

1 DR. GORDON: Okay. So we can take a look at
2 that and maybe either pull some out, but there is
3 agreement that we need some background. Is that correct?

4 If I seem repetitive at times, it is because I
5 want to really make sure that we do have a general
6 agreement about what needs to be in the report, and the
7 more we can get clear about what needs to be in there in
8 this meeting, the easier the rest of the process is going
9 to be for everybody.

10 MS. LARSON: I would like to move very quickly,
11 that we are decided on that, and that we can get through
12 to Tom's area, wellness, because we have half an hour
13 before we are going to break.

14 But what Wayne outlined and what Jim has said,
15 yes, we are already doing this. Then the specifications
16 of the contextualization, I think, are really important,
17 but I think that we can continue to beat a dead horse
18 right now.

19 DR. GORDON: Is there anything you want to say
20 about that before we stop beating that horse?

21 MS. LARSON: I have, maybe, two sentences, but I
22 think I will table them for another time.

1 SISTER KERR: Can I take your two sentences?

2 Thanks.

3 I just want to say that for me it is
4 tremendously important that the Interim Report have this
5 context. I know we just said it. To me, it is symbolic
6 that if we do not do it and just move into these
7 recommendations, it is not emphasizing what we understand
8 is the spirit and the call from the people to do this, and
9 it sets the stage for the listening. I truly believe
10 that. Thank you.

11 DR. GORDON: Okay. Tieraona?

12 DR. LOW DOG: Yes. I echo that.

13 Could we just focus so that we are not in danger
14 of scope creep throughout this day? Could you please
15 define again for us, real clearly, what is the actual, in
16 just a couple sentences, intent of this report, and who is
17 the audience, and who are we aiming it for, so that we are
18 very clear on that throughout the deliberations.

19 DR. GORDON: Sure. The intent of the report,
20 and Steve will correct me if I stray, is to provide an
21 update to the Secretary, and through the Secretary of
22 Health and Human Services, to the President and to the

1 Congress, about our activities so far. That is sentence
2 one.

3 It is also to provide an update on our
4 activities, to make some specific recommendations about
5 which there is general consensus, which may be used to
6 help shape legislative and/or administrative initiatives,
7 and to give some sense of where we are headed with the
8 Final Report, but that is really subsumed. I see that as
9 emerging out of what we have been doing so far.

10 So that is the basic intent.

11 Would you agree, Steve?

12 DR. GROFT: Yes, I think that really summarizes
13 it. One additional fact or direction is that we have to
14 give the public some information about where we are going,
15 and give them the opportunity to comment on what our
16 feelings, our beliefs are, and the direction of the
17 report. That is part of it.

18 DR. GORDON: The primary audience is Secretary
19 of Health and Human Services, the President and the
20 Congress, and through them -- and this is what Steve is
21 emphasizing -- to the public, to give us feedback about
22 the report, to tell us where we are on target as far as

1 they are concerned, where we are not, what else we need to
2 be looking at, what concerns we have or have not
3 addressed, and how they feel about how we are proceeding.

4 DR. GROFT: I think, as Tom mentioned, CAM
5 started back in 1991-92, with the introduction of that
6 terminology. The same with this Commission, where the
7 introduction of the concept of the Commission was probably
8 1998. So we are three years down the road, and to say,
9 are we, as we see it, going on the right track, or does
10 the public feel that we should be going on another track,
11 or picking up additional information that we haven't
12 considered at this point in time, I think that is
13 important also.

14 DR. GORDON: Okay. Any other questions about
15 that? About the intent and the audience?

16 [No response.]

17 DR. GORDON: Okay.

18 SISTER KERR: Is there any addendum to that,
19 where you said that this report is to speak where we have
20 consensus? If I were the public listening, I may go,
21 well, for gosh sakes, why aren't they talking about that
22 and that? Is there any way to clarify that for the public

1 reading?

2 DR. GORDON: Clarify what? I'm sorry.

3 SISTER KERR: These are only the points of
4 consensus.

5 DR. GORDON: Yes. We can certainly make that
6 clear. I think that is a very good point. We will make
7 it clear.

8 Does that make sense? I think that what we need
9 to do is to make clear exactly what we are doing and not
10 doing in this report.

11 DR. LOW DOG: That is not what we said just a
12 little while ago, though, because now we are saying that
13 this report is clearly where we have consensus, and
14 earlier we were saying that we may have ambiguity, we may
15 not have unanimity.

16 DR. GORDON: We have consensus that we have
17 ambiguity. No, I am not just playing with words, what I
18 am saying is that we will say where we are. If we have
19 ambiguity about certain areas, or if certain areas are
20 unresolved, I think it is important to say that, that we
21 understand that.

22 The point is that the consensus is about all of

1 these issues. Consensus doesn't necessarily mean that we
2 are in agreement about the particulars. It means that we
3 are in agreement about where we are with the particulars.

4 Joe?

5 DR. FINS: I think the best way to address this
6 is with text. I mean, I think it depends on where we are,
7 and I think we should go to the Tom thing so we can take
8 advantage of his leadership on this.

9 DR. GORDON: Okay. The Tom thing.

10 [Laughter.]

11 DR. GORDON: Do you think that is an appropriate
12 title in the report? We will call it "The Tom Thing." Is
13 that okay with everybody? Can we move on to the Tom
14 thing?

15 No, seriously, can we move on to the section on
16 wellness at this point. So we will move right ahead?

17 As we are turning to that page, Joe Kaczmarczyk
18 left me a note, that Professor Orzak, who presented the
19 testimony on the evolution of professions, is developing a
20 more expanded version of his testimony, which will be
21 available to us. Joe mentioned that we can ask him, if we
22 want, to supply other sociological and historical

1 information.

2 So that may be one way for us to go.

3 MR. CHAPPELL: Are you ready for my thing?

4 DR. GORDON: Yes.

5 MR. CHAPPELL: Could you turn to page 19, and
6 turn off any other mikes, please?

7 **Discussion Session VI: Wellness, Self-Care and Prevention**

8 MR. CHAPPELL: On page 19, lines 7 through 29,
9 there is a good contextualization of the evolution of
10 wellness, self-care and prevention as a way of taking care
11 of yourself.

12 I want to direct the Commission's attention to
13 the next page, page 20, lines 9 through 17, and in
14 directing you to these lines, I don't have anything to
15 process that was otherwise in our booklets here of a menu
16 of suggestions because they will just have to stand as a
17 menu of suggestions that fall within the guidelines of
18 these five categories in 9 through 17.

19 The first category is addressing education. The
20 second category is really talking about education, again,
21 and then the third within the health care professions,
22 more education, and then four is the workplace, and five

1 is sort of national initiatives for the entire population.

2 So this circumscribes the suggestions that have
3 been coming forward in the hearing process, and I think
4 the report appropriately targets these areas of attention
5 and need and development.

6 So, first of all, teaching, promoting and
7 encouraging CAM approaches to wellness, self-care and
8 prevention at all levels of the educational system.

9 Is there consensus that we should be striving to
10 bring education of CAM services, products, at all levels
11 of education?

12 DR. GORDON: I just want to make a point of
13 process. What Tom is doing is not addressing up front the
14 text, and you are not addressing it because you are
15 satisfied with it --

16 MR. CHAPPELL: Yes.

17 DR. GORDON: -- or you have no particular
18 concerns about it. So do you want to address the text if
19 anybody else has any concerns afterwards, and go to the
20 recommendations first? Or would you rather address the
21 text first?

22 MR. CHAPPELL: I will come back to it, if you

1 would like me to.

2 DR. GORDON: Is that all right, or do you want
3 him to address it first?

4 MR. CHAPPELL: I would like to be focused.

5 DR. GORDON: Okay.

6 MR. CHAPPELL: At this point I would like to be
7 focused on these five areas.

8 DR. GORDON: Okay. Is that fine with everybody?
9 I would like to let people who have taken the lead in
10 these areas take the lead in the discussion, and then if
11 we want to go back and go over it a different way, we will
12 do that later. Okay? Is that all right?

13 SISTER KERR: Where does it fit in if you have
14 comments on language? Now or later?

15 DR. GORDON: What Tom is asking is that we look
16 at the recommendations now and that we come back to the
17 previous text, though we can obviously deal with the
18 language of the recommendations, but that we deal with the
19 text that leads up to the recommendations after we have
20 dealt with the recommendations.

21 DR. FINS: I think that the way it is
22 textualized, the recommendations, is problematic, and so I

1 think it is sort of hard to dissect that out. Let me just
2 give you an example of what I am thinking about. On page
3 19, you know, in lines 17 to 20 or so, there occurs what
4 will call CAM creep, where CAM becomes prevention and not
5 a subset of prevention.

6 I think we really need to avoid CAM creep
7 because I think it decreases the credibility of CRAM --
8 CAM.

9 DR. GORDON: You mean canned CLAM.

10 [Laughter.]

11 DR. GORDON: I hear you, Joe.

12 DR. FINS: Let me just finish. I think explicit
13 mention here of , for example, and the excellent efforts
14 of the United States Public Health Service in promoting
15 prevention and health education and those kinds of things,
16 that this is in conjunction, that CAM does not replace
17 prevention, but is an integral part of these wellness
18 strategies.

19 Then we go to the following page, where you have
20 your five recommendations, and the way it is written now,
21 it sounds sort of like we are proselytizing for CAM, when
22 in fact we are now advocating an approach to prevention

1 which includes CAM.

2 I don't know if I am clear, because I am tired,
3 but that is --

4 MR. CHAPPELL: That is okay. I am trying to
5 help us avoid a CAM of worms here and get us right to the
6 recommendations to see whether or not we have any
7 consensus.

8 SISTER KERR: Where are the recommendations? I
9 am on page 20.

10 DR. GORDON: Page 20. Charlotte, are you
11 looking at the one with the numbers on the side of the
12 page?

13 SISTER KERR: Yes.

14 DR. GORDON: It's line 9 through 17 there.
15 There are five recommendations.

16 MR. CHAPPELL: I would just ask if I could be
17 the facilitator of this section, please. I have been
18 asked to do something, and I would like to be given a
19 chance to do it.

20 So for everyone's benefit, what I would like to
21 do is to take you first to the recommendations in lines 9
22 through 17, after whether or not we actually have

1 agreement, so that the reporters can know our wishes. And
2 then we will go back to see if we need to clean up any of
3 the other language, the precepts to that.

4 Yes?

5 DR. LOW DOG: May I respond to that? I have
6 problems with the recommendations, because they are too
7 vague for me. And it goes back to our ambiguity of what
8 CAM is.

9 MR. CHAPPELL: I was going to take them one by
10 one.

11 DR. LOW DOG: Well, with all of them, but where
12 we say CAM approaches to wellness, self-care and
13 prevention at all levels, integrating CAM approaches into
14 programs of health education for children in elementary
15 schools, what exactly does that mean that you are teaching
16 my second-grader? I mean I am interested in prevention
17 and I am interested in self-care, but that is way too
18 vague for me because CAM is huge. I have no idea what
19 that means.

20 MR. CHAPPELL: So you are really asking whether
21 we have a curriculum in mind, how would the curriculum be
22 developed. So this is not specific enough.

1 George?

2 DR. BERNIER: Again, I want to stay focused
3 where you have us, Tom, on the recommendations. But I
4 agree in the sense of the vagueness, but I wonder if it is
5 vague because in the previous text we don't say, you know,
6 in this context wellness means good nutrition, exercise,
7 not smoking, doing the things of self-care to take care of
8 yourself, and that this has been shown to reduce chronic
9 illness and other disease.

10 By specifically saying this is what it is, then
11 you put into a context later when you are basically making
12 recommendations.

