systems, the biological systems
12 with which we commonly deal, are non-mammalian systems.
13 The well-known fruit fly, and the yeast, and so on. So
14 the question, then, obviously arises, of what relevance
15 is all of this to CAM? Indeed, at the present time, our
16 investment in the areas related to CAM is pretty minimal.

17 We are currently providing partial support to
18 one of the centers, Centers for Dietary Supplements. I
19 think Dr. Coates is going to be talking about those
20 centers later on. We are investing in one of the
21 projects in one of those centers. It is not a large
22 investment, obviously, compared, certainly, to some of

1 the others that you have heard and will hear around the
2 table.

3 So, what is there that could be of interest?
4 There is one aspect, and I will just go into it briefly.
5 One could argue that much of the fundamental research in
6 biology over the last 40 years is putting things into
7 bins, understanding the molecular mechanisms of
8 biological systems, breaking them down into their
9 components, as you would strip a car down into its
10 individual units, understanding how they operate and what
11 they are.

12 That is where we have been. That is where we
13 are, for the most part. We are now trying to put it back
14 together again. There are lots of different ways of
15 doing this. One of the ways is trying to understand how
16 systems operate in time and space. After all, biological
17 systems are not static. They respond to their
18 environment and they interact with each other.

19 So over the last two and a half years, in
20 particular, we have begun programs aimed at something
21 that I would call complex systems. This is an area which
22 is fairly broad. It goes well beyond biology, in fact.

1 It is sometimes referred to as the study of interacting
2 systems that result in emergent properties, that is, the
3 systems are not necessarily the linear combination, that
4 is, the properties of the system cannot be considered as
5 the additive combination of their individual components.

6 I don't know, really, how true that is.

7 Certainly, there are aspects of interacting systems that
8 seem unusual relative to the individual properties, the
9 individual mechanisms of the systems, but that doesn't
10 mean they can't be understood in terms of their
11 mechanisms and/or interactions. A simple example is that
12 there are oscillating components in many biological
13 systems, and they oscillate in a sine wave.

14 If you have two of these and they interact
15 together, and they are in phase, what you get is another
16 sine wave. If they are 180 degrees out of phase, what
17 you get is a straight line. The straight line doesn't
18 look like the sine wave, but that doesn't mean that you
19 can't understand it in terms of the properties of the
20 elements that are involved. You just have to understand
21 how they interact.

22 We are in a very early phase of all of this.

1 It is extremely complex. Not all of the tools have yet
2 been developed. We don't really know necessarily how it
3 is going to evolve, and right at the moment we are
4 keeping an open mind as to the kinds of approaches that
5 are going to be most appropriate in dealing with this
6 next phase, I think, in the understanding of biological
7 systems.

8 There are a lot of different opportunities to
9 do that and, in general, they still will require a basic
10 understanding of the properties of the systems. You need
11 to have measurable quantities that one can evaluate
12 before you try to assess how systems operate. That
13 involves, obviously, the interaction of many disciplines,
14 and we are trying to bring other areas of science in even
15 closer contact than they already are with biology to
16 ensure that we can get a useful synergy out of all of the
17 contributing individuals and disciplines and fields that
18 are involved.

19 I think that is really about all I can tell you
20 at the moment, but I will be happy to answer any further
21 questions.

22 DR. GORDON: Thank you very much. It is

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1 actually very exciting to hear, especially about this new
2 research interest. I think that a number of Commission
3 members will want to ask you questions about it.

4 Our next speaker is Dr. Steven Hausman.

5 DR. HAUSMAN: Thank you very much for inviting
6 me to speak. I am deputy director of the National
7 Institute of Arthritis and Musculoskeletal and Skin
8 Diseases.

9 Complementary and alternative medicine poses, I
10 think, a rather special challenge for our diseases. We
11 typically characterize them as consisting of the four
12 C's: chronic; common; costly; and crippling. The problem
13 with the chronic disease, especially with arthritis and
14 the various forms of arthritis, is that they wax and
15 wane. They are chronic.

