able to work with those recommendations.

MR. GROFT: Including trying to prioritize the recommendations for each section.

DR. GORDON: Well, that is a whole other issue.

MR. GROFT: That is a whole other issue that we will have to get to. And actually, we will try to do as much as we can before the February meeting, and hopefully we can bring you that final report and it will have the priorities, so we may be doing a lot of e-mailing back and forth to get your views of the priorities.

DR. GORDON: Steve, do you want to discuss the prioritization process now, too, just a little bit and how we may approach that? And then we need to discuss approximately what will happen with the February meeting, too.

MR. GROFT: Yes. We haven't even talked about that as far as trying to develop a prioritization process. I think it is something we are going to have to deal with next week and try to come up with some plans and get them out to everyone to look at.

DR. GORDON: So, a plan for prioritization I will work on with the staff. We will send that out to

everybody then within the next couple weeks?

MR. GROFT: Hopefully by the end of next week we can get something out.

SISTER KERR: Where do we build in the time for whatever our role is -- it may be nothing -- for the implementation of this? Do we just, again, deposit it to DHHS, period?

MR. GROFT: That is it.

SISTER KERR: We don't do anything with strategy in Congress? Nothing?

MR. GROFT: No.

SISTER KERR: Well, why the heck did we have a political consultant?

MR. GROFT: Excuse me?

SISTER KERR: Why did we have somebody I thought was advising us on how to move this in Congress? I thought that is what that guy was doing.

MR. GROFT: No.

SISTER KERR: All right. Well, that is all right.

The last question I have is in March. Is that actually a day we will have as well soon?

MR. GROFT: March 7th is the end.

SISTER KERR: I mean do we gather on March 7th, then?

MR. GROFT: No.

SISTER KERR: So, we just end it in February, right?

MR. GROFT: End it in February, yes.

SISTER KERR: We don't have any grieving process time or anything?

MR. GROFT: I don't have details on --

SISTER KERR: No hospice care?

MR. GROFT: No. I am trying to arrange some other events that you would not be involved with as commission members but as former commission members but they have not been finalized. I am working on that now and I really can't address it because we have not come to that conclusion. But if we are able to pull it off, it will be nice. It is going to be an appropriate way to present the final report.

DR. GORDON: And Steve, in February we will be working on the final text and final issues of prioritization?

MR. GROFT: I think we would like to get agreement at the February meeting on the text and the priorities that we have established and how we have presented them at that point.

DR. GORDON: Okay. And then, we will be contacting people for input about ways to educate the public about the report and to move the report forward in a public fashion, so that is something we will be doing over these next weeks, right, Steve?

MR. GROFT: We actually were going to do that at this meeting if we had enough time but we didn't have the time at lunchtime to go over the mechanism. So, again, I will write something up and get it out to everyone so we can discuss it through e-mail messages. And there will be a thread going through.

DR. BERNIER: Steve, I would just like to add that I think at this point if people start sending in comments they need to send them to everyone so we are not doing things in isolation, so that we can respond to other people's comments.

MR. GROFT: I mentioned that, that next week we will get a note out and everybody just hits a "reply to

all."

DR. BERNIER: Okay.

MR. GROFT: So that everyone then gets it. Whatever comes in to me, if it is not forwarded to everyone, if I see the e-mail message, I will forward it to everyone, okay?

DR. GORDON: The other point I want to make again is that when staff is arranging for calls for the specific work groups everyone will get a notice. So those who want to make specific points and want to be particularly involved in a work group, there will be the opportunity for everyone who is interested to be involved in those work groups.

I just want to get one final count on particular people who may want to be involved in this division thing. Just let me see those hands again, okay? Just want to write names down.

[Show of hands.]

DR. GORDON: Okay. I have Tom, Effie, Veronica. Okay. That is fine.

And again, we will talk and whatever we do we will send out to everybody.

DR. LOW DOG: Do we have a date?

MR. GROFT: We are looking at the 21st and 22nd.

DR. FINS: Would it be possible to start on the 22nd and do the 23rd?

DR. GORDON: 20th and 21st?

DR. FINS: The 21st is my problem day.

MR. GROFT: We will try to save your concerns for the 22nd.

DR. GORDON: Joe is concerned about everything.

DR. FINS: Well, I just can't do the 21st. That is the problem.

DR. GORDON: Were there any other days, Steve?

MR. GROFT: The 14th and 15th, but I think that was a problem for many people as well. Valentine's. A lot of heads shaking there.

DR. LOW DOG: Other than Joe, is there anyone else who can't make the 21st and 22nd?

DR. FINS: Is there any way to do the earlier part of that week, the 18th, 19th, or 20th?

MR. GROFT: I think the 18th and 19th was when a number of people were not available.

PARTICIPANT: The 18th is a federal holiday.

MR. GROFT: But that was bad. Several hands, I think, went up on the 18th and 19th. 19th and 20th?

DR. GORDON: Steve, are you asking a question about the 19th and 20th?

MR. GROFT: 19th and 20th. 19th and 20th?

PARTICIPANT: I hate to be a stickler but for those of us that are making a living in practice --

PARTICIPANT: I can't answer that without calling the office.

MR. GROFT: Okay. Let's stick with the 21st and 22nd and try to accommodate Joe the best we can. Whether we can patch him through on a teleconference or something, we are going to try to deal.

DR. GORDON: I will see what I can do as well on my side.

MR. GROFT: The 21st and 22nd. Ink it in. Okay. Best we can do.

I really want to thank you because the attendance has been outstanding at all of the meetings, and we hate to have a meeting of this importance that we don't have people but I think the people who can't make

it the 21st can make it on the 22nd. We will try to get those issues resolved at that point that are really major sticking issues for individuals, okay?

DR. GORDON: The 21st and 22nd.

MR. GROFT: Thursday and Friday, okay.

DR. GORDON: We are going to move ahead. We are going to do the two sections. We are going to do without a break. We are going to do Coverage and Reimbursement and then we are going to do CAM Central.

So Maureen is going to cover Coverage.

Are you without benefit of phone?