13 MR. CHAPPELL: Okay. Thank you, George.
14 Tieraona?

15 DR. LOW DOG: My response to that is that
16 throughout my medical training, exercise, lifestyle
17 management, smoking cessation, a month at the wellness
18 center, all of those things, and almost all of the
19 research that has been done and paid for by that has
20 actually been in conventional medicine. The Public Health
21 Department, OSHA, job training safety, all of this is in
22 and under the Public Health Department and in preventive

1 medicine.

2 So I am not clear when we say CAM approaches.
3 You are going to have to define what is different or
4 unique or distinct. If you are saying exercise,
5 lifestyle, nutrition, be clear what you are saying. But
6 to say CAM approaches, you have lost me there because that
7 is what public health officials have been fighting for
8 forever. And the work that has been done in that is in
9 conventional medicine.

10 DR. GORDON: Are there other comments about this
11 recommendation? Effie?

12 DR. CHOW: I think there is so much question on
13 this and ambiguity because again we don't have the
14 definition of CAM. I go back to my work. And back here
15 on 19 it begins to describe what CAM approach is, line 24
16 to 9 of the next page. But whether that is specific
17 enough for the discussion to then take a look at what CAM
18 approach means in the recommendations.

19 So in a way taking the recommendations without
20 kind of going through their principles, again --

21 MR. CHAPPELL: Yes. I am happy to take your
22 direction on this and turn now to 19 and start at the

1 beginning and just see whether or not we are absorbing all
2 of the precepts that go into the recommendations. So why
3 don't we take those paragraph by paragraph.

4 So I am at line 8 now on page 19. I just ask
5 you to bring your comment at this point on the three
6 paragraphs there, through line 19, if you could. Joe?

7 DR. FINS: Yes, I would just again go back to
8 the notion of trying to contextualize this. You used the
9 phrase before in our small group like CAM is value-added.
10 And so I would say here that CAM is that sentiment, and we
11 don't need to wordsmith it, but it is value-added to all
12 the primary and secondary prevention efforts and wellness
13 efforts that Tieraona and I have spoken about, that are
14 part of the mainstream medicine, which would have to get
15 us on lines 19 and 20, taking up this language.

16 I think it is patently untrue that prevention
17 activities frequently take place outside the conventional
18 health care system. It may take place outside the health
19 care system, but it also takes place within, and some of
20 the things that you are saying are truly preventive may
21 not be efficacious.

22 I mean, you know, we know pap smears are good

1 prevention, but we are not sure about some of the other
2 modalities which are cited in lines 26, 27, 28, as proven
3 to be preventive.

4 So I think we have to acknowledge the preventive
5 services that are in place, that are efficacious, and then
6 say that the people we heard from, consumers, also want
7 these other modalities for additional enhancement of
8 wellness and strategies for well-being and prevention.

9 MR. CHAPPELL: Jim?

10 DR. GORDON: You are making a distinction
11 between those activities in prevention for which there is
12 good evidence and others for which there may not be good
13 evidence, but people are using?

14 DR. FINS: There are two points. One is that
15 most prevention is happening within the mainstream,
16 mammography, pap smears, smoking cessation, cholesterol
17 lowering, exercise, et cetera, in the context of things
18 that you might see in the United States in the Healthy
19 People 2010 sort of thematic.

20 The second point is that those modalities have
21 proven intervention characteristics, and we talked about
22 yesterday some are better, some are worse. Quiacs are

1 less good than pap smears, for example, in preventing
2 colon cancer versus cervical cancer. We have that
3 information.

4 Some of the things that are down here that are
5 not as proven yet, it doesn't mean that they won't work,
6 but they are just not proven. So there are two points
7 that I am trying to make.

8 The more important one is to contextualize this
9 section against all the other efforts that have been led
10 by the United States Public Health Department.

11 DR. GORDON: Yes. No, that point I understand,
12 and I think we are clear on that one. That is a very good
13 point.

14 The second one, I think, is an important point,
15 too, and the question is how to work with that point. And
16 I think you are pointing to some kind of ambiguity in the
17 language that we may be focusing on some things which are
18 much more in the mainstream, and then we are focusing on
19 others that are CAM, and we are kind of lumping them, or
20 at least they seem in the text to be lumped together a
21 bit.

22 Yes?

1 MS. LARSON: My only point was to mention that
2 what you were saying is it is disease prevention. That is
3 a different thing versus wellness promotion, and this is
4 what we must make a distinction in. That is what we are
5 trying to get to here.

6 DR. GORDON: Does everybody understand that? So
7 your pap smear would be disease prevention.

8 DR. WARREN: Pap smear is not prevention.

9 MS. LARSON: It is detection.

10 MR. CHAPPELL: Just a moment, everybody. We
11 will just go in some order here, and we will give some
12 people a chance to speak that haven't had one. Don and
13 Julia, and then Tieraona.

14 DR. WARREN: Well, what I don't understand here,
15 you are calling a pap smear prevention. Pap smear is
16 detection, it is a screening. It doesn't prevent
17 anything. It picks up disease, dysfunction, just like a
18 dental X-ray picks up dental decay. It doesn't prevent
19 it.

20 MR. CHAPPELL: I agree.

21 DR. GORDON: I'm sorry, we are going to listen
22 to these other people now.

1 DR. WARREN: So I like what he has got here. I
2 like what is on this page. It describes it. It is
3 disease screening. That is exactly what he has listed it
4 as, and that is what it is. It is not prevention.
5 Mammogram is a screening, it is not a prevention. In
6 fact, it may be a causative factor in some studies. So I
7 think what we have got here is the right thing.

8 DR. GORDON: Julia?

9 MS. SCOTT: I was going to say pretty much the
10 same thing, except I see it as secondary. The things that
11 you are talking about are secondary prevention, but I
12 think the emphasis or the distinction here is a system
13 that is geared more to the detecting of diseases, whereas,
14 I think many of us believe CAM is an addition in wellness.

15 DR. LOW DOG: I think all of these are
16 important. I think that what I want to caution us against
17 is using divisive types of language and not acknowledging
18 the tremendous efforts that have been done in conventional
19 medicine towards public health, wearing seat belts,
20 bicycle helmets. My god, the big initiatives that have
21 been done on that. That is not disease-oriented, that is
22 to prevent you from dying in a car accident. It is

1 prevention, pure and simple.

2 Now, where we are talking about this with
3 meditation and biofeedback and stress management, things
4 that promote wellness and health, that is very different
5 in some ways, but there is overlap. I think all we have
6 done is, one, I think we need to rework some of those
7 sentences there to honor all the work that has been done,
8 but then to say, we find that there is potentially some
9 very exciting techniques or whatever -- somebody smarter
10 than me with words -- there is some very exciting stuff in
11 CAM, and then mention them: meditation; biofeedback;
12 imagery; tai chi, that may serve to promote wellness and
13 improve health.

14 I think we just need to be careful with our
15 language, and I think there are some exciting areas here
16 that can improve health.

17 MR. CHAPPELL: If I am getting the sense of the
18 comments, it is that we want to be as inclusive as
19 possible here about what has gone on before and what has
20 been added to, what has been contributed to.

21 DR. LOW DOG: And be inspirational. It is
22 exciting work. What is out there that can help us.

1 MR. CHAPPELL: So far, I am hearing that we need
2 to be clearer about the credit that needs to be given to
3 the movements that have preceded and what CAM has
4 contributed. I am just hearing that.

5 Joe, and then Effie, and Charlotte.

6 DR. PIZZORNO: One of the huge dangers is
7 defining CAM as anything that is not conventional. We
8 must remember there is overlap in these fields.

9 Second is I am concerned that we not lose our
10 understanding of why the public is going to CAM
11 professionals. While it is true that there is some
12 prevention taught in conventional medical schools, and I
13 understand that now most medical schools actually even
14 offer courses in nutrition, that is only a recent
15 development. The reality is that what is described on
16 this piece of paper: nutrition; lifestyle; health
17 promotion, people go to CAM professionals to get it
18 because they do not get it from the conventional medical
19 practitioner.

20 There are some enlightened people like Tieraona
21 and others, actually many sitting around this table today,
22 who are medical doctors who understand that, but the vast

1 majority of services being provided to the public don't
2 get that, and that is why people go elsewhere.

3 In terms of the numbers, I agree that there are
4 some significant problems with Dave Eisenberg's work.
5 However, let's just do some simple math. There are
6 600,000 medical doctors in this country. My understanding
7 is, only half of them actually see patients. There are
8 about 100,000 alternative medicine practitioners, when you
9 look at chiropractors, neuropathic doctors,
10 acupuncturists. If you add massage therapists to that,
11 that comes out to 200,000. So the reality is there is a
12 tremendous amount of care being provided right now.

13 If you look at areas like Washington State,
14 where we have equality of insurance, equality of life
15 insurance, one community hospital did a survey -- this was
16 in Kirkland -- and 75 percent of the people in Kirkland
17 went to a CAM professional within three months before the
18 survey was done.

19 So realize, this really is happening out there,
20 people are getting services they don't get from
21 conventional medicine.

22 DR. GORDON: Let me just interpolate. Can you

1 give us that survey? Because that is a very interesting
2 one.

3 DR. PIZZORNO: I will see if I can get others.
4 That was three years ago, and probably the numbers are
5 higher now.

6 MR. CHAPPELL: Effie is next. Thank you, Joe.
7 Effie.

8 DR. CHOW: Some of the basic principles, adding
9 to what Joe says, is that prevention in a medical system
10 is still doing things for the fear of disease, and
11 prevention in CAM is really doing things to promote
12 health, for the love of being healthy. It is a positive
13 aspect.

14 I would add to his list, Joe's list, of why
15 people go to CAM practitioners, because they are listened
16 to and they are touched, physically touched and mentally
17 touched.

18 So I think I like the gist of what this is
19 saying. It does need to be elaborated on. Do give credit
20 to the Western system about the prevention, but you see,
21 it is still all sort of fear of accident and those things.
22 You know what I am talking about?

1 So anyway, I like the gist of this, but it needs
2 to be elaborated.

3 DR. GORDON: Tom, let me just interpolate. If
4 you are making a suggestion for what needs to be
5 elaborated on, aside from the references to prevention and
6 Healthy People [2010], which we got, we have got that one
7 down, what other elaborations?

8 If you have something specific, please say it
9 now. The more specific people can be, the more helpful,
10 the more we can get a consensus. Then we can get it down
11 here, okay.

12 MR. CHAPPELL: Go ahead, Charlotte.

13 SISTER KERR: I want to keep, for myself, using
14 the discipline today of going back to what we identified
15 as our guiding principles. One of the principles is that
16 people have a right to choose the modality and the
17 practitioner of choice.

18 Having said that, and pointing to Jim's request
19 of what other elaboration, I am wondering if we need to
20 include the possibility of what may be there as healing
21 opportunities, that which is not spoken yet as health
22 promotion; the inclusion of practices that may not be

1 spoken, but are things like the coins on the back or the
2 bee stings for the MS.

3 How do we create the space to safeguard the
4 right to choose what the person wishes? Do you
5 understand?

6 DR. GORDON: Charlotte, what I would like to do
7 as the guardian of the overall structure is to say, I
8 would like to put that into access because that is really
9 about treatment. This is really about wellness and health
10 promotion.

11 MR. CHAPPELL: This is also trying to describe a
12 background to specific recommendations. So it is pointing
13 us to five recommendations.

14 Wayne, I think you were next.

15 DR. JONAS: Yes. I think I agree in general,
16 but I think we should go back to the principles that we
17 outlined, and I wish we could get them up on the wall so
18 we could refer to them.

19 I think Number 3, that we identified, really is
20 that we believe enhancing the healing capacities, and that
21 this provides an important, my wording, perspective and
22 opportunities for prevention, treatment, palliation of

1 disease, and the enhancement of wellness.