16 Conventional medical therapy finds it difficult
17 to deal with many of these things, and when conventional
18 medicine finds it difficult to deal with these things,
19 then alternative methods of therapy tend to come about.
20 People want to be cured of their disease, they want to be
21 free of pain. In many cases, that is not possible. They
22 try all sorts of things.

1 I would only point out the use of gasoline and
2 WD-40 for the treatment of arthritis for many years. In
3 some cases it worked because, naturally, the arthritis,
4 of its own, tended to go away periodically, and
5 occasionally people tended to associate that with the use
6 of these alternative therapies. Copper bracelets are
7 another thing.

8 Our institute has been involved in
9 complimentary and alternative medicine, although I guess
10 we didn't call it that for many years, starting back even
11 before we evolved as an institute, when we were a
12 division of another institute in the Multi-Purpose
13 Arthritis Centers Program.

14 The Centers Program was responsible for funding
15 what was known as the Arthritis Self-Care Program. This
16 program really taught patients how to deal with their own
17 disease. It was a wellness promotion program as well.
18 It has been disseminated in recent years throughout the
19 United States and throughout the world.

20 The program is actually rather effective, and
21 in many cases was shown to be equally effective as many
22 of the drugs used for arthritis. More recently, we have

1 been involved in osteoarthritis treatment, carpal tunnel
2 syndrome, pain management, low back pain. I will
3 probably get into those.

4 We have worked closely with the National Center
5 for Complementary and Alternative Medicine in the study
6 that was mentioned earlier by Dr. Rosenberg in studying
7 the efficacy of glucosamine and chondroitin sulfate. We
8 decided that that was something that needed to be done.
9 That has now been taken over by the NCAM. We are still
10 working on it, actually, in our Contracts Branch.

11 We have a new scientific director that leads
12 our intramural program. He is a renowned rheumatologist
13 and has been involved in conventional therapy, practices,
14 and treatments for many years, but he also studies
15 something with a fairly exotic name called thundergod
16 vine, which is a Chinese herbal treatment for
17 inflammation for rheumatoid arthritis, and it might
18 actually be used for other conditions in the future.

19 The area of low back pain is one that is
20 especially amenable to approach. Low back pain is a
21 chronic disease, a chronic ailment. Probably nine out of
22 10 people around this table have had it in the past, if

1 not more. It causes many hours of disability, low
2 productivity, pain, suffering, reduced quality of life.
3 I think there is a vast opportunity to use regular and
4 non-conventional modalities.

5 We are currently a multi-center, randomized
6 clinical trial on low back pain which is comparing
7 conventional treatments versus some other treatments,
8 including acupuncture.

9 Let me address some of the questions that you
10 posed. The first one, about expanding federal research.
11 I think the existing mechanisms of federal research
12 support can be used by CAM as well. These consist of,
13 obviously, research grants, training mechanisms, and so
14 forth.

15 I think researchers trained in CAM areas could
16 profit by receiving training in conventional research
17 methodologies. This, in fact, to address Dr. Chow's
18 question, would make them less fearful of getting into
19 the system. You need to work with the investigators to
20 get into the system to know how it works.

21 In terms of the overlapping areas of research,
22 I would point out that "Arthritis Today," a magazine

1 published by the Arthritis Foundation, did a survey
2 several years ago. They surveyed patients and primary
3 care physicians. They found that 78 percent overall were
4 interested in alternative therapies. This was even
5 though 84 percent of the patients were seeing a
6 rheumatologist and 89 percent of the patients were taking
7 prescription drugs, which indicates, to a certain extent,
8 that they perhaps were not working quite as effectively
9 as they could.

10 The patients' favorite therapies, other than
11 Bayer aspirin, were prayer, meditation, glucosamine,
12 magnets, metal jewelry, Qigong, Tai Chi, and so forth.
13 Physicians actually recommended other therapies as well.
14 Their favorites were capsation, which actually has been
15 shown to work, biofeedback, meditation, yoga. They
16 advised against, however, megadose vitamins, fasting,
17 DMSO, copper bracelets, bee venom, and so forth.