MS. MILLER: Yes. George may call in while we are doing this, but he is experiencing a delay.

I would like to say I am an extension of George at this point, not a substitute because he certainly is not one that would be easily substituted for.

DR. FINS: A little suggestion.

MS. MILLER: Yes?

DR. FINS: Is George expected to call in?

MS. MILLER: He is expected, but we don't know when.

DR. FINS: Why don't we do Don first? Is that

possible? Chances are he won't, then?

MS. MILLER: Yes. It is a good possibility he will not be able to call in.

Discussion Session IV: Coverage and Reimbursement of CAM

MS. MILLER: Just a quick overview of what we did since last October, from the October meeting, is that we basically kept our approach of the barriers to coverage and reimbursement, which is an approach that we identified with and people seemed to concur with, or there seemed to be a broad range of agreement on that approach at the last meeting. So we have kept that.

We have broken out one area, which is the overall fair and equitable treatment of CAM. It had been merged into each of the sections but we felt it was a bit awkward and we went ahead and broke it out as a separate section and moved a couple of the recommendations where appropriate into that section.

We generally have the same recommendations. Most of them have been refined or reworded and they will probably, I am sure, go through more of that. But there seemed to be, again, a general consensus with the underlying issues and concepts as the group has been

working with them.

So having said that, there is one other change that we made but I don't want to talk about that until we get to it, which is of course the section where we talked about medical necessity and the decision about when to pay or provide a service, but we will get to that.

And lastly, we have to address this one remaining recommendation that George had included in his memo, and it appears to me that it sits most appropriately in this first section on fair and equitable treatment, so that is where I plan to discuss that.

So with that, I think we can move right into the recommendations, which begin on page 7. And in this section there are three recommendations and they address this new, broad area which we feel is the lead area, the overarching area, which is fair and equitable treatment, safe and effective CAM intervention.

The first recommendation is that the purchasers and other health plan sponsors -- generally, that is the category of purchasers. Then the persons who actually carry out the insurance benefits, the insurance companies and managed care organizations, that they offer packages

that include CAM benefits, so without reading it word for word that is the intent there.

There are some edits that I would like to make to that personally because I realize we have had this effort internally, as you all know, to try and make the recommendations shorter, clearer, more concise and to the point. And I am realizing sometimes when we do that we occasionally lose a subtle concept, a nuance that is important. And in this context what needs to be differentiated is the role of the purchaser versus the role of the insurance company. I would like to make the recommendation a little clearer that would clarify that we would like the insurance companies to have benefit packages that include this, that they would offer coverage of CAM benefits in either their basic packages that everyone gets or as an optional supplemental where an individual could choose to buy it.

And if we put somewhat strong language out on that and we then follow that up with the concept that we then recommend that purchasers, such as employers, consider offering this because it is really their choice. But the strength here, in George's viewpoint, is getting

the insurance companies. And we did hear from the largest insurance company in the United States that isn't doing much in this area. And what we would be saying is that you need to at least be putting the packages out there and then let people decide. Let the employers decide, let the consumers decide if they want to buy it. So that is where we were coming cut.

DR. GORDON: Discussion?

DR. TIAN: I noticed the omission of the "safe and effective CAM interventions." Does that mean the licensed?

MS. MILLER: No. This means that services and products that have undergone some research, clinical and probably health services research too, whereby they meet some threshold of safety and efficacy.

DR. TIAN: Well, if it is possible I can make a suggestion, I think all the CAM services -- let's forget about products -- the services, if they are licensed, that means a general understanding they are safe and effective. If they have already proved by a certain level they are safe and effective, they should be covered.

DR. GORDON: I think that is what it says, "Coverage of safe and effective CAM interventions." I think if we start getting into the realm of licensure we are going to start muddying things up. We are just making a general recommendation here, as opposed to coming down on the side that everything has to be licensed, because then we run into naturopathic physicians are not licensed in this state, massage therapists are not licensed in that, acupuncturists are not licensed in the other.

I shouldn't be talking so much for you, I'm sorry.

MS. MILLER: Well, if I can interject here before it goes too far, we do have a recommendation on licensure in No. 8, that we have tried to keep precisely focused to just coverage and reimbursement, and this whole approach of barrier, how is licensure a barrier to coverage and reimbursement. But we don't get there until No. 8.

DR. TIAN: Okay, until later.

MS. MILLER: Wayne?

DR. JONAS: Where is the term so frequently

used by third party groups, "appropriateness"? There is another term that is used that is more than "safe and effective," excuse me.

DR. FINS: Medical necessity.

DR. JONAS: "Medical necessity," sorry. Yes.

MS. MILLER: Well, we actually addressed that in Section 4, on when to provide and how to provide services, but if you all want to discuss any of that now, we can.

DR. JONAS: If this is the up front, overarching recommendation, shouldn't that terminology be placed in here? Because that, for most places, has a very specific definition. Like safety and efficacy, it has a particular set of standards that are used for determining medical necessity.

MS. MILLER: Well, usually when an insurance company builds a benefit into a package, whether it is hospice care or whatever, it automatically includes medical necessity and appropriateness, and they work at a more micro-management level of defining what that is.

To me, it opens a broader question, which we tried to deal with in our previous write-up of the

problems we confront with establishing medical necessity and appropriateness criteria for CAM.

Go ahead. Joe seems to be biting at the bullet here.

DR. FINS: One of the problems is that for something to be safe and effective, achieving a CAM-like goal, but sometimes "medical necessity" implies that you are improving. So, like hospice care or physical therapy, if it improves rehabilitation it may meet a medical necessity requirement. However, if it just makes you feel better but it doesn't really lead to an improvement, it may not be medically necessary.

So to get entrapped in that in this context, I think, would really put it --

DR. JONAS: Isn't this recommendation saying that their benefit packages should be offered? Shouldn't that follow the current approaches taken by these groups to determine when they offer them, which includes medical necessity?

DR. FINS: Medical necessity, I think, is often a federal phrase. Each private company could set up the terms and conditions. No, the company could opt to say,

we think pain relief is an outcome of physical therapy, not necessarily improved mobility, and so therefore, we can establish that as the criteria to offer the service, or to continue to offer the service.