2 I think that that is the core issue that we are
3 talking about in here. I agree that we need to
4 contextualize this within the tremendous efforts that are
5 going on in conventional medical care for prevention. We
6 need to use that word "prevention." That is what it is.
7 We need to explain that. I think by describing those
8 efforts in Healthy People 2010 is a great way to ground
9 that.

10 Then we can add onto that and say that there are
11 a number of practices outside the conventional health care
12 system, apologize for David Eisenberg's address, focus on
13 health promotion that may be useful in the prevention and
14 the treatment of disease, and the enhancement of wellness
15 and self-care, and in this way acknowledge this, and then
16 acknowledge that there are additional items that are not
17 necessarily addressed in those activities that we still
18 feel are very important, not just for prevention, but
19 enhancement of wellness, also for the treatment.

20 I mean, health promotion, and the health
21 promotion practices are also useful as treatment, and
22 Dean's program is an example of this.

1 MR. CHAPPELL: Okay. Thank you, Wayne.

2 I think Wayne has summed up the sentiments that
3 I have been hearing, that we have been trying to refine in
4 reacting and responding to the text as it was presented.
5 I just want to find out whether any of our writers have
6 captured Wayne's statement. I don't mean Number 3, but --

7 DR. GORDON: No, no, no. I have those, and I am
8 sure Jim Swyers does as well. I have them down.

9 Tom, I just wanted to remind you of the time,
10 and that we need to come back to the recommendations as
11 well, if you are ready to do that.

12 MR. CHAPPELL: I think we are ready to do that.
13 Corinne?

14 MS. AXELROD: Just to say, as a primary author
15 of this section, I will certainly work with Wayne and
16 everybody else to make sure that we have captured
17 everything people have said.

18 MR. CHAPPELL: Good. Thank you.

19 I appreciate you bringing your concerns forward,
20 everyone. Now we will turn to page 20, line 9. On the
21 first recommendation, it has been pointed out that it is
22 too simplified to refer to CAM approaches if we are going

1 to recommend a curriculum to an entire educational system,
2 that we need to be more specific. In fact, we need to
3 develop a curriculum.

4 DR. GROFT: If I may caution you, Tom?

5 MR. CHAPPELL: What is that?

6 DR. GROFT: Tom, I don't think it is really our
7 position to develop a curriculum. I think we have to
8 think beyond that, that someone else is going to have the
9 responsibility for implementing these recommendations. I
10 think for us to try to develop everything that we are
11 suggesting is impossible.

12 MR. CHAPPELL: Okay.

13 DR. GROFT: I think it is more important to
14 identify what needs to be done, and then have it
15 implemented.

16 MR. CHAPPELL: Tieraona is recommending that we
17 be more specific when we use the term CAM approaches.

18 DR. LOW DOG: My problem was integrating CAM
19 approaches into health education for children in
20 elementary school. I mean, to me, I could not support
21 that sentence because that is just too ambiguous for me,
22 of what you are going to teach my child in school.

1 DR. GORDON: I think there is potentially a
2 middle ground of giving some examples. We can't
3 articulate the whole curriculum. Clearly, we can't be so
4 vague, if we talk about nutrition, exercise, stress
5 management, however you want to say it, as examples.

6 Yes?

7 MR. CHAPPELL: Charlotte?

8 SISTER KERR: I just want to say again, I would
9 like the group to either say yea or nay on what I will
10 continue to point out, unless you can convince me
11 otherwise. When we say CAM approaches, I do believe this
12 morning was very important, that what we want if we are
13 going to do school programs or whatever, we want the
14 principles and the practices to be taught, and that goes
15 all the way through everything, integrating CAM principles
16 and approaches.

17 Do you agree with that or not? I mean, we are
18 going to grow in explaining what those principles are.

19 DR. GORDON: I do, but I think it is a question
20 of asking that you are asking everyone the question.

21 SISTER KERR: My fear is that we are talking
22 about integrating approaches means integrating modalities.

1 It is like how every course looks that says we now
2 integrate CAM in our continuing education program. And
3 what is it?

4 There is a lecture on biofeedback, there is a
5 lecture on acupuncture. Nobody does a conceptual
6 framework, which we haven't even gotten into in terms of
7 energetic concepts, at least the principles.

8 MR. CHAPPELL: Any other comments? Effie?

9 DR. CHOW: That is my platform, too, constantly,
10 is that we have to have the overall as well as the
11 technique. Perhaps we could say "appropriate CAM
12 approaches," and then give examples. Then, of course,
13 "appropriate" is up to your school, what is appropriate to
14 it.

15 MR. CHAPPELL: That does seem to be the
16 sentiment of the circle.

17 Yes, Dean?

18 DR. ORNISH: Just again, in the same spirit of
19 avoiding using targets, because if you are not specific,
20 you are going to have people saying, oh, so you are going
21 to stick needles in my kids? You know. I mean you are
22 going to have my kids taking herbal supplements that I

1 haven't approved? I mean let's not give them any easy
2 targets.

3 MR. CHAPPELL: Thank you. I think the second
4 recommendation is the same as the first. Could I ask for
5 clarification of the writers on this?

6 DR. TIAN: Yes. What would you say, Corinne? I
7 would say it is a subset of the first, yes.

8 MR. CHAPPELL: And so we move to the third item,
9 assuring that all conventional health professionals have
10 some training and education in CAM approaches to wellness,
11 et cetera.

12 SISTER KERR: I still don't feel like I have
13 either gotten affirmed or negated on CAM principles and
14 practices to wellness and self-care. Are we going to
15 leave out the word principles? Or beliefs? Whichever one
16 we decide on.

17 MR. CHAPPELL: It is my understanding that we
18 are going to be incorporating that throughout the entire
19 document, where appropriate.

20 DR. GORDON: Let me say my intention of using
21 the word approach is that an approach is not just a
22 technique, it is a mindset as well. And that is why I use

1 the word approach, and I am pretty sure that is my word
2 that is there, because it includes both. So it is also a
3 word that is somewhat more neutral and is not likely to
4 raise a red flag. I just give you that.

5 MR. CHAPPELL: Wayne, please.

6 DR. JONAS: I just had one suggestion that might
7 help with this, and that is that we alter that to say, for
8 example, in No. 3, assuring all conventional health care
9 professionals, and we could do this in the others, have
10 some training and education in the role of complementary
11 and alternative medicine in wellness, self-care and
12 prevention. And that would be a little broader, and it
13 could be done throughout.

14 DR. GORDON: Tom, does that work for you?

15 DR. JONAS: The role of complementary and
16 alternative medicine.

17 MR. CHAPPELL: Well, we will take that under
18 advisement.

19 Go ahead, Joe.

20 DR. FINS: I think that fits with the notion of
21 how we modified cross-training yesterday, that people were
22 aware of the other modalities, but they weren't being

1 trained to do the other modality, and a conventional
2 practitioner needs to know about the role, but may not
3 necessarily endorse.

4 I would also say that on line 9, I want to just
5 point out, because of what Dean said and what Tieraona
6 said earlier, that we are not necessarily recommending
7 this, we are saying there is strong interest in this,
8 which I think also is kind of -- it puts a little distance
9 from the Commission from the recommendation. But we are
10 just saying we are reporting back what we heard.

11 MR. CHAPPELL: So, in the interest of time,
12 then, let's concentrate on edits, and we have one edit to
13 the Item 3, the third recommendation.

14 DR. GORDON: Tom, before we do that, I want to
15 make sure that everybody understands the point that Joe
16 made, and that we are in agreement about that point. It
17 is that we are at a slight remove from making these, and
18 that was conscious, right, Corinne? This is a conscious
19 choice that we are at a remove from making these as
20 recommendations.

21 In some instances we are making recommendations.
22 Here we are saying there is significant public interest in

1 this area, and leaving the room open to make
2 recommendations more specifically in the Final Report.
3 This gives everyone a chance to respond to these. I think
4 that is the thinking that we have.

5 MR. CHAPPELL: Thanks, Jim. Yes, Effie?

6 DR. CHOW: That is portrayed right from the
7 beginning of the article here. So witnesses testified,
8 and et cetera, et cetera.

9 MR. CHAPPELL: All right.

10 SISTER KERR: My last comment is just to say I
11 believe this is a teaching document, and for myself in a
12 few seconds of reflection, even though I appreciated Jim's
13 interpretation of approaches, I think because the mind has
14 not moved, that approaches still means modalities. I
15 would personally like to invite the group to consider
16 again whether or not we want to say things like principles
17 and practices or some other word that implies we are in a
18 consciousness change. No consciousness change, no new
19 creation of health in my mind.

20 MR. CHAPPELL: Okay. Gerald? Thank you,
21 Charlotte.

22 DR. GORDON: You are asking for some kind of

1 agreement or disagreement around the circle, right?

2 DR. FINS: I think maybe at the outset, in the
3 early part of the report, we might say by approach we mean
4 something greater than modality, and somehow have a
5 definitional footnote or something, so that we can say
6 when we are talking about a modality, we are talking about
7 approach, we are talking about a more comprehensive system
8 of care or something.

9 Yes?

10 MR. CHAPPELL: I would like to comment on this
11 point. Approach is sort of an implementation. Belief is
12 a very clear grounding. And wherever possible, we should
13 be pulling the beliefs into the text, the word belief into
14 the text, to give authenticity and strength to the
15 recommendation, and to give integrity to the whole
16 document.

17 So I agree with Charlotte that approach needs to
18 be re-looked at, revisited, to see if we can strengthen
19 the recommendation in terms of its relationship to what it
20 is we said we believe in.

21 I would like to just see whether or not that is
22 a sentiment of the Commissioners. Do we need to spend a

1 little more attention on that?

2 Yes, Julia.

3 MS. SCOTT: I think I agree with that, but I
4 also want us to be careful when we are talking as
5 Commissioners, and when we are talking as what we heard or
6 what people told us. I don't know that we heard that
7 people told us what Charlotte is inferring and you are
8 inferring. This sentence starts with "Information
9 provided to the Commission indicates there is a strong
10 interest."

11 So I mean, I hear what you are saying about the
12 word "approaches" kind of losing the meaning, but I think
13 I am more in favor of what Joe has suggested, that in the
14 beginning of the report, we are very clear about how we
15 are going to sharpen our definition for beliefs or
16 principles.

17 SISTER KERR: I have a response to that, if I
18 may.

19 MR. CHAPPELL: Yes, Charlotte.

20 SISTER KERR: If you remember, it wasn't
21 everybody, but in New York. I forget the names of the
22 people, but they were founders or foundresses of schools.

1 They were two women doctors, I believe, who had a long
2 history in complementary medicine. They spoke, and I
3 remember it because of my own bias, without the work at
4 the level of the philosophical level, epistemological
5 level, that nothing changed, and if you didn't get to the
6 essence of the change at the level of consciousness and
7 conceptual thinking, it wasn't the real thing.

8 So I heard it, and I thought it was a great
9 point, Julia.

10 DR. ORNISH: Well, again, playing my role here,
11 I can just say that the word all in Points 3, 4, and 5, in
12 lines 13 through 17, that all conventional health
13 professionals have some training, that we integrate CAM
14 approaches to wellness, et cetera, into all workplace
15 health activities, we explore placing CAM approaches into
16 national health and wellness initiatives for the entire
17 population.

18 I really think it would be wise to try to tone
19 that down a little bit, because even if you say there is a
20 strong interest in these things, that semantic distinction
21 is going to get lost. I can just tell you, people are
22 going to say -- I mean, you just have to appreciate what

1 kind of reaction that is going to get in the workplace,
2 for one thing.

3 I mean, employers are going to look at this, and
4 they are rolling back the repetitive stress industry. The
5 Commission spent four years and thousands of witnesses
6 talking about the importance of repetitive stress
7 injuries. They have completely rescinded it because even
8 something as well documented -- we are not talking about
9 epistemology here, we are talking about something that is
10 pretty obvious to everybody -- that was well documented,
11 and when employers saw that, they were able to lobby to
12 get it removed. Just that line alone will get a lot of
13 people against this report.