18 In most cases, we would be hard-pressed, in
19 fact, to find any evidence, either pro or con, for many
20 of these treatments. There are actually probably
21 relatively few studies that would indicate whether heat
22 or cold is better for some cases. These things need to

1 be done.

2 Clinical research is something that is
3 paramount and absolutely necessary in the area of
4 complementary and alternative medicine. If that is not
5 done, then anything beyond that going into mechanisms
6 will not be able to follow.

7 Additional areas of opportunity. I have
8 mentioned some of those, including the placebo effect is
9 one. There is going to be an NIH conference on this
10 coming up relatively shortly. There is the opportunity
11 to test some of these interventions by existing
12 mechanisms, such as the Small Business Program.

13 Some things that have already been tested or
14 are underway are things like topical aloe vera for skin
15 conditions. I suspect that that is one of the most
16 commonly used substances. You find it in everything from
17 hair shampoos to skin creams, and so forth. Does it
18 work? I don't know. People have aloe vera plants on
19 their shelves and window sills, and they put it on cuts,
20 and so forth.

21 There are Chinese herbal teas for eczema, there
22 are devices that can be used to increase bone mass, and

1 there is some evidence that they, in fact, do work.
2 Standing on a plate with a low vibrational frequency can,
3 in fact, seem to increase bone mass. All these
4 modalities have to be tested, however.

5 What are some of the obstacles to the
6 solutions? Well, obviously, validated evidence obtained,
7 probably, through clinical trials. I suspect that few
8 physicians would be willing to implement a new therapy
9 without evidence of its effectiveness. You need more
10 research in this.

11 There is another, though, psychological aspect,
12 and that is the reluctance of established investigators
13 to even consider doing research in this area. One of the
14 areas that we deal with is fibromyalgia syndrome. Many
15 years ago, in fact, 15 years ago, fibromyalgia was not
16 even recognized as a clinical entity. The American
17 Rheumatism Association did, in fact, about eight years
18 ago, establish diagnostic criteria.

19 Several years ago, we convened an
20 interdisciplinary workshop which brought mainstream
21 investigators together with investigators from outside
22 the field, people who had never been involved in any of

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1 these areas dealing with fibromyalgia, sleep research,
2 neurological research, and so forth.

3 We have gotten a number of very interesting
4 projects, which are a little bit too soon to know if they
5 will bear fruit, but that is the typical way to bring
6 people into the field, interdisciplinary workshops,
7 conferences, coming up with research recommendations. I
8 guess, one thing I would have to stress is collaboration,
9 collaboration, and collaboration. It is not going to
10 work otherwise. One area can't do the research on its
11 own.

12 Another potential issue that might be an
13 obstacle is a new policy regarding Medicare reimbursement
14 for Medicare beneficiaries in clinical trials. There is
15 a presidential order indicating that Medicare
16 beneficiaries would receive reimbursement for those
17 things that, in fact, are things that normally would be
18 paid for by Medicare while the patients are in clinical
19 trials.

20 However, it is my understanding that the law
21 will not pay for things that are excluded. Many
22 complementary and alternative medicine modalities are not

1 included in this. This might, in fact, provide a
2 somewhat small obstacle, but obstacle nonetheless, to
3 their participation. Our diseases are diseases also of
4 the elderly, people who are elderly on Medicare. So you
5 are talking about obstacles there.

6 Finally, let me talk about the role of the
7 public. It is clear there is a role of the public in
8 setting research priorities. As a part of the entire
9 mix, people should be invited to give their views, just
10 as they are going to testify before the Commission.

11 I will be happy to answer questions.

12 DR. GORDON: Thank you very much, Dr. Hausman.
13 We appreciate it.

14 The next speaker will be Dr. Paul Coates.

15 DR. COATES: Good morning. Thank you for the
16 opportunity to speak with you today. One of the great
17 things about being last in a panel such as this, is that
18 pretty much everything that I wanted to say has been
19 said.

20 So my first remark is, I endorse it. I think
21 you have heard about a lot of exciting possibilities that
22 are already in existence at the NIH, and that we are

1 thinking about other ways in which to accommodate the
2 important needs of the CAM research community.