DR. JONAS: I understand what goes into medical necessity. I'm asking why it's not in here if we are recommending that these become part of benefits packages?

MS. MILLER: Let me give you my own opinion, and I don't hold myself out as a CAM expert. I am not a CAM practitioner. However, I think there is this issue that we are then tying CAM strictly to the current conventional way of practicing, that you have to have a disease or injury first before something can be done.

You would have to look at several of our other recommendations, including the tax one, to know that we believe there should be a shift where this concept of health promotion or maintaining a health status should be included in the overall perspective and philosophy.

So, if we put it in here, we are actually narrowing -- well, let me see.

Joe, you want to start off? You are a member of the group, so I imagine you are going to do some

prefacing and then come to this side of the table.

DR. JONAS: Well, I don't see where this has been related to wellness in here. I mean, you just brought up wellness. I mean, I am speaking for Dean here. I like the spirit of what you are saying, but as Dean would say, why are we applying different standards for this than we do in conventional medicine?

DR. FINS: I think there are two issues. There are things that are disease-altering interventions, like Dean's protocol could meet a medical necessity expectation in lieu of, say, bypass surgery.

On the other hand, there are some CAM interventions which will not meet the medical necessity expectation because it is not treating a disease condition. It may be just, not just but it may be promoting wellness.

I think what I would suggest is that this issue gets put into the text somewhere and addressed and maybe we should say that they should use criteria such as medical necessity but not limited to medical necessity.

DR. GORDON: Joe, just for my information, how does this work in terms of hospice care?

DR. FINS: There is a Medicare hospice benefit with established interventions, but if people are, say, terminally ill and dying and they have not enrolled into a hospice and they were getting physical therapy, which maybe helped them with some kind of symptom relief but they weren't actually getting better, it might be hard to prove medical necessity and the benefit could cease. So I want to avoid that pitfall.

DR. JONAS: It is also equally hard to prove that it was safe and effective or has not been proven.

MS. MILLER: Okay. Right. Joe, you had your hand up? And then Veronica, and Julia, did you have a comment? Okay.

MR. PIZZORNO: I totally agree with the same standards approach. Unfortunately, the term "medical necessity" has been extremely effectually used by the insurance companies to eliminate reimbursement of CAM not only to CAM professionals but also to holistic M.D.s. It just, unfortunately in this particular example, Wayne, doesn't work.

MS. MILLER: Okay. Veronica?

DR. JONAS: Between that and "safe and

effective." I mean you can use the same thing with "safe and effective" as you can with "medical necessity."

DR. FINS: But "medical necessity" implies a kind of a curative model.

MS. MILLER: Yes, Veronica?

MS. GUTIERREZ: I would like to echo what Joe Pizzorno just said. "Medical necessity" has been used more than any other reason I know of to deny chiropractic care. I have no problem with "clinical necessity." In fact, any contract that I sign for delivery of health care, I always amend it. I scratch out "medical necessity" and I put in "clinical."

I talked to the insurance companies about that, and they just use the phrase because it is the most commonly used phrase, no other reason. It would be very easy for us to change that right now, as we are changing the paradigm for health care or wellness.

So I would like to change "medical necessity" terminology to "clinical necessity."

MS. MILLER: Okay. Tom?

MR. CHAPPELL: Yes, I support the point of view that CAM is not as narrow as the term "medical

necessity." I would like to, as I did when the Aetna people were here, use the example of dental hygienists in dental insurance plans. That was not originally a benefit, eligible coverage, but it came back. It ultimately got expanded as a product area, not because it was medically necessary but because it was safe and effective, and a good way to prevent long-term reimbursement that they would eventually have through therapeutic. It was preventative.

So I think this language, "safe and effective," is the right language because there are modalities that are clearly safe and effective but are not medical necessities. I do think we need to protect the paradigm that we are trying to build here, and this language, as it is drafted, does that.

MS. MILLER: I will just throw in here, this will tie directly to the changes in the tax laws that we will be discussing in just a few minutes.

Tieraona?

DR. LOW DOG: I don't really like "medical necessity" here, but I think there needs to be something. I am not sure if the word is "appropriate" or not. I

think that there needs to be a stronger move towards primary, secondary, and tertiary preventive types of strategies, and that would include even the secondary prevention like screening, for Pap smears for older women, expanding this beyond medical necessity.

Tertiary prevention actually includes a lot of things that CAM does because a lot of patients are at a place where they have plateaued, I think, as somebody said the other day, and they are moving past it. You can use "PT" for rehab or chiropractic, et cetera.

So I think maybe "appropriate." I think there needs to be something in there other than "safe and effective," maybe "appropriate" or "preventive."

DR. GORDON: It is time for some wording, and then let's see if we have consensus. We have had a fair amount of discussion.

DR. FINS: The paradox of this recommendation was, I think, when it was written, we wanted the same standard so CAM practitioners and modalities, and all that, were not discriminated against, but it looks like the way it is written, we might have written it into a dead end, if we link it to "medical necessity."

DR. LOW DOG: Yes. I vote not "medical necessity."

DR. FINS: I guess the rationale is, we didn't want them to have a higher standard to adhere to, was what this recommendation was meant to convey, I think.

Right, Maureen?

MS. MILLER: Right, it was. It was fairness. If you are looking at safe and effective conventional treatments to put into your benefit plan, then you should do the same with CAM. That is all this was trying to say.

Actually, we have already gone through the process of prioritization in this section, where we have started out at the broad, and gone down to more specific. The issue of appropriateness and medical necessity is something done down at the health insurance plan by people farther down.

The green-eye-shade medical directors contribute to this, but they get into specific details of how many visits will we get for what reasons. That is a very narrow process, and this is a 30,000-foot level policy recommendation, where we were trying to go.

DR. LOW DOG: So you think it is appropriate to leave it the way it is?

MS. MILLER: Yes. I think these issues that you are raising are good ones, but what I might say is, maybe they are more appropriate to put that kind of language in once we get down to some of the recommendations a little later on. Thank you.