14 DR. GORDON: So, Dean, I think your point is
15 well taken. In places where we are too inclusive, or we
16 seem like we are mandating something, we have to tread
17 lightly.

18 DR. ORNISH: We are mandating this, when you are
19 talking about everyone, the entire population.

20 DR. GORDON: I understand. I understand. We
21 are not actually mandating it. We are saying that people
22 suggested, but I think you are right, the distinction will

1 get lost.

2 DR. ORNISH: By the time you get seven lines
3 down, there is a very small distinction in most people's
4 mind between strong interest.

5 MR. CHAPPELL: Fine. I think Corinne points out
6 it is already out. Thank you, Dean.

7 Tieraona?

8 DR. LOW DOG: I appreciate so much the use of
9 the word "belief and principles." I just want to be
10 careful where and when we use it, because if you read the
11 sentence, "integrating CAM approaches into programs of
12 health education for children in elementary school," it
13 sounds very different than when you say, integrating CAM
14 beliefs into programs for children in school.

15 Now, you may be talking about the same thing,
16 but people hear the word "belief" in different ways. So I
17 think, in some places, we want to talk about our beliefs
18 and our values, and in other places I think that word
19 might not be the best word. I would keep the "approach"
20 here, and I would define "approach" earlier, but I
21 wouldn't shy away from using it in places where I think it
22 sounds appropriate.

1 But here, I know I can tell you, as myself, I
2 have some issues with beliefs and when you start talking
3 about what things, what kind of beliefs you are going to
4 teach my child in school.

5 SISTER KERR: I couldn't agree with you more,
6 which is why I don't like the word "belief," and principle
7 includes belief, but it is coded as guidelines. I
8 couldn't agree more, but I am not arguing on the content
9 you were. I was arguing for when we make a statement of
10 what we want to do, that we be sure we put it in a
11 theoretical framework.

12 MR. CHAPPELL: Yes. Let me point out that the
13 operating word universally for beliefs is "values." You
14 can use them interchangeably. When you want a more
15 neutral response from an audience, "values" is the word.

16 I am also hearing Tieraona say, let's also be
17 specific where we can if we have got practices. So I
18 think all of these are great sensitivities.

19 Effie?

20 DR. CHOW: Actually, I didn't hear Charlotte use
21 the word "belief." She used "principle." Tom's word is
22 "belief." Okay. Everybody has been directing belief at

1 Charlotte.

2 [Laughter.]

3 DR. CHOW: I just want to protect you a bit,
4 Charlotte. The thing is, I think "philosophy" may be a
5 good word. I want to throw out "philosophy," "philosophy
6 and approaches."

7 MR. CHAPPELL: May I hear from Jim, please?

8 DR. GORDON: My suggestion is, first of all, I
9 think we are agreed that there are certain core principles
10 that go with the practices, that we have to be careful,
11 that that has to be part of the introduction, and we have
12 to be judicious about which words we use when.

13 I also think, Tom, that you have taken us
14 through this. We only have the fifth, the last item to
15 go, and we really need to break for lunch, because this is
16 only a couple pages of the report that we have gone
17 through, and we have a significant amount still to do.

18 SISTER KERR: Wayne wants to use commandments so
19 we can get faith in.

20 [Laughter.]

21 DR. GORDON: Wayne, is that a tactic or a
22 strategy?

1 DR. JONAS: A strategy.

2 MR. CHAPPELL: Jim has called this to a
3 covenantal issue here, and that is lunch. We thank you
4 for everything.

5 Could we look at Item 5, Exploring ways to
6 integrate CAM approaches and practices into national
7 health and wellness initiatives.

8 Jim.

9 DR. GORDON: I mean, I am happy with dropping
10 out for the entire population. I think this makes it
11 general, and anybody who doesn't join in is going to be in
12 big trouble.

13 I think this is a perfectly appropriate way.
14 This certainly reflects the sentiment of what we have
15 heard from many, many people as well as within the
16 Commission, and it gives us a subject for debate. People
17 can express their opinions, and I think it is something
18 that will attract interest without being a mine for us.

19 MR. CHAPPELL: Any other comments?

20 DR. GORDON: Except perhaps a gold mine.

21 MR. CHAPPELL: Well, thank you all very much.

22 [Applause.]

1 DR. GORDON: Okay, so we are going to go to
2 lunch. We will come back at 1:05, okay?

3 [Lunch recess taken at 12:28 p.m.]

4 + + +

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

A F T E R N O O N S E S S I O N

[1:26 p.m.]

DR. GORDON: I want to make a point to the Commissioners and also to the rest of you who are here with us, to the public, that the discussions today and what we have up here, this is not the Interim Report. The Interim Report is what we are working on developing, and so that the critiques that are coming up, the additions, the suggestions, the debates, this is all preparatory to creating the Interim Report, and I want to make sure that everyone knows that the Interim Report has to go through a couple of more iterations before it is ready. So what is involved is pulling together everything that we have heard at this meeting, fashioning another draft which in turn will be reviewed by all of the Commissioners.

So the principles, perspectives, the concerns that have been raised, are helping to contribute to the creation of the Interim Report.

We will present the Interim Report to the Secretary of Health and Human Services on the 16th of July as planned, and it then, before it becomes public, it goes through a clearance process. And once it has gone through

1 the clearance process, the Secretary will present the
2 report to the President, and the report will be available
3 for Congress as well.

4 So I just want to make sure everybody
5 understands that the drafts that are discussed here are
6 just drafts. What is put up on the wall are simply
7 principles that we agree to. How this is all going to be
8 formed in the Interim Report is still to be determined.

9 Are there questions about that from any
10 Commissioners? I wanted to make sure that was clear to
11 both Commissioners and the public. Yes, Julia?

12 MS. SCOTT: So if I am understanding you, Jim,
13 what you are saying is Commissioners are not responsible
14 for releasing the report?

15 DR. GORDON: Right. The Commission is not only
16 not responsible, the report goes from us to the Secretary,
17 and once it has gone through clearance, he will release
18 it. And the first place that he will be releasing it is
19 to the President, and also he will be releasing it to
20 Congress as well.

21 So until that time, this is still very much a
22 work in progress. So thank you, Julia, for clarification.

1 Okay. Bill has to leave in a few minutes, so I
2 wanted to give him a little chance to speak at this point.

3 DR. FAIR: Well, thank you. I distributed a
4 brochure from our health center. Now this isn't what I
5 think is ideal. All I can tell you, this is a result of
6 one person's search for something that I can coordinate
7 CAM medicine in my own problem, and I found out that,
8 first of all, you don't know who is good.

9 Secondly, when you find that out, at least in
10 New York, they are all over the area, and I was running
11 back and forth.

12 And thirdly, and most disappointing, they don't
13 talk to one another. So the way we have set up this is
14 that each patient comes in, we have no physicians in the
15 center, and that my role is simply the scientific validity
16 of it, and basically we run it with nurses, nurse
17 practitioners, and the person comes in, gets an evaluation
18 by the nurse practitioner, and then goes and spends 30
19 minutes with a nutritionist and an exercise physiologist
20 and someone in stress reduction and someone in movement
21 therapies, yoga and so forth, and then after that we sit
22 around in what I still call a tumor board. It's not a

1 tumor board, because we treat people who don't also -- it
2 is not all cancer. But a case management discussion,
3 where the approach is what is the specific diet for Joe,
4 with his cancer, or Mary with diabetes, or whatever, and
5 so forth, put together a program, and then if the client
6 so wishes, communicate this with the person's physician.

7 I mean what we are trying to do is to keep the
8 physician in the link, to communicate. The subtle message
9 is also to educate physicians as to what CAM has to offer,
10 and basically that it is an approach, we think of this as
11 an extension of the physician's office, not we are the
12 competition of the physician.

13 So, again, I don't mean this to be the only way
14 to go. It is one way, and I just wanted to share it with
15 you, because, as I said, it came out of my own search.

16 DR. GORDON: Thank you. Thank you very much,
17 Bill.

18 DR. FAIR: Thank you for giving me the time.

19 DR. GORDON: Yes, I would encourage the
20 Commissioners to take a look at the material, because this
21 really comes out of Bill's personal search, as well as his
22 understanding as a physician and surgeon. I think that is

1 a real power.

2 I also would ask other Commissioners if you have
3 materials that you would like to share with us. One of
4 the things of the nature of the Commission has been to ask
5 other people to come and tell us what they are doing.

6 Obviously the people who are sitting around this
7 table have also been spending their lives doing some very
8 interesting and important things. So what we, I think,
9 would welcome is if you want to share the work that you do
10 and the perspectives that you have with all the
11 Commissioners, if you would make available material -- I
12 hope I am not speaking out of turn, because I haven't
13 talked with Steve, but I am assuming that we can
14 facilitate this.

15 If you want to make available the materials, we
16 can make that available to all the Commissioners, so that
17 we can have the benefit of not only each other's comments
18 on the issues that are raised here, but also the benefits
19 of seeing what your work is like. I think that would be
20 very, very useful.

21 So, thank you, Bill, for leading the way in
22 doing this.

1 DR. FAIR: I might also add that anyone else, I
2 would just ask them to send me a bunch and it came out
3 just about a bunch equivalent to the Commissioners, but if
4 anybody else wants it, just give me a call or drop me a
5 note and I would be happy to send it to you.

6 DR. GORDON: Thank you. Okay. It is time for
7 us to move ahead. We have the majority of the Interim
8 Report to go over, to discuss, as we discussed the
9 wellness section, and what I would like to do is to
10 proceed with the different sections, moving through them,
11 and again hearing issues that are raised, concerns that
12 you have, places where you think the tone may be off, and
13 then moving from a discussion of the text to whatever
14 recommendations there may be, if indeed there are any
15 recommendations at the end.

16 Does that sound like a reasonable way to proceed
17 with the rest of this? Yes. Okay.

18 We have approximately two hours to do this, so I
19 am going to take the liberty of moving things along
20 quickly so that we can make sure we cover all the sections
21 and everybody gets heard.

22 Please, if somebody has made the point, and we

1 are looking for consensus, and everybody agrees, let's
2 just agree, we don't have to have a great number of
3 concurring speeches. In the interest of saving time,
4 let's really try to be disciplined.

5 **Discussion Session VI: Draft Interim Report**

6 DR. GORDON: So let's start. We have had
7 discussion already of the opening and the introduction.
8 We have an outline and a sense of what needs to be
9 covered, and the way it needs to be covered.

10 The pages 2 and 3 are basically -- and I note
11 that on page 2, the fourth task of the Commission was
12 somehow omitted, there is a typo. But basically page 2
13 and 3, and the Commission's progress to date are pretty
14 much simply factual accounts of what has happened so far.

15 So I would like, unless there is some particular
16 concern in those, to move right into a coordination of
17 complementary and alternative medicine research.

18 MR. DeVRIES: Just a quick comment. Under V,
19 Commission Membership, Sister Charlotte, you may want to
20 check, because it doesn't have you specified as a licensed
21 acupuncturist or as a nurse.

22 DR. GORDON: Well, thank you. If there are any

1 other errors in titles, please let the staff know about
2 that. Thank you, George.

3 Dean, do you want to make any opening statement
4 about the research section, since you have led the
5 discussion and have been so intimately involved with it?

6 DR. ORNISH: Well, I guess I would just be
7 curious to know if anybody has any changes that they would
8 like to make based on what is here. We had a whole
9 session on it, but now that we are actually getting down
10 to the nitty-gritty, what are your thoughts? I guess we
11 are on pages 4 and 5 now, is that right? Four, 5 and 6.

12 DR. WARREN: Remember that, on page 5, right
13 after line 14, Wayne had something that he thought needed
14 to be added there. Of course, he is not here.