3 Our office, the Office of Dietary Supplements,
4 was created in the Office of the Director in 1995. I
5 became director last year during a period of considerable
6 growth. We have an exciting array of programs that we
7 think can be useful to the community of scholars in
8 complementary and alternative medicine.

9 I think the biggest one, certainly the one that
10 gets most of our attention and most of our dollars is the
11 botanical or Dietary Supplements Research Center Program,
12 to which Dr. Cassman alluded briefly.

13 Let me use it as an opportunity to tell you why
14 I think it is one of the ways to answer Question 1, which
15 you developed for us. What is needed to expand efforts?
16 It is interdisciplinary. No. 1 addresses an issue that
17 Dr. Hausman just alluded to, the collaboration component.

18 We think that this is an important way of
19 developing important scientific evidence about botanical
20 and herbal products that are used in quite common
21 practice. The nature of these centers is such that we
22 require quite a range of disciplines to be represented in

1 a successful center, ranging from botany and
2 pharmacognosy to physiological science, all the way to
3 clinical science.

4 We feel it is the combination of those things
5 and the synergistic effect that you get when you have
6 people from different disciplines approaching a common
7 problem, where we think we are going to get the most
8 excitement, and hopefully a lot of bang for the public
9 buck.

10 We couldn't do it ourselves. The initiative
11 for this Centers program emerged from the Office of
12 Dietary Supplements with some recommendations from
13 Congress. I think it is important for people to note
14 that that is a way to make your voices heard. We shaped
15 this in collaboration with our other partners at the
16 National Institutes of Health, largely in CAM, but we
17 also enjoyed the participation of a number of other
18 institutes and centers, in both the planning and in the
19 funding of these centers.

20 We now have four such centers that deal with
21 different, we believe, overlapping but very different,
22 approaches. The thing that you ought to know about is

1 that these centers are designed to be interactive and to
2 feed off one another so that at a number of levels, we
3 feel as though we are going to be able to see the benefit
4 of this sort of interaction.

5 So that is one example. There could be others,
6 but I will use that as my example of how I would like to
7 think that we are contributing to expanding the federal
8 effort to bring CAM products and practices into the
9 mainstream. We will, obviously, keep checking the pulse
10 of this program and see whether this is where we need to
11 be investing further resources and effort, whether there
12 are checks along the way that we need to be sure about.

13 It gives me the opportunity to actually jump to
14 your Question No. 4: What additional areas of opportunity
15 exist for research on CAM intervention? It seems to me
16 that those opportunities are almost limitless. When I
17 think about the area of dietary supplements, a modality
18 that is frequently used in CAM practice, our interaction
19 with you is a big one. It is not all that we do, but
20 when I think about the area of dietary supplements, they
21 are in common use.

22 It makes it a bit of a challenge to decide how

1 to approach the science of dietary supplements, but at an
2 absolute minimum, we feel as though there needs to be
3 evidence for their use. How that evidence is developed,
4 it depends a little, but we would like to have you
5 recognize that, from our point of view, from the point of
6 view of the Office of Dietary Supplements, those that are
7 used in complementary and alternative medicine practice
8 are the same. We approach them the same way as we do
9 those that are used in other practices, that there needs
10 to be an evidence-based approach to their use.

11 It seems to me, that consumers, health
12 professionals and, indeed, the dietary supplements
13 industry will benefit from such a systematic approach to
14 evaluating and, if necessary, developing the evidence for
15 efficacy and safety of dietary supplements as they are
16 used in this country.

17 Finally, I wanted to mention something about
18 the obstacles, conceptual and otherwise, and possible
19 solutions to accomplishing the goal of integrating CAM
20 products and practices. There is a suspicion that I
21 think would be very nice to overcome. The suspicion that
22 is not necessarily shared by everybody, don't get me

1 wrong, but the suspicion that evidence to support the use
2 of some traditional CAM practices is outside of the
3 American medical paradigm and, hence, doesn't qualify.