DR. GORDON: Okay. Can we call for a consensus on the recommendation the way it is written now? Do we have consensus on this? Can we live with this one?

MS. MILLER: Yes.

DR. GORDON: Great, thank you. Maureen?

MS. MILLER: Okay, the second one is that -- this long list of people here -- that everyone involved, basically, in the coverage process, that they maintain an expertise regarding CAM, and including CAM experts, on appropriate advisory bodies, working groups related to health benefits and health coverage, reimbursement policies, and any relevant or applicable processes, including coding.

So it is, again, forcing all the people who basically control this process, from the government down

to an HMO or insurance company, to open their doors to these discussions and to CAM experts.

Yes, Joe?

DR. FINS: I don't like this phrase, "processes to CAM." Maybe just say, "in health care organizations, make use of CAM expertise in crafting health benefit plans, health coverage reimbursement, and applicable coding."

MS. MILLER: Okay.

MR. PIZZORNO: How about insert in front of "process," "advisory process"? Because they do have advisory processes. You are just saying, include CAM people in them.

MS. MILLER: Okay. So instead of on the third and fourth lines of the recommendation, that it would basically read, "which influence health policy and interventions, these organizations open their" -- I'm sorry. Not "open." Where was it? Yes, that's not right.

DR. FINS: "Make use of CAM expertise through advisory bodies," or something, "and internal mechanisms as they craft health benefit plans," et cetera, et

cetera, and "devise coding."

DR. LOW DOG: "Which influence health policy and interventions, maintain an expertise regarding CAM." Can't you just leave it the way it is, but just taking out, "open their processes to CAM"? Then you just have "health policy and interventions, such as maintaining an expertise."

DR. GORDON: What is the wording then, Tieraona?

DR. LOW DOG: "The Commission recommends that purchasers and other health plans sponsors, insurance companies, managed care organizations, and health care organizations which influence health policy and interventions, maintain an expertise regarding CAM and include CAM experts on appropriate advisory bodies," blah-blah-blah-blah.

DR. GORDON: Okay.

DR. LOW DOG: Is that okay?

DR. GORDON: Okay with everyone?

[No response.]

DR. GORDON: Great.

MS. MILLER: All right. No. 3, "The Commission

recommends that professionals working in complementary and alternative health care actively seek out opportunities to advise and participate on public and private bodies that address issues related to health services research for CAM and health care generally, CAM-related demonstration projects, coverage and payment for health services and products, and improvements of coverage-related processes, such as coding." This is the flip side.

And this is in there in part because Don White from HCFA testified that they had opened up their technical advisory group and invited and no one came forward.

DR. GORDON: It seems sort of unexceptionable except somehow what is happening doesn't get out to the people. So the connector between 2 and 3 is how the information about those advisory boards gets out to these folks in the field who may want to participate on them. And I feel there needs to be something in there about that.

MS. MILLER: Well, the federal agencies, the federal purchasers here, CMS, OPM for the Federal

Employees Program, VA -- well, I am less sure of VA and DOD -- but they actually publish, in the Federal Register, their invitations. The bigger nut to crack is the private insurance companies, and there, you just really have to lobby yourself.

DR. GORDON: But even with publishing in the Federal Register, not everybody gets the Federal Register, and I think there has to be a little bit more outreach so that, for example, if we know a list of major CAM organizations that they are on the mailing list for these federal organizations when they start to promulgate rules or think about research programs.

MS. MILLER: Your point is correct. In the world of conventional health care and these processes, the people who take care of making sure that their doctors or nurses, or whomever, get on these bodies are the associations, so it is incumbent upon the CAM associations to inform their memberships and to help with that process. Actually, they usually should be the ones sending in the applications and the letters, and what not.

DR. GORDON: But we need those words in there

for the government to send out the appropriate information to all of those CAM groups.

MS. MILLER: Well, again, the initial action is on the part of the private party. It takes the association contacting like CMS and saying, "I want to be put on your mailing list." HCFA -- and it is hard to go from HCFA to CMS -- is not going to do the outreach here.

DR. GORDON: Even if we asked them? Because NCCAM, for example, has in recent years begun to do more of that outreach. So, for example, when the strategic plan comes out, there are all these people on the mailing list who get copies of the strategic plan.

MS. MILLER: Well, I'm staff here. I will do anything, put in anything you guys want me to put in, but let me just tell you, if you want this to work, that is all I can say, give you my opinion.

I'm not sure I would count on CMS doing outreach to associations. They do a lot of outreach. They have a whole outreach effort, but it is totally targeted at beneficiaries. I'm just being candid and honest.

SISTER KERR: I think Jim's point, though, what

you are getting is information.

MS. MILLER: Yes.

SISTER KERR: But we can't get any action, given the two realities. The organizations don't know, and the other bodies don't want to tell them.

So what action is needed? Because I haven't seen anything, for example, through the acupuncture groups. I consulted with a couple people. I don't know that it went out, for example, from HCFA.

MS. MILLER: Joe?

MR. PIZZORNO: Perhaps we could ask CAM Central, as we now are calling it, to maintain a list of such opportunities and advise the associations of them.

MS. MILLER: There you go, and we can add language to that effect, and deal with it.

I heard Linnea say, off mic, that we could also discuss this more fully in the text, and that certainly can be done.

So what I am hearing here is, we have this general recommendation, but it has to be revised to include the CAM organizations. Likewise, we, either as a separate recommendation or as part of this one, tie in

the proposed CAM Central to take on an outreach effort here to connect the two parties.

DR. WARREN: I like the connection part. I have got a question. Can we take No. 2 and No. 3 and combine them into one recommendation instead of having all this verbiage in there?

MS. MILLER: We did that originally, but it ended up being very long. We also felt that it was more powerful to talk to the insurance companies and HMOs directly, specifically let them have their own recommendation.

Often what happens, having worked in those kinds of situations, is the staff get an assignment to take these reports, go through it, and pull out what recommendations apply to them. This will be very clear that this gets on their list. Again, I think it is a strategic decision.