15 DR. ORNISH: I think one of the things that we
16 talked about was whether on page 5, line 12, the
17 creativity and research methodology and flexibility in
18 study design, whether we want to get into that level of
19 being prescriptive, whether that raises issues of, is
20 there something less rigorous about what we are proposing;
21 would it be enough to just simply say that the research
22 methodology should be appropriate to the approaches and

1 techniques being studied, and leave unstated the second
2 part, which, again, it is an issue of being skillful in
3 not pushing people's buttons early on.

4 I know this is a big button for a lot of people,
5 the Marcia Angells and the Arnold Relmans, and others,
6 that somehow CAM has a less rigorous approach, that it is
7 more sloppy. There is no point in me even raising that
8 issue if we don't need to, at this point, and save it for
9 the Final Report.

10 Beyond that, I don't think I have any real
11 suggestions. I think that this was very well written. I
12 want to compliment -- I am not quite sure whether it was
13 Corinne or Gerri, I guess it was Gerri -- for doing this.

14 I would be curious to know if anyone else has
15 anything that they would like to have changed, based on
16 what is here.

17 DR. FINS: Just one little thing, on page 4,
18 where we mention the thousand speakers, we might want to
19 make some mention of the folks we didn't hear from.

20 Then on the section that Dean was referring to,
21 I think in the paragraph that ends on page 5, Safety and
22 Efficacy, I think somewhere in there I would like to have

1 language about hypothesis generation.

2 DR. GORDON: Joe, could we take you back to the
3 suggestion that Dean made? I would like to deal with that
4 in an orderly way, about you raised the possibility of
5 eliminating Number 2.

6 DR. ORNISH: Number 2, line 12, page 5. Then
7 somebody mentioned, Wayne, that you had some thoughts you
8 wanted to float, around line 15 on page 5, on the numbered
9 document, on page 5, in between the paragraphs that end on
10 line 14 and begin on line 16. They may be mistaken, but
11 somebody said you might want to add something here.

12 DR. JONAS: I think what we were talking about
13 is the importance of research being a tool for providing
14 information to particular audiences for particular uses,
15 and I think the phraseology I had suggested was research
16 should be designed to provide the types of information
17 most useful for those seeking delivery of CAM services.
18 It is an issue about prioritization.

19 DR. ORNISH: Would you be comfortable if we
20 added to that a line something like, "using the most
21 rigorous and appropriate scientific method" or "scientific
22 design"?

1 DR. JONAS: Well, we actually have another
2 section that deals with rigor and that type of thing,
3 which I think is important, and there would be some easy
4 ways, when we get to that, to addressing that.

5 DR. ORNISH: Well, I am just trying, again, to
6 avoid pushing people's buttons.

7 DR. JONAS: I agree. I would like the idea that
8 research design, selection of the research design, needs
9 to be targeted towards the type of information you want
10 your audience, that is going to use it. Within each of
11 those research designs, you should use the best and most
12 rigorous science that you can use, and that should
13 definitely be stated in there. That was already stated in
14 a different section.

15 DR. ORNISH: Towards the audience or towards the
16 question?

17 DR. JONAS: It is towards the question. You
18 select the design and your goals, based on the type of
19 information that you want.

20 DR. ORNISH: Right. Okay.

21 DR. JONAS: From that, then you put together the
22 best, most rigorous methods to achieve those goals.

1 DR. ORNISH: Well, I think, maybe, to make it
2 even less questionable, just say that based on the
3 hypothesis that is trying to be answered -- Corinne, you
4 look like you want to say something.

5 MS. AXELROD: Yes. I did want to say something.
6 Where it says, "the studies need a focused question," line
7 9, I had originally written, "studies need a clear
8 hypothesis," and I changed it to "focused question"
9 because I thought that actually broadened it. The word
10 "hypothesis" is very conventional.

11 DR. ORNISH: Well, why don't we do this? I
12 mean, again, my goal is to try to have us be as skillful
13 as we can, and when the Arnold Relmans and the Marcia
14 Angells, and the others who are just waiting for us to
15 mess up, read this, they say, well, I am glad we got
16 through to them; I am glad they listened to me.

17 So if you say the studies need a clear
18 hypothesis, a good study design, and then leave out Number
19 2 on line 12 through 13, we can always elaborate things on
20 the Final Report. I think this will pass muster with them
21 and then make them allies, or at least neutral as opposed
22 to giving them an easy target and it sounds sloppy to

1 them.

2 MS. AXELROD: All right. So basically, the
3 "clear hypothesis" which I originally had, plus the
4 "focused question" in parens.

5 DR. JONAS: Let me just modify that a little
6 bit. I mean, because there are very important and very
7 rigorous types of studies that explicitly do not do
8 hypothesis testing and generate hypotheses. They are
9 extremely important types of research, and often get at
10 the more relevant issues related to what the patients
11 want. So it is important that we not make a blanket
12 statement about all types of research as a general aspect.

13 This is why I suggest that there be wording in
14 there that you need to do high-quality research, and that
15 research needs to be appropriately designed to answer the
16 types of questions that you need for the type of
17 information that you want, or the audience that you want.
18 We can rephrase that.

19 So I think the issue is that we need to use
20 high-quality science, we need to use the best methods and
21 methodology for answering the research questions,
22 obtaining the type of information that we need, and that

1 can be a blanket statement.

2 To say, then, that everything should be
3 hypothesis-generated ignores one area. Now, you can say
4 that you need to have hypothesis-driven, hypothesis-
5 generated research when you are seeking cause-and-effect
6 relationships, for example, in clinical trials, which are
7 trying to make statements about attribution. Then
8 hypothesis generation is clear.

9 When you are trying to look at mechanisms, for
10 example, you have to do hypothesis generation. That is
11 the whole basis for basic studies, is the hypothesis. So
12 I don't want to go into the details, but what I am saying
13 is, that you can use a phrase like high-quality research
14 -- okay, science, the best evidence for obtaining the most
15 relevant information, and this type of thing.

16 DR. ORNISH: I can go with that. Highest
17 quality science to obtain the most relevant and useful
18 information. That is perfect.

19 DR. GORDON: One point I want to make, though,
20 is, we need to remember who our audience is. So "highest
21 quality science" is fine. We don't want to become
22 obscure. This is for lay people. Even though the

1 scientific community will read it, it needs to be
2 completely intelligible to our primary audience,
3 otherwise, we will lose them.

4 DR. ORNISH: Well, I don't think there is
5 anything unintelligible about "high-quality research."

6 DR. GORDON: No, but when we start talking about
7 "hypothesis generation," I am responding to that. I am
8 just laying out a thought for future discussions.

9 DR. ORNISH: Okay. Well, that is why I thought
10 putting both in would be useful.

11 DR. JONAS: I mean, "hypothesis generation" is a
12 little too esoteric, I think, in this area.

13 DR. ORNISH: Let's not get bogged down in this.
14 I was saying you can say "hypothesis," paren, "focused
15 question," closed paren, so that it is clear to everyone.

16 MS. AXELROD: I was just going to ask whether it
17 would make sense to say "clear hypothesis" or "hypothesis-
18 driven," or something -- I would have to play with it --
19 or "focused question," because in any study you have to
20 have a focused question, whether or not it is a
21 hypothesis. It is a question.

22 DR. ORNISH: I don't want to get bogged down in

1 it. If you could just put "hypothesis," "focused
2 question," it is going to be clear to everyone. It is
3 going to be an Interim Report.

4 The main thing I am concerned about is the
5 people who are waiting for us to slip up. This is exactly
6 where they are going to be looking for it, and we won't be
7 making ourselves vulnerable to that. That is all. That
8 is my primary concern here.

9 MS. AXELROD: Okay.

10 DR. FINS: It is in the same section, but on
11 line 10, before "research." Can we say "qualified
12 research"?

13 DR. ORNISH: Sure.

14 DR. FINS: Well, "qualified," has different
15 meanings.

16 DR. ORNISH: Yes, that is good.

17 DR. FINS: "Qualified." I mean, we had that
18 whole thing yesterday about the Nuremberg Code. It
19 relates to that. So, "qualified."

20 DR. GORDON: Where?

21 DR. FINS: Right before "research."

22 DR. GORDON: There is no "research" there.

1 DR. FINS: Line 5.

2 DR. GORDON: Oh, 5. I'm sorry. Okay.

3 Wayne, go ahead.

4 DR. JONAS: I just want to make one suggestion,
5 and I don't know if I want to go into wording here, but we
6 did this in the development of the center work.

7 What we want is a variety of types of research,
8 and we want good research in all of those variety of
9 types. So you can actually list the main ones. We talked
10 about them: outcomes research; health services research;
11 randomized control trials; basic science research.

12 My suggestion is that what we put in here is a
13 paragraph which says that it is generally agreed that
14 research of high standards and study design and execution
15 is required. This includes a variety of research types
16 that address the needs of those seeking delivery in and
17 understanding CAM services and products. This includes,
18 and then you can say randomized control trials, health
19 services research, outcomes research.

20 DR. FINS: I wouldn't use the word "needs,"
21 because it sounds like we are tailoring the methodology to
22 the physician. I would just stay to the question, again,

1 not the needs.

2 DR. JONAS: The question is derived from the
3 need, right? I mean, you design your goal based on the
4 type of information you want, and the type of information
5 you want is based on how you are going to use it, and how
6 you are going to use it is what you need.

7 DR. GORDON: Let me say there there is a
8 difference here, and the difference, I think, has to do
9 with whether research is directed by the needs of the
10 people for whom one is doing the research, or whether it
11 is driven by questions that arise from science or the
12 state of the science, or the science of an establishment.
13 I think that is a difference. I don't know if it is real
14 or apparent.

15 DR. JONAS: It is not an either/or. This is not
16 an either/or. In fact, you don't have to use the word
17 "needs." I didn't actually use the word needs in here:
18 "Provides type of information most useful for those
19 seeking the delivery and understanding of complementary
20 and alternative medicine practices." I didn't use the
21 word "needs."

22 DR. FINS: How about if we said the most

1 information necessary for delivery of safe and effective
2 CAM modalities or something?

3 DR. JONAS: I think that is okay, except then
4 that eliminates understanding, which is a basic science
5 question. So I mean, it is inclusive. I am not saying
6 that we do either/or. I think it needs to be inclusive.
7 And then if you list the major types of research that you
8 think need to go on, basic research, health services
9 research, outcomes research.

10 DR. ORNISH: I think all of that is good, I like
11 that. And again, what I am really trying to avoid, and
12 what they are going to be gunning for, is anything that
13 gives the appearance that there is a different quality of
14 research or a different level of science or a different
15 standard, and nothing that you said really pushes that
16 button.

17 DR. JONAS: I agree. And, in fact, if you want,
18 and I would be happy to do this, I could word this in a
19 way where it is absolutely razor-sharp in terms of saying
20 science is, you know, following our principle number
21 whatever it was, 2, that is up here, that science is the
22 absolute, I mean we believe that science is the important

1 tool for doing this.

2 DR. ORNISH: Well, I have complete confidence in
3 you, Wayne, so why don't you do that?

4 DR. GORDON: Let me check in with everybody
5 else. Is everybody else comfortable with that, too?
6 Wayne, do you want to say what you are going to do, then,
7 just very quickly? Does everybody understand? That is
8 okay?

9 DR. JONAS: Yes, I will just put a paragraph in
10 here that emphasizes the importance of science and science
11 is the basis for understanding complementary medicine and
12 its delivery, and that includes type of research, high
13 quality research and the types of research design that is
14 needed to do that.

15 DR. GORDON: Okay.

16 DR. JONAS: And list the basic ones that have
17 been discussed in the last few weeks.

18 DR. GORDON: Okay. Everybody comfortable with
19 that, then?

20 [No response.]