4 Likewise, the feeling, on the other hand, the
5 products and practices that are in traditional use don't
6 need to be evaluated in this manner because of their long
7 history of use. There is an opportunity to see those
8 impressions merge. It is something that I live with
9 every day in my position as director of the Office of
10 Dietary Supplements. I am not finding it insurmountable.
11 It is, however, a challenge to our communication.

12 It gets back to the issue of partnerships. I
13 spoke briefly about the partnerships that we have
14 developed within the NIH. That is part of why our office
15 was created to encourage and coordinate research
16 activities around our area of dietary supplements.

17 We think that those partnerships can be
18 expanded to include other organizations, the not-for-
19 profit organizations, the private sector, including
20 industry. Examples of this, from our point of view,
21 include the fact that we co-sponsor workshops and
22 conferences with the private sector, in areas where we

1 think that the development of new knowledge will be
2 important for all concerned.

3 Likewise, we partner with other organizations
4 to support conferences, not just within the NIH, but also
5 internationally, such as next year's International
6 Scientific Conference on Complementary Alternative and
7 Integrated Research. Same month, also the International
8 Society for Technology Assessment in Health Care.

9 We would welcome the opportunity to hear your
10 views about where our programs are going because they are
11 such an integral part of where you are going. Thank you.

12 DR. GORDON: Thank you very much.

13 Before we get into questions, I just want to
14 thank all of you for coming. You are all, I know,
15 extremely busy, and I thank you for coming and sharing
16 with us, not only your programs, but your perspectives.
17 I regard this as an important step in the dialogue and
18 the collaboration that we are trying to expand.

19 Let's go around. Who would like to begin?

20 DR. ORNISH: I also want to say how much I
21 appreciate everyone coming here and how grateful we all
22 are.

1 The NIH budget in its various forms, and the
2 different divisions and ventures that you all represent,
3 there is so much evidence showing that behavioral
4 approaches, mind-body approaches, alternative medicine
5 approaches, things like that, play important determinants
6 in health and well-being, and yet, the relative amount of
7 the NIH budget in each of the different branches, a
8 relatively small percentage of that, is going to these
9 kinds of approaches.

10 Each of you has talked about the importance of
11 doing good science. I certainly completely agree with
12 you, and yet, good science is dependent on adequate
13 funding. I know the budgets for the NIH have been
14 increased substantially and are going to be increased
15 even more, but the relative ratio of how those budgets
16 are spent doesn't seem to be changing.

17 I am just wondering, do any of you have any
18 thoughts about whether that should be changed and, if
19 communication, how?

20 DR. COATES: Let me take a crack at it.

21 We have noticed in arthritis that the number of
22 projects being submitted in that area are increasing. I

1 think our program staff have to work with the applicants
2 to make sure that the projects that are submitted are
3 high quality. We, in fact, have just hired a
4 psychologist on our staff to work with those applicants
5 and to increase that area of research in our program.

6 So that is one step you can take. Another
7 step, of course, would be to have more workshops and
8 conferences that bring that aspect of it into play. The
9 Arthritis Centers program has had a number of
10 psychosocial studies throughout the years. Things like
11 that are useful and have proven their worth, I think.

12 Health services research in arthritis is
13 something that didn't exist 20 years ago and now has its
14 own journal or two.

15 DR. LENFANT: Dr. Ornish, I am sure you know
16 that the world of behavioral medicine was actually
17 invented in our institute. It preceded the creation of
18 the Society of Behavioral Medicine by a few years.

19 We do increase, actually, this component of our
20 program quite significantly. Perhaps not for something
21 that relates directly to what you are interested in here,
22 but is quite relevant to it, is that we can come up with

1 all the best prescriptions and ways to treat patients,
2 but unless they comply and adhere to the prescriptions
3 given to them, nothing is really going to happen.

4 One thing that we see, certainly, in many other
5 areas of medicine is the ever-increasing gap between what
6 we know and what is applied and used by the patients, and
7 therefore, that is the reason why we focus so much on
8 adherence and compliance research.