DR. GORDON: So, do we have a consensus, then, on No. 3, with those additions that Maureen has mentioned, dealing with the text and moving the outreach function over to CAM Central?

[No response.]

DR. GORDON: Great.

MS. MILLER: Before we leave this section, if you all could pull out this one-page piece of paper that you got yesterday, the third page of the George DeVries memo.

If you need a copy, Corinne has extra copies. We have a stack of extra copies. If you don't have a copy, raise your hand.

[Show of hands.]

MS. MILLER: This is actually a concept that came up at the October meeting, which was to look at the tax laws, the Internal Revenue code, the policy of which, though, is directed by the Treasury Department, not the IRS, to look into that and consider a recommendation that would address some of the barriers to coverage of CAM that are currently found in our tax code.

Steve and Corinne and I went down and met with Treasury. They were very open to us. We met with a very senior-level official. George participated in that meeting by phone. The major barrier that we found is that in their regulations is a provision that the services be under the direction, or basically, be

referred or ordered by a physician.

That was one, and that is a big one. Then, from there, it goes into the issue of medical necessity.

So we felt, in the time given, that we couldn't go into the regulations, that we would probably need a lawyer to help us to identify specific sections of the regulation that needed amending, and instead we are offering a more general regulation here, that this be taken on by Congress and the Executive Branch.

Let me read it, just so we can then begin our discussion. This recommendation currently reads: "The Commission recommends that the Internal Revenue code should be amended to provide equitable tax treatment of health insurance coverage of various CAM health care services and products.

"Specifically, the Commission recommends that congress hold a hearing and consider legislation on equitable tax treatment and the executive branch consider administrative relief for employers who include coverage for dietary supplements and for CAM health care services and products that have been shown to be safe and beneficial."

Okay, Tieraona?

DR. LOW DOG: Just for clarification, "who include coverage for dietary supplements and for other health care services and products." Why have you --

MS. MILLER: I think it was shared with us the last time. There is a bill that has been introduced that specifically addresses equitable tax treatment for dietary supplements and that is already out there. Then we also get into this issue of the sensitivity of using certain terms and we can't use the words "safe and effective" with regard to dietary supplements, so we need to carve them out and handle that separately because if you do then they become drugs. Otherwise, we have to drop the terms "safe," "beneficial," "effective." We have to drop all that.

PARTICIPANT: How about "safe and wonderful"?

[Laughter.]

MS. MILLER: Okay.

DR. GORDON: Okay. Any other issues on this or do we have consensus?

Joe?

DR. FINS: What kind of tax relief do employers

currently get from -- that was the beginning of the question -- for other kinds of insurance products? So, if an insurer has a drug benefit as part of their insurance package, do they get tax relief for providing the drug benefit?

MS. MILLER: Yes. It is tax deductible to them.

DR. FINS: Okay. So, basically we are putting this in the private sector with giving it parity?

MS. MILLER: Correct.

DR. FINS: Only in the private sector?

MS. MILLER: Well, that is where the tax issue applies.

DR. FINS: Right. So, if a company decides to provide this in a package and employees opt for it is what we are talking about, they will get some kind of tax incentive to do so?

MS. MILLER: Yes. That is the way the system works right now.

To be fair and honest, the concern of the Treasury Department with this, they have two concerns, one of which is that they were very open to this as long

as there was evidence that the products and services were safe and effective.

It is hard to know when to use those three little words. Dean wants us to use them all the time, but we have found we can't always use them.

That was their first concern. Their second one was the assessment of the impact on the tax revenues on the budget that we need to support all these other roads and schools and education. We are not addressing that here because it is pretty standard operating procedure, when they consider a bill like this for CBO, to do a cost estimate on it. So that will be taken care of, and if Congress sees it costs too much money, they won't do it.

DR. GORDON: Okay.

MS. MILLER: But on the other hand, to balance this out, employers, usually they decide how much they are going to spend per person on premiums. So when CBO looks at this -- and they are already pricing out the Dietary Supplement Law -- what they are looking at, from what I am being told, is that they are looking at, basically, fixed premiums. If they are spending $800 per person, then they are likely to be offering the dietary

supplement within the $800, and there won't be premium creep. That is an issue.

A hypothesis that they are considering is, will this cost money. There is no evidence that it will save money yet, but will it be done within the context of current premium levels.

DR. FINS: At the risk of sounding politically incorrect and just raising the possibility of any perceived conflict of interest in this recommendation and whether or not it is self-serving to certain industries and whether or not we want to recommend it in this context.

MR. GROFT: Some would say almost everything that we do has some degree of conflict of interest. But it is our recommendations to the administration and to Congress what we think needs to be done. I think that is what we have been asked to do.

MS. MILLER: It has been reported to us that this is a barrier for employers offering coverage is right now there is this incentive. They can deduct the typical conventional packages. If they want to offer a package of three or four CAM services, they are doing it

without any ability to deduct that and have any financial relief.

Joe and then Tieraona.

MR. PIZZORNO: I think this is a great idea and I support it strongly. I think the idea of the "safe and beneficial" is an important part of this because, clearly, we don't want to open this up to everything but those things that are safe and beneficial. I can think of all those men with cardiovascular disease, a third of whom who have significant, offering some B6, folic acid, and B12. I can think of all the pregnant women who this might be just be the thing that will get them to take the folic acid and avoid prenatal defects. It makes a lot of sense to me.

DR. GORDON: I just want to interject a process note. It is 20 of 3 already, and I would like to move through as quickly as possible with only comments that bear immediately on the recommendation and then to make a decision on the recommendation as quickly as possible.

DR. FINS: What criteria will Treasury use to determine whether something has crossed a threshold to say that it is safe and effective?

MS. MILLER: Again, I raised that issue in some conversations over the last few days, and what I am told is that Treasury will not do that and that is the way the current policy works for conventional medicine. What will then happen is it gives the insurance companies and the employers the freedom to design those packages and they decide what is safe and efficacious, which is what happens now on the conventional side.

DR. FINS: No way linked to Medicare determinations?

MS. MILLER: No.

DR. FINS: Okay.