21 DR. GORDON: Good. Dean?

22 DR. ORNISH: I think it is great. I guess the

1 last part has to do, on page 6, in lines 7 through 17,
2 were there any concerns that people had? Well, actually
3 even on the previous page, beginning at line 23. I am
4 trying to remember whether there were any concerns that
5 were expressed about that.

6 DR. LOW DOG: I was just wondering if Wayne was
7 sort of going to be taking in that outcome study and this,
8 if that may actually end up sort of replacing that,
9 because you are going to word into this, right?

10 DR. ORNISH: He will weave it into that.

11 DR. JONAS: This is slightly different.
12 Actually, Dean, I will send this to you so you can look at
13 the phraseology of all of these items and then you can
14 circulate them among anybody else that you want.

15 DR. ORNISH: Good.

16 DR. JONAS: But I think that the issue here in
17 this paragraph is that we want to make sure -- there are
18 agencies that already do other types of research and that
19 have it as their main focus, and so we should put that in
20 there.

21 One suggestion I had is that we stick in, for
22 example, after agency for health care research quality or

1 key to research progress, that it is clear that similar
2 support and coordination efforts are needed in other
3 federal research agencies. Okay?

4 So, in other words, we talked about the success
5 of the NIH's effort in these areas and some of the other
6 agencies, and we should put a statement in there simply
7 saying we like this trend, we think other agencies should
8 be involved in this, so we recommend providing similar
9 support in other federal research agencies.

10 DR. ORNISH: But would you say in all of them?

11 DR. JONAS: Excuse me?

12 DR. GORDON: Would you turn on your mike,
13 please, when you speak?

14 DR. LOW DOG: Sorry.

15 DR. GORDON: He is on page 6.

16 DR. LOW DOG: I thought that where we were at --
17 okay. I was in the wrong place. Go ahead. I was on page
18 5. I thought Dean had us between 16 and 23, and I was
19 just saying is that part of what you were doing?

20 DR. JONAS: Yes, exactly.

21 DR. GORDON: Yes?

22 MS. AXELROD: I have a question then. The

1 outcomes, you will be replacing this reference to outcome
2 studies. But what about the sentence that starts with
3 anecdotal reports? Are you going to replace that as well,
4 or does that remain?

5 DR. JONAS: Yes, I think we can weave it into
6 it, yes. Okay.

7 DR. ORNISH: It is going to be woven into it.
8 And I apologize for skipping around here. So that takes
9 care of 16 through 21. Lines 23, on page 5, through line
10 6 on page 6, any comments about that? Any changes anybody
11 made?

12 DR. JONAS: I had one general question as to
13 whether we wanted to say anything about -- this is a land
14 mine, so maybe we should put it off for later -- patents,
15 along the lines, or something along the lines of
16 incentivizing investment in private research into these
17 areas. Whether we say it is patents or not may be
18 debatable, perhaps leave that out, but some phrase about
19 the importance of incentivizing private sector research.

20 DR. GORDON: Are you referring to the sentence
21 in funding initiatives for studying unpatentable products?
22 Or are you referring to something else?

1 DR. JONAS: Yes. What I am suggesting is that
2 we also add in there that we would like to see incentives
3 for correcting this problem, which is lack of incentives
4 to fund research in these areas.

5 DR. GORDON: I am wondering if we shouldn't
6 wait. The way we have it is general. If we can wait
7 until we really develop specific -- I would rather wait
8 until we have specific recommendations on that, rather
9 than go out sort of halfway with it.

10 DR. JONAS: Okay, but wouldn't you agree that it
11 is important and we would like to try to incentivize the
12 private sector in investment in that? That is what I am
13 suggesting.

14 DR. ORNISH: Why don't we make it in the most
15 generic terms, just like you said, encouraging the private
16 sector to invest in CAM research.

17 DR. JONAS: This is sort of negative. This is
18 like, well, nobody is going to invest in this area.

19 DR. ORNISH: Yes, I think that is a good idea.
20 So, Gerri, can you just add some language to that effect,
21 or Wayne, when you e-mail me, can you just put that in
22 there? I like that.

1 DR. GORDON: Say it again, and let's make sure.

2 DR. ORNISH: It is saying to encourage the
3 private, on page 5, line 27, something like encouraging
4 the private sector to invest in CAM research and delivery.

5 DR. GORDON: But that is in addition to what we
6 have said here.

7 DR. ORNISH: Yes.

8 DR. GORDON: Okay. So is everybody clear that
9 there is a distinction here, that there are two
10 initiatives that we are talking about? One has to do with
11 encouraging public research funding for those approaches
12 that can't be patented. And then this is in addition,
13 which is having incentives for people in the private
14 sector to --

15 DR. ORNISH: No. We are not getting into that.
16 It is a red flag. We are not saying we want to offer
17 incentives. We are just saying we want to encourage the
18 private sector to invest in CAM research.

19 DR. GORDON: But I am just saying those are two
20 different topics.

21 DR. ORNISH: They are two different topics. One
22 is a red flag, when you talk about --

1 DR. GORDON: No, no, no, those are not the two I
2 am talking about. One is public investment, and the other
3 is encouraging private investment. Okay?

4 DR. ORNISH: I am only saying we are going to
5 encourage private investment, that we don't put
6 incentivizing in. That is all.

7 DR. GORDON: Understood. Okay.

8 MS. AXELROD: On page 6, 19 through 21, does
9 talk about federal agencies -- wait. Private sector,
10 rather, I'm sorry, including foundations, manufacturers
11 and pharmaceutical companies. So that is private sector.
12 Where do you want to put the addition you just made? Do
13 you want to put it there, or do you want to put it --

14 DR. ORNISH: It goes better there, you are
15 right.

16 MS. AXELROD: At the end?

17 DR. ORNISH: Yes.

18 MS. AXELROD: Add it there?

19 DR. ORNISH: Yes.

20 MS. AXELROD: Okay. Okay.

21 DR. ORNISH: Encourage.

22 MS. AXELROD: Encourage.

1 DR. GORDON: Okay. I want to say just one word
2 on process. We need to move quickly, but if people are
3 confused and don't understand, please, you know, raise
4 your hand and say so, and we will try to clarify it as we
5 go.

6 DR. ORNISH: Yes, just in the interest of
7 process, if we could just agree that the burden of
8 responsibility is on you to jump in and say I don't
9 understand, or slow down, or, you know, I don't agree with
10 you. And the silence is taken as an assent.

11 But I do have a problem on line 19, on page 6,
12 when you use the word required. I would say encouraged.
13 ON page 6, line 19. Adequate support for CAM research is
14 not only required, I would say encouraged, to avoid
15 pushing people's buttons, because then you are basically
16 requiring the private sector foundations, et cetera, to do
17 these things.

18 You know, what we haven't done is the previous
19 paragraph, line 7 through 17. Any comments, suggested
20 revisions, problems?

21 DR. FINS: I have just a generic question, and
22 this is not the level of specificity here, but the

1 question is what do we mean by strong support? How much
2 against what? You know, do we have to justify this in the
3 context of a current allocation to NIH? Is it additional
4 money? Because I think that will be, you know, a red
5 flag.

6 DR. ORNISH: You want to just take out the word
7 continued? Or are you saying the other direction?

8 DR. FINS: Well, I am asking the question, you
9 know. And the other issue which has been brought up on
10 other occasions, whether or not NC CAM is -- we all agree
11 that that is the entity that we are seeking to maintain
12 and support, and whether or not there is language about
13 fostering even more collaborations with the other
14 institutes.

15 Can we state it stronger, like to -- I think
16 some kind of language that just, you know, stresses the
17 importance of enhanced collaboration. I mean recognize
18 the current existence of collaboration, but that we
19 believe that to bring the basic science talent, which --

20 DR. ORNISH: But lines 12 through 14 address
21 that. You want to reword that in some way?

22 DR. GORDON: I will tell you my problem, which

1 is related to this, is I don't like the passive voice. I
2 think this has got to be more active. Passive voice
3 always comes off sounding weak, no matter what you are
4 saying. So I think we need to make these statements, and
5 I think it will clarify our intention if we make the
6 statement in the active voice.

7 DR. FINS: Encourage. You know, we recognize
8 collaboration between NC CAM and other NIH research
9 institutes, and we encourage additional collaboration,
10 especially with their basic science colleagues at the NIH.
11 I mean that sort of language, and that is the intent.

12 DR. JONAS: Yes, I guess I wouldn't highlight a
13 specific thing that we think the NIH should do with its
14 own colleagues. I would be a little bit hesitant of that.
15 I do think we should put something more strong in there,
16 and I mentioned this before, but I will say it again, is
17 that, right before -- and I wrote this. I didn't write it
18 on the numbered thing because I didn't get that until
19 yesterday -- but right after the Centers and Agency for
20 Health Care Quality and Research is key research.

21 Just before it, during the testimony, the
22 importance of CAM-associated activities, we should put in

1 a phrase that is stronger, that is, it is clear that a
2 similar support, meaning similar to what has gone in
3 already to the NIH, and coordination efforts are needed in
4 other federal agencies.

5 DR. ORNISH: But then aren't you doing the very
6 thing that you are saying we shouldn't be doing, which is
7 dictating to the NIH what they should be doing?

8 DR. JONAS: I am not dictating this to the NIH
9 at all. I am dictating this to the Congress and
10 President, that they should do this with all federal
11 agencies.

12 DR. GORDON: I think, Dean, this response to
13 your question and concern about red flag, I think we have
14 to come down, if we believe that more research funding is
15 necessary, we need to say so quite clearly.

16 DR. ORNISH: I don't have any objection to that.
17 I actually support it.

18 DR. JONAS: And I do want to put in, I do think
19 we should say something about basic science research in
20 there, and I guess --

21 DR. ORNISH: I like that, too, and I think that
22 is only going to make our case stronger with the people

1 who are going to be our most vocal critics.

2 DR. JONAS: I would suggest actually it go up
3 above after safety and efficacy on page 5, line 21, that
4 we simply add another phrase in there that emphasizes the
5 important basic science research, such as an effort to
6 investigate the underlying mechanisms, assumption of CAM
7 modalities is also needed.

8 DR. ORNISH: That is good. Gerri, are you okay
9 with that?

10 DR. CHOW: Yes, I want to say that this is still
11 coming from the voice of the people, and I agree, we need
12 to be strong. Whereas we can't change the strength of
13 what the people are saying because we are afraid of land
14 mines, and it isn't us that are stepping in land mines.
15 And so I just want to bring that out again because we are
16 afraid because we think it is coming from our mouths, and
17 it isn't, it is coming from the people's mouth.

18 DR. ORNISH: Well, let me just clarify, as
19 someone who has been the most vocal proponent of that
20 particular concern, I am not afraid of this. I am only
21 trying to be as skillful as we can in not getting shot out
22 of the water before we begin. I think all the things that

1 Wayne and Joe and others have proposed I think actually
2 makes this stronger. I don't see any land mines in the
3 things that they talked about.

4 So it is really a non-issue, but in general, it
5 is not a question of being afraid or whose voice it is.
6 It is really a question of being skillful.

7 DR. GORDON: But I would add with Effie that it
8 has to be clear it is both the people's voice and it is
9 our voice, and that we are reflecting the people's voice.

10 DR. ORNISH: Well, then maybe we need to say
11 that at the very beginning, because that would apply
12 throughout the document, something that this is a
13 synthesis of the testimony that we have heard, in addition
14 to our own perspective, or something like that, because it
15 is important for the reader to know who is speaking, and
16 who they are speaking for.

17 DR. CHOW: Excuse me. It is in here.

18 DR. ORNISH: But I do think we have to be
19 careful that since we have heard so many diametrically
20 opposing points of view, that we are not necessarily
21 speaking for all the people, because if we were, that
22 would be impossible.