9 DR. GORDON: Do you have any thoughts, while
10 you are discussing that point, of how we can make more of
11 what we know in this field, in complementary and
12 alternative medicine, behavioral medicine, available to
13 patients, what role your institute or others could play?

14 DR. LENFANT: Yes. Once interventions are
15 validated, there are a number of educational programs,
16 which are developed for physicians, and the public as
17 well. One thing that has happened during the last few
18 years is that in the old days, if you want, what
19 physicians were saying was almost the voice of God, and
20 everybody would start bowing and listening, and doing
21 what they said.

22 Today, the voice of the patient is very

1 important, and that is why we, all the time, have a
2 component in public education for some of our activities,
3 because we know that the patients are going to go to the
4 physicians and really engage into a discussion, which, in
5 our view, is going to result in a better dynamic between
6 the physicians and the patients.

7 DR. GORDON: Any other responses to Dr.
8 Ornish's question before we go on to the next one?

9 [No response.]

10 DR. GORDON: Okay, thank you.

11 Dr. Fair, Bill Fair, and then Joe, and then
12 Tom.

13 DR. FAIR: It seems like every major society
14 meeting that I go to, like the American Urologic,
15 American College of Surgeons, there is always a session
16 for young investigators about writing NIH grants and how
17 to prepare for grant funding. It would seem to me that
18 that would be a reasonable approach, also, for CAM
19 practitioners.

20 I guess I will ask Jeff, are there any of the
21 institutes that have similar programs to encourage grant
22 proposals from CAM practitioners at major CAM meetings as

1 there are at major medical meetings?

2 DR. WHITE: Well, yes. We have twice done
3 exactly what you are talking about, and we certainly now
4 have opportunities to expand beyond that. The two
5 specific situations in which we have done it have both
6 have been at the Comprehensive Cancer Care Conferences,
7 Dr. Gordon's conferences, in 1999 and in 2000.

8 In 1999, we had a session, one of the
9 concurrent sessions and a two-hour session, in which we
10 talked about NCI- and NCCAM-funding opportunities for
11 complementary and alternative medicine where we had
12 individuals there that were actually describing the
13 process and answering questions, and working with the
14 interested people at the conference, and getting into the
15 process of grant application.

16 In 2000, we opened it up beyond the NIH.
17 Actually, we did it in 1999 also, but more emphasis in
18 2000 in non-NIH funding opportunities. We brought in the
19 American Cancer Society and the Department of Defense to
20 speak about opportunities there for complementary
21 medicine research.

22 DR. FAIR: I think you need to do this more

1 conventional medicine, also to get more physicians
2 involved in this. The comment has been made several
3 times that physicians are reluctant to use treatment
4 until it has been proved to be effective. I don't agree
5 with that at all.

6 We recently have the example of autologous bone
7 marrow transplantation in women and it is still being
8 done today with no evidence of effect. So I don't think
9 physicians are totally driven by what has been shown to
10 be effective. I think the more information that we can
11 get out to young physicians, particularly to interact
12 with CAM practitioners, that will be the best way that we
13 can stimulate the acceptance of some of these things, as
14 investigational procedures, among the young physicians.

15 DR. GORDON: Thank you.

16 Would anyone else like to respond to the issue
17 of encouraging young physicians or other investigators to
18 do CAM research?

19 [No response.]

20 DR. CASSMAN: I am not going to speak for the
21 National Center for Complementary and Alternative
22 Medicine, and I hope that you will have the opportunity

1 to ask Steve later on.

2 As part of our own role as an office, we feel
3 as though we have an obligation to encourage and support
4 research training in these areas. So, it is not strictly
5 CAM practice, but that part of it that relates to our
6 program, we certainly try to encourage people to
7 recognize the opportunities.

8 One way of providing opportunities is by
9 providing funds. As institution, the NIH, over the last
10 few years, has increasingly recognized its role in
11 developing clinical academic careers. This could surely
12 be considered part of that.