DR. LOW DOG: I just say I support the recommendation and I don't have any further edits or anything.

DR. GORDON: Can we have consensus on this? Yes? Okay.

MS. MILLER: Okay.

DR. GORDON: Can you live with it?

PARTICIPANT: I can live with it.

DR. GORDON: Okay.

MS. MILLER: Okay. Joe, we can live with it.

DR. GORDON: Let's move on.

MS. MILLER: Okay. The next section was medical effectiveness, and there are two recommendations in this section and they start on page 10. And the first one is that we recommend that the Secretary of HHS convene a public-private task force to develop a multi-year research plan. And the intent of this is to get all parties, all the stakeholders, all the groups together since there are limited resources, limited budgets, identify what needs to be done, what the actual research issues are, how some of these methodologies are the same or different from but certainly of the scientific quality. Basically, what it is that we need to do in health services research for the next five years to give everyone guidance on this.

Yes, Joe?

DR. FINS: I am just wondering. It just is a semantic question about whether or not this should go into the Research section as a recommendation because it is basic clinical epidemiology and public health research methodologies. And it is certainly in the Access and Delivery theme, but the question is there is a whole side

of CAM research that is not basic science or clinical but health services. So I am just wondering as an editorial decision where the next couple go.

MS. MILLER: Right. I think we will work with that.

DR. GORDON: You will work that out?

MS. MILLER: We will work that out.

DR. JONAS: If you do bring it into the Medical Research section you will have to cut it markedly down because we don't do anything that we have to take a breath on.

[Laughter.]

DR. JONAS: And I do want to point out that we spent a lot of time in the Research section cutting out a lot of these wordy extended things which we are now keeping in these, and I think this is an issue that will need to be addressed. If we are going through and wordsmithing things right now and end up deciding, well, gee, we want the more tight, pithy recommendations later, then a lot of this stuff is going to get cut out anyway. Or, perhaps if you don't want to do that, then we need to go back and look at what we cut out in the Research

section to make it more flowery.

We do have a section on health services research, by the way.

DR. FINS: It should be basically in one place or the other.

DR. GORDON: Can we defer this to a discussion between the committees as long as we are clear on the recommendation at this point?

MS. MILLER: Okay.

DR. GORDON: So we have consensus on this one?

Okay. Let's move on.

MS. MILLER: Okay. No. 5 in this section is that federal agencies, the states, and private organizations then fund this research as well as demonstrations. And in particular we identify the underserved and vulnerable populations with this regard, the various models of integrative and collaborative CAM, providing CAM services that have been mentioned as just some examples of what would be done, which in the pithy note we could take that out.

PARTICIPANT: Move it to Research.

MS. MILLER: I'm sorry?

PARTICIPANT: This one belongs in Research.

MS. MILLER: Okay. Is there general consensus, though?

DR. WARREN: You have got another part to this, don't you? That is the next recommendation. Looks like it could be included into the same one and then passed off to Research.

MS. MILLER: You mean 4 and 5?

DR. WARREN: The cost and cost effectiveness needs to be all in one in this demonstration project. You don't need two different demonstrations.

MS. MILLER: Right. We have kept them separate to now and I mean I think this will ultimately be like Steve's decision when we were looking at how the report pulls together because these were very critical issues to the Coverage and Reimbursement issue. And the kinds of health services research which we will want to explain more fully in the text the next go-round will get at those kinds of issues, not to say that Gerry Pollen and Wayne aren't interested in these issues.

Gerry is saying another possibility is to just reference them and tie them together if we are going to

leave them in separate sections.

DR. FINS: I think that all the health services research should be in the same place and we should have some sort of hierarchy. We recommend health services research to do cost benefit analysis, integration, stuff that was in our last session that is in Wayne's area. We should bring it all together.

MS. MILLER: Right.

DR. JONAS: The intent was to go through the recommendations, get agreement on them, and then reconstruct where we are and where are we going.

DR. GORDON: Okay. So, do we have consensus on No. 6? Yes? Everybody? Okay. No. 6. Health services research and demonstrations.

MS. MILLER: Right.

DR. GORDON: We have got 5, we have got 6.

MS. MILLER: Right.

DR. GORDON: Let's go to 7.

MS. MILLER: And then there is 7, which specifically addresses coding. This is a little different. As we discussed last time, this coding is a complicated area. There are a number of competing

interests and political issues here that cannot be resolved during the course of this Commission. So what we were suggesting in this recommendation is that it be done within the Department. It would probably be spearheaded by this CAM Central Office, but to basically pull the right parties together, conduct a study, do a report, and make recommendations on taking care of this.

Can people live with this? Okay.

DR. GORDON: Okay. Good.

MS. MILLER: All right. Then the next section is licensure, and I think we mentioned this earlier in Access. We have kept this here and we have kept it on our agenda specifically as a barrier to coverage and reimbursement, and that is the sum total of our interest in this topic. All other aspects, of course, are in Access and were fully discussed at the prior session.

So, specifically in our mind, the barrier here is really action at the state level, whatever they choose to do and whatever advisory groups or whatever happens. We are not speaking to that but what we are asking here is that as states confront this issue of licensure that they build into it the fact that they are blocking access

to CAM services if there is no licensure.

DR. GORDON: The question is whether licensure should be specifically mentioned as a barrier because that doesn't appear in here so it is a little hard to know what we are talking about.

MS. MILLER: At the time we drafted this the language of choice was "legal authority to practice" since that is broader and it covers licensure, registration, the various types of regulation.

DR. GORDON: Then maybe it needs to be made clearer in the text what we are talking about and why. It is hanging out there without more justification.

MS. MILLER: So, is there general consensus?

DR. GORDON: Okay.

MS. MILLER: Okay. The next section is where we have dealt with medical necessity and appropriateness. I have to say the last time there didn't seem to be a lot of enthusiasm for that discussion. There wasn't any palpable excitement in the room on that subject. And in our work group discussions what we came back to was, okay, well, in dealing with this micro-level process of who determines whether a service gets paid for, it is

covered as a benefit. Say again hospice care, as an example, is covered but when will it be medically acceptable for it to be covered because not just anyone who wants hospice will get it.