1 DR. GORDON: Wayne?

2 DR. JONAS: I have a suggestion as to how to do
3 this. I think it is important. It is one of our six
4 principles, Number 6, actually, up here on our principles.
5 My suggestion is again there is a very simple way to do
6 this that I don't think would raise a lot of land mines,
7 and that is under page 6, Item 17, to simply add a phrase
8 to that effect, Effie, such as procedures for the more
9 effective input of public interest and priorities in
10 research are needed.

11 DR. GORDON: Great. I like that.

12 DR. JONAS: Does that sound all right?

13 DR. ORNISH: In a way it extends what Effie was
14 saying, that we are speaking for the public here, but we
15 are encouraging the people to make their voice heard. I
16 like that.

17 DR. GORDON: I would like to call time, unless
18 there is a major sticking point, because we really need to
19 move on to the next section.

20 DR. ORNISH: This is a process, Wayne, where you
21 are going to send me an e-mail that incorporates all the
22 things that we talked about, and a copy to Gerri? And

1 Gerri, who is going to do what first, just so we know?

2 DR. JONAS: Why don't you modify what we talked
3 about?

4 Gerri, send it to me. I will send it back to
5 both of you, and then you can do whatever you want with
6 that.

7 DR. GORDON: Let me just say that any
8 emendations that we make, this has all got to move very
9 fast, okay? So if anybody is being asked or is taking on
10 the responsibility of doing a piece, it has to come to the
11 staff within a day or two at max. Okay?

12 Thank you, Dean. Are we okay now to move on?
13 Regulatory activities. Tieraona, do you want to move with
14 this?

15 **Regulatory Activities: Research**

16 DR. LOW DOG: So we are just starting where we
17 left off there, on page 6. Again, this is where we are
18 looking at the whole discussion about dietary supplements,
19 primarily.

20 Comments? I will give you a minute to kind of
21 look it over.

22 DR. JONAS: I would just like to make one

1 general comment about it, is, I thought a lot of it could
2 be condensed. It seemed like sections of it were kind of
3 redundant. We were saying things more than once.

4 For example, starting with line 15, those two
5 paragraphs, I had the sense that those had been stated in
6 other ways, and I would just suggest that you look back
7 through this section and maybe see if you can condense
8 some of those. Page 7, starting with line 15, those two
9 paragraphs, I am not saying eliminate them, but I am
10 saying that they could be condensed.

11 There is another, the paragraph on public
12 testimony, the end of that, also, again kind of reiterated
13 the same idea about supplement quality, et cetera, et
14 cetera. I mean, the point is that we want good quality
15 supplement aspects, and we don't need to say it three
16 times, if we could say it once.

17 DR. GORDON: So basically, this is an editorial
18 comment, not a context comment?

19 DR. JONAS: Exactly.

20 DR. GORDON: Okay.

21 DR. CHOW: Wayne, I am not clear about the two
22 paragraphs. The one starting on line 15, and then the one

1 on 22?

2 DR. JONAS: The two paragraphs starting on page
3 7, line 15 through page 8, line 3.

4 DR. CHOW: Okay.

5 DR. JONAS: And then the end of the paragraph,
6 starting on page 8, line 25. Those two -- those three
7 paragraphs seem to have a lot of redundant material in
8 them, and you might just look at condensing that.

9 DR. GORDON: Thank you. Michele's hand is up.

10 DR. LOW DOG: Michele?

11 MS. CHANG: Yes. We had talked a little bit
12 about wanting to be positive, to acknowledge the good
13 things that agencies or organizations have already done.
14 One of the things that we heard testimony on was from the
15 FDA to say that they have made headway along the lines of
16 developing these good manufacturing practices and
17 guidelines, but they are just not out.

18 So it has kind of gone in and out of this
19 version as to whether or not we should make passing
20 reference to the fact that FDA has done something that the
21 public is calling for, that everyone wants, and yet it
22 hasn't been seen yet.

1 So, again, to kind of walk that fine line
2 between not getting squelched --

3 DR. LOW DOG: I think we really want to put in
4 there, though, they need to get those GMPs out. They have
5 been sort of keeping those things for quite a while, and
6 the industry is waiting for them. So I think there needs
7 to be the recommendation that they pull those GMPs out.

8 I think, also, just for clarification on lines,
9 when we get to 23, 24, and 25, the FDA's regulations on
10 GMPs, where you are talking about accurate labeling, that
11 is not a GMP function there. So you just need to separate
12 those out, GMPs and what they deal with, and be clear what
13 they are. A lot of people are not clear what those will
14 do, but that is not about your labeling.

15 You want to separate that out, that labeling is
16 important and that the FDA needs to make sure that
17 companies are in compliance with DSHEA structure and
18 function claims on their labels, that they need to meet
19 the requirements that have been set out in DSHEA.

20 Yes?

21 MS. MILLER: I just want to add to what Michele
22 said, just for a little clarification. The GMPs are out

1 of FDA. It is the Office of Management and Budget that
2 they are not out of. So it is not FDA that is holding it
3 up, it is OMB right now.

4 DR. LOW DOG: Can we also be a little bit more
5 specific where we are talking about method validations,
6 where we are talking about needing to support programs
7 that are developing, methods?

8 DR. GORDON: Tieraona, where are you in the
9 text?

10 DR. LOW DOG: Well, it is kind of down here on
11 28 and 29, page 7. We use interesting language like
12 "standardizing the identity and purity."
13 "Standardization" is its own term in this category. I
14 would be more clear that methods for identification,
15 standard methods and characterization, need to be done
16 because we only have them for a few herbs.

17 DR. FISHER: The operative word is
18 "compositional quality."

19 DR. LOW DOG: There you go, Ken.

20 DR. GORDON: Okay. Now on this, if there are
21 those kinds of technical issues, it is important that that
22 be conveyed either here or afterwards, between you and the

1 staff.

2 DR. LOW DOG: Who is the staff person that did
3 this? Okay.

4 Well, can part of it be where just the staff and
5 I could talk?

6 DR. GORDON: I think you just need to let people
7 know where that is going to happen and get a general
8 assent that that is fine, and then you can do it.

9 DR. LOW DOG: Right.

10 DR. GORDON: Okay?

11 DR. LOW DOG: Well, I will do it tonight on the
12 plane, and then I can just e-mail it to you, and then it
13 can go around to anybody. But I think it is all very
14 good. I think there is some redundancy, and I think some
15 of the language is a little confusing when you use
16 standardization and you use other things. So I just think
17 we can tidy it up.

18 DR. GORDON: Okay. Xiaoming?

19 DR. TIAN: I think for this paragraph, I feel
20 the tone is tight or connective because this regulatory
21 research, page 6, mentions GMPs. They have so many
22 problems, but it is my understanding the majority of this

1 population that take dietary supplements do not have
2 problems. The minority, only a few problems should be
3 addressed. We have plenty. We mention here plenty,
4 right?

5 Should we put a few sentences to give an
6 impression that, generally speaking, dietary supplements
7 are safe and people are using them?

8 Otherwise, we see all the problems. Mention
9 that dietary supplements do not meet GMP. GMP is for
10 drugs. We are not talking about a drug, we are talking
11 about the dietary supplement. So there is no such
12 standard.

13 Must everything meet the standard as a drug?
14 Which is impossible, especially for all the small
15 factories that can make that.

16 DR. GORDON: Steve, do you want to respond?

17 DR. GROFT: Ken is going to.

18 DR. FISHER: I was just going to correct that.

19 As Corinne said, they are waiting to be vetted in OMB, but
20 we can't say that. What you need to say is, and it
21 practically says it, the way it is written, there is a
22 need for good manufacturing practices for dietary

1 supplements. That will get the message across right
2 there. There is no use pointing a finger at who is
3 holding it up.

4 DR. LOW DOG: There will be GMPs. There will be
5 GMPs, and the GMPs are actually under food for now.

6 DR. TIAN: Not yet.

7 DR. LOW DOG: No. There are GMPs because they
8 are dietary supplements.

9 DR. TIAN: No, not yet. There are small
10 companies, they have a license to make that. They don't
11 need a GMP to sell the product.

12 DR. LOW DOG: Yes. That is right, a small
13 company.

14 DR. TIAN: It is high-quality check, with this
15 issue, with the FDA, and there is no need because that is
16 the qualification for the drug. For each state that they
17 have license, they have to meet the license. They have to
18 go there to the state level. They will check all the
19 factory, if you want to produce any product.

20 So if we had to meet GMP, I am afraid there
21 probably is 10,000, maybe more than 10,000 small factories
22 that cannot make products.

1 MR. FISHER: Ming, you are correct when you
2 refer to drugs. You probably got an answer from the drug
3 side of the house, but there are GMPs on the food side of
4 the house, as well as standards of identity, and now in
5 the mill are basically good manufacturing practices for
6 supplements, and that is what has not yet been publicly
7 available.

8 So you are correct for drugs, but this is
9 something on the other side of the house.

10 DR. TIAN: In the future.

11 MR. FISHER: Well, it should have been about
12 three or four years ago.

13 DR. TIAN: Well, it is still in the future,
14 right?

15 MR. FISHER: Yes.

16 DR. TIAN: Whenever it is available --

17 DR. GORDON: We need to move along.

18 DR. LOW DOG: Joe, do you have a comment?

19 DR. FINS: I'm sorry I missed a little at the
20 beginning of this conversation, so I have some other
21 comments when you are done with this section.

22 DR. LOW DOG: Okay. I think one of the

1 proposals made was about putting a positive spin on it. I
2 do think that that is important, that many companies are
3 trying to do good quality, and that there is a huge
4 consumption of herbs, and that there have been problems
5 identified within the industry, but I think we probably
6 want to put that in a realistic perspective instead of
7 just, this is a renegade industry and everything is in
8 disarray.

9 DR. GORDON: Yes. I think that the other thing
10 that perhaps needs to be even stronger than it is here, is
11 that the companies have been active in promulgating GMPs.

12 DR. LOW DOG: Yes. So all of those things, I
13 think, should set the tone for this, looking for
14 maximizing the benefit and the optimism of these.

15 DR. FINS: One of the things we talked about
16 yesterday is that this is a consumer-driven movement.
17 Consumer protection is part of the enfranchisement of
18 being an enfranchised consumer. I think that in this
19 area, under the second paragraph of the section -- what
20 page is that?

21 DR. LOW DOG: Page 7.

22 DR. FINS: Page 7, right. Okay, got it. There,

1 I think we need to mention explicitly the Blendon study
2 about not withstanding the interest in access and dah-dah-
3 dah-dah-dah, a recent study also demonstrated a desire for
4 increased regulation, maintenance of safety, et cetera, et
5 cetera. So it is balanced. We have a parity between
6 access, consumer-driven, and consumer protection at the
7 same time.

8 DR. GORDON: Just one point about the Blendon
9 study, there was even more interest in having access.

10 DR. FINS: Right, right. I mean, the paper said
11 it, exactly. That is the point, access is something that
12 is not safe, it is not an access that we want to foster.
13 I think, at the same time, we don't want to leave the
14 impression that all this stuff is very dangerous. I think
15 we want to be balanced. I think Blendon works very well
16 in that context.

17 DR. JONAS: Principle 3: Accountability and
18 access must be linked. I had a sentence that I did not
19 understand at all. I couldn't understand it after reading
20 it, and this is on page 8, the paragraph that begins with
21 page 5, in this last sentence that starts on line 9, 9 to
22 13.

1 "To accomplish this, current AER systems must be
2 strengthened by both the private and public sectors, and
3 outreach activities to communicate to CAM and conventional
4 health professionals and consumers the importance of AER,
5 of CAM products, must be improved."

6 I don't understand that. Is that a --

7 DR. GORDON: Well, Wayne, you know why? You
8 have got two sentences there, to begin with.

9 DR. JONAS: Oh.

10 DR. GORDON: So it makes it a little more
11 difficult.

12 DR. JONAS: Is there a period somewhere in
13 between there?

14 DR. GORDON: There should be.

15 DR. JONAS: Oh. Okay, well, maybe that could
16 just be rewritten.

17 DR. FINS: It is the German reporter.

18 DR. JONAS: It is the German reporter.

19 [Laughter.]