13 DR. GORDON: Thank you. Joe.

14 DR. FINS: Thank you all for your comments.

15 There is a population of people who are users
16 of CAM, and that is the dying or the terminally ill. Dr.
17 Hausman talked about collaboration. Indeed, a lot of
18 what your institute is working on could be considered
19 palliative care, and pain and symptom management.

20 I am wondering if you all could briefly comment
21 on the relationship for synergy for the needs of this
22 population, the dying and the terminally ill with the

1 burgeoning palliative care research establishment and
2 those kinds of interests, and their relationship, and
3 whether or not these kinds of issues, palliative care
4 under CAM or traditional medicine, should be explicitly
5 mentioned in your mission statements for your institutes
6 and your respective offices.

7 DR. WHITE: In the mission of my office, we
8 broadly describe it to include cancer patient management,
9 and we mean also survivorship issues in that. I think
10 there are several research initiatives that NCI is
11 involved in that address these kind of programs, most of
12 them not directly through my office but through either
13 the Division of Cancer Control and Population Sciences,
14 and the Survivorship Office there.

15 So there are certainly initiatives, and
16 actually, there is an initiative that is coming out --
17 Dr. Straus made mention of it -- from the NCCAM, that
18 addresses specifically end-of-life issues, soliciting
19 grant applications in that area. This is an area that we
20 plan to sign on to, to give NCI support.

21 DR. GORDON: Thank you. Tom.

22 MR. CHAPPELL: Thank you.

1 Dr. Coates, could I inquire about the botanical
2 research? Is it seeking exclusive compounds, or does the
3 research incorporate blends of herbs at this point, or
4 are we still looking for evidence of single-herb
5 solutions?

6 DR. COATES: Both of those paradigms exist in
7 the Centers program. Indeed, two of the centers are
8 enthusiastically pursuing the issue about single-active
9 principles and mixtures, with the hypothesis being
10 tested, that mixtures of similarly acting compounds in an
11 extract, for example, may actually have synergistic
12 properties over and above the activity of a single one.

13 I have no idea how that will turn out. This
14 program is pretty new, but I am very enthusiastic about
15 hearing this as an approach.

16 DR. GORDON: Thank you. George, and then
17 Effie.

18 DR. BERNIER: Yes. I would like to thank you
19 all very much for participating today.

20 I have a question for Dr. White. We have
21 learned, in the last few months, of a number of really
22 exciting clinical trials that have been underway and

1 initiated with a combination of the National Center for
2 CAM and the support of the NCI.

3 You have indicated today that there are a
4 number of areas that do not seem to lend themselves to
5 CAM research activity. What do you view as the biggest
6 impediment to expanding the field of CAM clinical
7 research? Is it attitudinal, or is it the nature of the
8 beast?

9 DR. WHITE: Let me just think of some, and then
10 I will see if I can rank them for you. Certainly, there
11 are attitudinal problems or awareness problems, as we
12 have discussed before, about education of what CAM is.
13 There is also the two-cultures problem that I have just
14 alluded to, in which we are basically talking about
15 practitioner communities, often, versus research
16 communities. That is conventional and complementary and
17 alternative. Those are two cultures on some level.

18 If you are talking about taking interventions
19 that are already in practice, bringing them into a
20 research environment, there are several problems. One is
21 that within CAM, a lot of CAM is individualized, either
22 patient to patient, which is a relatively unusual process

1 in clinical research, but also individualized by
2 practitioner. A practitioner of acupuncture may do
3 acupuncture very differently from another practitioner.

4 So finding a way to develop protocols that are
5 uniformly agreed upon by the practitioner community and
6 the research community, I think, that is a challenge.
7 Most of the challenges, I think, develop or can be dealt
8 with by collaborations and by education.

9 I think there is a cadre of investigators out
10 there that are willing to address a lot of these issues.
11 If they are teamed with the appropriate individuals in
12 the practitioner community, I think you will see a growth
13 in the quality of the research.

14 DR. GORDON: Effie.

15 DR. CHOW: Thank you for your innovative kind
16 of comments. I appreciate it.

17 In the 1970s and 1980s, there was a concern
18 about poverty and minority/ethnic programs. I had the
19 pleasure of working with Dr. Lenfant, in that, the Heart,
20 Lung, and Blood Institute had an advisory group on
21 minority/ethnic representatives, and dealt with the
22 problems.