And when we looked at CAM and how this is currently working in the outside world, what is being effective, what came out of that was the NIH consensus conferences on acupuncture where there is a federal body, either ARC or NIH, that comes out with some statement about CAM that consolidates all the research literature and provides some guidance to when this is a useful, safe, and efficacious procedure or intervention. And so we opted to switch to that tactic to get your reaction rather than to get into the nitty-gritty of insurance companies and their processes. I think there was some sense that that would be faster than trying to deal with the insurance companies.

Yes, Joe?

DR. FINS: I don't understand. There are two parts to 9, it seems to me. And Part 1 is that all those agencies -- and I think I would add ARC to that list since they would probably expect to be on that list -- to

identify CAM interventions of importance to patients, health care providers, and the general public, which is one question. And then the second part of it is where there are areas of disagreement you need consensus statements. I think the first half is important. The second half is a different issue. I mean there are things that are important that people will agree on and there could be things that people find important but there is disagreement or a lack of accord on what the appropriate intervention is.

And also, a consensus statement or consensus panel means something very specific. It is usually in the context, how do we treat hyperparathyroidism and how high does the calcium go before we do the operation, you know what I am saying?

MS. MILLER: Yes.

MR. GROFT: Well, I think we said "state of the science conferences" rather than "consensus development conferences."

DR. FINS: It is different in health services. One is sort of a public needs assessment of public impressions and the other is where there are

controversies in the science, it seems to me. At least that is how it is to me.

DR. GORDON: I don't see necessarily the controversies part. I mean I don't see it. It is not spelled out there.

DR. FINS: If you are talking about reaching a consensus usually you have a disagreement.

MS. MILLER: I did review the consensus guidelines, actually Wednesday before we came here. There was a broad ranging participation and topics discussed on acupuncture and it was different from the sense that they didn't talk about treating one medical condition but they talked instead about all the research where acupuncture has been proven or not proven to be effective and they laid that all out.

And from what we are told, that has actually been the document that has been driving coverage of acupuncture around the country. That is what they used. They set their coverage guidelines around the NIH consensus conference on acupuncture. We may have heard that in May but I know we have heard it subsequent.

DR. FINS: Maybe you simply want to add

coverage consensus statements on issues of coverage and reimbursement.

MS. MILLER: And I am not sure NIH would do that.

DR. JONAS: Yes, I think that is the point, actually, is that this is misplaced, I think. Consensus conferences are used for a variety of reasons, not just single reasons, often to address controversy, as you have mentioned, but also sometimes to get the information out about data that does exist. It is something that is safe and effective and it is not being utilized, then they will have a consensus conference and say that. They aren't necessarily focused on payment, and as you have said, I think it is probably unlikely that the NIH would do that. And there is also no statement in here about payment, so I think if that is the goal of this recommendation it is not hitting what you want to have it do and so it needs to be changed.

DR. GORDON: One possibility is that it be part of Information or Research rather than here in Reimbursement, or else that it be justified as part of Reimbursement. Is that what you are saying, Wayne?

DR. JONAS: Yes. I mean in the Research section we actually have a whole section that deals with doing summaries of the current state of the science and evidence, so this is already dealt with in that. It isn't necessarily targeted towards any application of that but it is often used for that. And even though the consensus conference on acupuncture is being used by some groups to make determinations about payment, that is not what its goal was. And if so, it is not very effective for that because there were only two conditions in which it was stated to be effective and those weren't even the ones that acupuncture is usually used to treat.

MS. MILLER: Yes, Tom?

MR. CHAPPELL: I like this recommendation. I think it helps provide evidence ultimately for the different insurers to reimburse because there is a process, there is agreement, and I think in many, many cases they are looking for some general body of agreement on certain things rather than making an arbitrary decision. So I like the opportunity here that could result in greater and broader agreement on reimbursement.

So I would like to see the recommendation

passed with the edit to the last phrase where we say, "conduct conferences to produce consensus statements that lead to reimbursement."

MS. MILLER: No?

MR. CHAPPELL: "That can lead to reimbursement."

DR. FINS: When we tried to reconstruct how we got to this recommendation in the group -- and I might have missed one of the phone calls but -- there were several tracks that were going into whether or not something could be considered for funding, for reimbursement as an entitlement of some sort. One, was it safe and effective? The second was based on public desire and interest, that they really were clamoring for this thing to be covered. And I think what this was meant to do, at least in an earlier iteration, was establish a mechanism to decide whether or not something might be considered for funding for inclusion in a benefit package. And also, I think the consensus phrase was meant to invoke a priority-setting process, to rank order or something like that, to reach a consensus on what the priorities were.

But I think as it stands right now there are a lot of things that are implicit in here.

DR. GORDON: Do you like the edit?

DR. FINS: I like the first half, like what people find important, which might have been addressed elsewhere. I think the state of the art of the science is addressed in the current knowledge things that were in the Research section. And I think that this was really meant to reach a consensus on whether things should be covered or reimbursed.

DR. GORDON: Let me ask in the interest of time that either we come up with wording now or we ask the committee to reconsider this one -- there are a lot of implications -- and then come back with a recommendation, okay?

MS. MILLER: I am seeing heads shaking for the latter, that we go back as a group and work on this.

DR. GORDON: Okay. Great.

DR. JONAS: I would just suggest you take out NIH so that it doesn't get tagged with that process -- but that also broadens what Health and Human Services can do -- and that you tag it to reimbursement if that is

what you want.

DR. GORDON: Great. Thank you.

MS. MILLER: Good suggestions. Thank you.

Okay. The last section that addresses a barrier is supporting coverage and reimbursement through information. And I have to admit this is one place where we are saying we want something more than fair and equitable treatment. We think an extra boost is needed here because payers and providers often just don't have the information or know necessarily where to get it, and the growing body of CAM literature is a bit overwhelming at this point. And I do reiterate "at this point."