20 DR. FINS: Right here, I think it makes sense to
21 mention explicitly the OIG report.

22 How do people feel about that? Because it

1 really is adverse event reporting. It is recommendation
2 that is out there. I think it is very prudential. How do
3 folks feel about that? It would go here, I think.

4 DR. LOW DOG: So the Inspector General?

5 DR. FINS: The Office of the Inspector General.

6 SPEAKER: Also, there are two GAO reports on
7 this topic as well that I think might be helpful.

8 DR. LOW DOG: I think where you can put some
9 data, where people have actually looked at this, I think
10 it is important to build some data into this report.

11 DR. GORDON: Let me just say something. We have
12 three more minutes for this topic.

13 DR. JONAS: I mean, like we have said with other
14 topics, we really need to contextualize this within the
15 current ongoing efforts on adverse event reporting and
16 safety, and that kind of stuff, and say CAM should be
17 included in those as an important area to address.

18 DR. FINS: We could say, constant with the
19 efforts of the OIG's report, we endorse increase vigilance
20 for AERs.

21 DR. ORNISH: When I was just outside taking a
22 phone call, somebody came up to me and said that there

1 were a number of things in here that he is concerned
2 about, that are inconsistent with some legal things that
3 are out there now, and suggested that we have an attorney
4 who is well versed in this area take a look at it so we
5 don't look foolish.

6 So I am just being the messenger here.

7 DR. LOW DOG: Right. We are aware that there is
8 some real stuff in here. We are going to clean it up.

9 DR. GORDON: Charlotte?

10 DR. LOW DOG: Oh, Charlotte, I am going right to
11 you. George has been waiting.

12 SISTER KERR: Oh, sure.

13 DR. BERNIER: On page 8, the first full
14 sentence, I don't understand. That is, "In its
15 consideration of these global issues, the efforts of the
16 World Health Organization will be reviewed by the
17 Commission."

18 DR. TIAN: I don't understand it either. What
19 material are you asking me to review?

20 DR. GROFT: That would be the report that we are
21 awaiting from the World Health Organization on botanicals,
22 I believe it is, that we have been in touch with.

1 DR. BERNIER: Well, it ought to precede this
2 item, because I think it sort of stands alone.

3 DR. GROFT: Okay.

4 DR. LOW DOG: It is kind of vague. You are not
5 clear what it means. So that is kind of an editorial
6 comment. The sentence, it is unclear what it means.

7 DR. GORDON: I think you are right, but the
8 previous sentence describes what the issues are, and then
9 this one is hanging out there a bit.

10 DR. LOW DOG: Charlotte?

11 SISTER KERR: Mine is probably an editorial
12 request. I keep thinking of this more and more as a
13 teaching tool for the great population that will read it.

14 When you think about how you wording things, can
15 you think of it as a teaching tool or user friendly as
16 much as possible? Like Wayne's paragraph, I really think
17 is a teaching paragraph in the research. What you are
18 saying, even the different language, the AER, that really
19 is for the beginner and the consumer and the legislators.

20 DR. LOW DOG: The congress people.

21 SISTER KERR: Thank you.

22 DR. LOW DOG: Okay. Good point.

1 Joe?

2 DR. FINS: The same section, but a different
3 theme, on page 9, sentences 11 through 20 or so. We are
4 talking about research regulation, and I want to say
5 something here specifically about the need for adequate
6 informed consent, protection of human subjects.

7 Then this verb really bothers me, "navigate the
8 IRB process." It sounds like you want to navigate around,
9 and that is certainly not what we want to imply. You want
10 it to be consonant with the highest ethical principles and
11 standards, and I think that needs to be explicitly stated.

12 DR. GORDON: I think the intention there was
13 what was testified to by a number of practitioners who
14 said they needed help with creating an IRB or working with
15 an IRB. So your point is well taken. That was the
16 intention of the statement.

17 DR. FINS: Yes. Good.

18 DR. JONAS: We also heard individuals say that
19 IRBs need help in knowing how to handle and deal with CAM
20 proposals.

21 DR. FINS: Talking about contextualization, I
22 think we want to mention Greg Kosky's [ph] office and the

1 Office of Human Research Protection, the important work
2 that that office is doing consonant with that effort, et
3 cetera.

4 DR. JONAS: And the efforts, really, to revise
5 the whole look at the IRB procedures and membership and
6 that type of thing, which is currently going on now,
7 stimulated by an entirely different area, but still
8 directly related to this.

9 DR. GORDON: How much of this do we want in this
10 paragraph?

11 DR. LOW DOG: I am not attached to the navigator
12 or working with it, but I think whenever we can give a
13 positive example of what is being done now and what is out
14 there to feed into this, wherever you can support it with
15 data, and wherever you can support it with what is
16 actively going on now, I think it gives credence to the
17 argument, I think it gives credence to the recommendation.

18 So if there are a few sentences that go before
19 this that would indicate how this is already being done or
20 who is doing it, I think it just gives the recommendation
21 more strength.

22 DR. GORDON: I would agree with that. I think

1 the issue here is, how much do we want to talk about the
2 IRB process in here. I think that we need to make a
3 general statement. It is something we can go into,
4 including all, as Wayne is suggesting, all of the
5 complexities of dealing with IRBs on both sides, or all
6 sides. That has got to come later. I think we can
7 indicate it, but not go into the detail here.

8 DR. FINS: I think the generic statement about
9 adhering to ethical standards, informed consent,
10 protection of human subjects.

11 DR. GORDON: I would also say collaboration
12 between the CAM and the conventional world in developing
13 IRBs is crucial.

14 DR. FINS: Right. I think because otherwise it
15 is not completely informed, and that it makes informed
16 consent impossible.

17 DR. LOW DOG: One other issue, just in this
18 section. Is there a reason why we sort of shied away from
19 making some sort of recommendation, that, also what we
20 heard was that DSHEA be fully implemented? Is there a
21 reason why we sort of just didn't say that?

22 Because if you read this, one could question if

1 we are questioning DSHEA or suggesting that it somehow be
2 reworked, and I don't think that is what we want to do,
3 but we never, in here, say anywhere really that DSHEA
4 should be fully implemented.

5 DR. GORDON: I think you are right. I think we
6 should say up front and clear DSHEA should be fully
7 implemented.

8 DR. FINS: That's right. Also, I think the
9 other issue is, fully implemented, and then it should be
10 evaluated, and then the appropriate oversight should go
11 back and revisit this.

12 DR. LOW DOG: George.

13 MR. DeVRIES: My concern is, in terms of DSHEA,
14 I think we should stay away from criticism or review of
15 the law. I think we should stay focused. A lot of
16 thought was given to it. It has not been fully
17 implemented. Our position should be fully implement it.

18 DR. FINS: Can you say fully implement it, and
19 then have it evaluated after an appropriate interval?

20 MR. DeVRIES: Why would you go there? We don't
21 say evaluate the FDA in their function.

22 DR. LOW DOG: I understand Joe's point, though,

1 because a lot of times there is some sort of
2 accountability or evaluation for lots of things we set
3 into place. I don't think we need to do that in the
4 Interim Report, though, but I do think we need to come out
5 -- I thought we had consensus on that, that DSHEA should
6 be fully implemented.

7 DR. GORDON: We do have consensus on that. We
8 need to say it clearly, and I believe we need to say with
9 adequate resources to accomplish this.

10 DR. LOW DOG: Well, especially if part of the
11 purpose of this Interim Report is for them to get their
12 budgets in line for what there might be money needed for.

13 DR. GORDON: Exactly.

14 DR. LOW DOG: This might be something they
15 should be aware of.

16 DR. GORDON: Tieraona, we are going to have to
17 stop here. I think we have covered just about everything,
18 so let's move on to the next section on training and
19 education.

20 Joe, do you want to guide this one through?

21 DR. PIZZORNO: Yes. I wish we had covered this
22 area yesterday before we had this conversation this

1 morning, because I think we might have been more willing
2 to be a little bolder about following through on some of
3 the conversations and recommendation we had gotten.

4 When we look at the content here, while I want
5 to give everybody a chance to think about it, in reality,
6 I think there is actually one word that probably caused us
7 some problems, and that was the use of the term "parity."

8 Now, I like "parity" in here. I really like the
9 way the staff wrote this up. At the risk of furthering
10 our discussions, I would like to suggest that we continue
11 the language as written here and not change. However, I
12 realize that there may be some who disagree with that.

13 MR. DeVRIES: Didn't we talk about more of an
14 incremental approach and the concept of equal access, I
15 think, Sister Charlotte or somebody was advocating?

16 DR. ORNISH: I still have the same concerns that
17 I expressed yesterday, so in the interest of time, I won't
18 repeat them, but I think, again, we want to just hold,
19 again, what is appropriate for Interim versus the Final
20 Report. I think "parity," you just might as well write
21 "land mine" on it.

22 DR. PIZZORNO: You know something, you are

1 right. I withdraw my last futile effort. I want you to
2 know that is just for the Interim Report. I am coming
3 back for this for the full report.

4 [Laughter.]

5 DR. PIZZORNO: So anyway, the use the language
6 we used from the discussion yesterday, I suggest it be
7 changed. I will leave it to the staff to change it, but
8 the language we came to consensus on was, "Provide access
9 of accredited or licensed CAM professions, educational
10 institutions, and practitioners to educational training,
11 funding, and other resources."

12 DR. FINS: Would it be helpful, just to save
13 time, to kind of recapitulate what we said yesterday about
14 this section, so that we don't have to wordsmith all over
15 again what we agreed to yesterday.

16 DR. PIZZORNO: I will just read to you what we
17 agreed to yesterday. So that was one thing we agreed to
18 yesterday, and the other one we agreed to, we agreed to
19 Number 1. Number 3, we modified it to "Encourage and
20 support joint- and cross-training of CAM in conventional
21 health professions in undergraduate and graduate
22 programs."

1 So I just want to say, this is the language we
2 came to yesterday. I think we should say to the staff
3 take a look at --

4 DR. FINS: The cross-training was one theme,
5 that you weren't going to cross-train me to do what you do
6 or vice versa, but I needed to become aware of what you do
7 and vice versa.

8 DR. PIZZORNO: It was training together.

9 DR. FINS: But we got rid of cross-training
10 because it implied all competencies.

11 DR. GORDON: Training from the lexicon here.

12 DR. PIZZORNO: Yes, and actually, as I think
13 about it, we left it to the staff to work on it. The idea
14 is that we would train together, not to learn each other's
15 skills, but to be comfortable in working together. So we
16 are going to leave the staff to work on some of the
17 language.

18 So yes, thank you for that clarification.

19 DR. GORDON: Do you want to go over some of the
20 other areas of agreement and see if there is anything else
21 that we do need that we did not address yesterday, because
22 we did a pretty thorough job that we need to attend to

1 her.

2 DR. PIZZORNO: Well, I think that what is
3 written here is consistent with what we discussed
4 yesterday, except for being clear about what cross-
5 training actually means, and removing the word "parity."
6 I read through this, and it looks pretty consistent other
7 than that, but how about if others take a look and see if
8 anybody sees something different.

9 DR. GORDON: And this is just the education and
10 training, at this point.

11 DR. PIZZORNO: Right, just education and
12 training.

13 Wayne?

14 DR. JONAS: I have another thing along those
15 line that I think should be changed. Let me find it in
16 the numbered one. Well, this is the reference to
17 internship and residency program. The last sentence
18 there, I think, is appropriate for what naturopaths,
19 chiropractors, and others of the more advanced, emerging
20 professions exist, but I don't think that should be used
21 as a general statement because it is not what they are
22 seeking or what they need, necessarily.