1 I know the NCCAM is doing a great job, but in
2 relationship to your specific areas, do any of you have
3 an advisory group on CAM within your institute? Does the
4 Cancer institute have that?

5 DR. WHITE: I do have an advisory group, an
6 internal NCI advisory group, on complementary and
7 alternative medicine.

8 DR. CHOW: I guess my question is, do you
9 people feel it is feasible to have an advisory group
10 within your institute? I would love to see that because
11 it will bring you closer to the people and the practices.
12 It is such a diversified field of complementary and
13 alternative medicine. Do you see it feasible to have an
14 advisory group?

15 DR. LENFANT: Well, that, I think, is an
16 interesting question. Our view would be that it would
17 probably be a mistake to have an advisory committee just
18 for that, because to me it would amplify the distraction
19 between the so-called alternative and complementary
20 medicine and conventional medicine. I think it would be
21 more useful to bring, which we do, actually, individuals,
22 who have interest in these approaches and make them

1 engage into constructive discussions with others.

2 So the notion of having a committee just for
3 anything that you are interested in is, at least in our
4 area, somewhat counterproductive.

5 DR. GORDON: Yes.

6 DR. COATES: If I can address as well, I agree
7 with Dr. Lenfant. A standing committee devoted solely to
8 that would probably not be as effective as they could,
9 but over the past five years, I can think of probably
10 about 15 different advisory group meetings that we have
11 had, virtually all of which were interdisciplinary, meaning
12 they not only working scientists, but members of the lay
13 public in the actual meeting. I think those things are
14 very useful when you are talking about a specific area to
15 get as broad a level of input as possible and our
16 advisory council as well.

17 DR. GORDON: Thank you.

18 I would like to ask a couple questions, and
19 then Wayne, and then Joe, and then Tieraona.

20 The first, is one of the things that we have
21 had a particular focus of, at our Center for Mind-Body
22 Medicine, on cancer.

1 Many, many people call us with questions, both
2 about treatment and research for many illnesses. With
3 Cancer, at the NCI I can speak with Dr. White. There is
4 a Best Case Series mechanism which researchers can enter
5 fairly easily. There is a panel, a CAPCAM panel, which
6 is a combined effort of NCAM and NCI, of researchers,
7 clinicians, members of the public, who are interested in
8 CAM research in cancer.

9 It is much easier, or at least seems much
10 easier, to advance research in the area of CAM approaches
11 to cancer, and particularly with researchers who have
12 never worked with the NIH before.

13 I am wondering if any of the other institutes,
14 or any of those of you who are here, are considering
15 extending more of a hand out into the community. Have
16 you thought about that, or do you have any thoughts about
17 what you are doing? Do you have comparable mechanisms to
18 NCI's mechanism?

19 DR. LENFANT: The Heart, Lung, and Blood
20 Institute, thinking what you started from, which is what
21 I would say behavioral approach is, we have a large
22 program in our institute with 10 or 12 people who are

1 doing just that, and therefore, they have extensive
2 communications with the interested community.

3 If it comes to all the components, which we do
4 not have a special group, but the fact that they can
5 become involved very easily in the discussions which are
6 taking place in the institutes, I have to admit that I am
7 not sure that it is always very successful when you have
8 one voice, or two voices, among 12 or 15 people. It is a
9 delicate balance of all these voices, and it is
10 difficult. That is also true for all the recipients in
11 their approaches.

12 DR. GORDON: Thank you. Anyone else?

13 [No response.]

14 DR. GORDON: One of the things that I would
15 just like to mention is, I think that it is difficult
16 enough, even when the mechanisms are in place, to reach
17 out, to bring first-time researchers in the area of CAM.
18 I just think that all of us, we need to consider
19 mechanisms for ways to bring these people in.

20 The other specific question I had was for Dr.
21 Cassman. What I am wondering is, is attention being paid
22 to some of the fundamental research questions that are