So we have four suggestions under this area, the first being that rather than having HHS set up a new website, which is the more general language we had the last time, is that the NCCAM through their clearinghouse mandate that they take this on, providing information specifically that has to do with health services research, with costs and cost effectiveness of health care. And I had discussed this with Corinne that we extend or expand what NCCAM is doing to include some of the research and topic areas that people in payment are

interested in.

DR. JONAS: Don't they already do this? I mean they have not excluded research on cost and cost effectiveness in their clearinghouse.

DR. GORDON: Is it there? Corinne, do you know? I had a related question.

DR. JONAS: Would you like them to do a summary of that information? Pull it out of PubMed, for example, and do a summary of it? Because you can find it. Just type in "cost effectiveness, CAM." They are tagged that way. You can find that information. You will find about four studies.

MS. MILLER: Yes. That was my next point, which is, I think we raised it because there is not a lot now, but we are pushing this agenda to build this mass of health services research which will be coming out in future years. It is basically to make sure that it has been in an accessible place.

DR. JONAS: I think if you are talking about producing information out of what is out there, then that is different. I mean then you are asking them, all right, we want you to produce a summary, we want you to

collect it in one place, do an evaluation of it, and do a summary of it, or something like that. That might be more useful. Again, I am not sure who should do that. They could do that.

MS. MILLER: Yes?

DR. FINS: I don't think they should be limited to just the lay public but professionals also need this information. And I think it fits more cogently in the Information section with all the other dissemination products.

MS. MILLER: Right. Again, that was part of the process when we go through the final report.

DR. GORDON: I agree, Joe, that we may want to change the location, but what about the recommendation itself, Wayne's suggestions, any other thoughts about it?

Wayne, do you want to reword it or do you want it the way it is?

DR. JONAS: Well, again, it depends on what the Commission's goal is. If the goal is to summarize the information on cost and cost effectiveness in CAM so that we can have that information to make decisions, then I think we should ask that specifically. We would like

NCCAM to do a summary of current information on cost and cost effectiveness pulled from various resources, not just their information, and make that information available through their clearinghouse. We can say that.

DR. GORDON: I would add to that that they do it on an ongoing basis, that it not just be one summary.

DR. JONAS: Okay. Ongoing summary, updates.

DR. FINS: Is the staffing at NCCAM constituted to be involved in a health services research arena or is it more like clinical science and basic science?

DR. JONAS: They actually have a mandate to do health services research in their appropriations language.

MS. MILLER: Yes. I thought I heard at one time that they really weren't quite up to full readiness on doing health services research, but we can build that up in the text, too, and talk about how to handle this.

So, my sense is there is general consensus but we need some rewording that targets more clearly a specific goal for this information.

DR. GORDON: And I think the question that Joe raised, too, that you are addressing now, Maureen, is, is

it appropriate to ask NCCAM to do it or should we ask that it be done? And maybe you can talk with NCCAM and see if they are appropriate.

But would you agree, Wayne, the important thing is for it to be done? Or do you think it is important that it be at NCCAM?

DR. JONAS: I agree. I don't think the particular location matters. I mean a variety of other agencies could also do this.

DR. GORDON: Okay.

DR. FINS: And since this is really on the health services research front, I would delete the "safe and effective CAM services and products," which is addressed in other parts of the dissemination model.

MS. MILLER: Okay.

DR. GORDON: I'm sorry. I didn't understand that, Joe.

DR. FINS: This is an Access and Delivery information piece, which is not about safe and effective services and products but really health services research and demonstration projects and cost models and cost effectiveness. It is this category of information we are

talking about, not whether or not something works, which is covered in other areas of the report.

MS. MILLER: They should include things that have been proven not to work.

Okay. Let's move on to No. 11, that "The Commission recommends that appropriate federal departments report to the President and Congress" -- we should add "periodically" or "every two years," something, "on the status of coverage and reimbursement and impediments to coverage and reimbursement within their respective programs."

This would be CMS for Medicare and Medicaid, the Defense Department, the VA, as well as OPM for the federal employees. And this is in here because having these large agencies on the line to report on this is a way of keeping them moving in this area. They don't like it.

DR. WARREN: Part of this report would be like a trans-departmental force, or what would it be to get this report out every two years?

MS. MILLER: Well, we discussed having one report for everybody but that would be administratively

impossible in the federal government so each agency would do their own. And we can make that more clear, Don.

DR. GORDON: Okay.

MS. MILLER: General consensus? Sounds like there is. Okay.

12. This is a general recommendation, again to the private sector, that the movers and shakers of health policy as they are sometimes referred to, primarily the various associations and provider organizations out there for the insurance industry, for HMOs, for hospitals, professional groups, practitioner groups, that they basically start talking about CAM at their various annual meetings and policy meetings that they have every year.

Yes?

DR. FINS: It is not like something we can really effectuate. I think that goes in the text. And I think it goes in the Education section better as part of what professionals need to know or executives need to know.

MS. MILLER: I think it was felt by some of the other work group members of using the Commission as a bully pulpit on this.

DR. GORDON: The question I have here is whether there is anything we want to ask the government to do to help to make this happen.

MS. MILLER: Jim, it is in there. Just wait. The last one is you.

DR. GORDON: Okay. That is good but I want to know if we want to do more than just provide information.

MS. MILLER: Oh, it was meant to be funding to help develop informational programs. I think that is what you had asked for the last time. I'm sorry.

DR. GORDON: Yes.

MS. MILLER: If this is a new idea --

DR. GORDON: No, no. That's fine. I did ask for that, and maybe that's enough to do it. The question is, what we can recommend to the government to make sure or to encourage Recommendation 12 to be enacted by the private sector.

MS. MILLER: I can't think of anything myself.

DR. FINS: Can anybody think of anything?

DR. WARREN: It still should be there.

DR. GORDON: What Maureen was saying is that in No. 13 we provide a bit of a carrot in terms of providing

money for information. I am asking if there is anything that the government might do to encourage insurance or managed care associations, aside from -- which is kind of dropped out until the end -- the whole issue of Medicare in particular but also Medicaid because one of the issues with Medicare is that if Medicare provides coverage that certainly pushes along the whole process for covered benefits generally.

MS. MILLER: That is true. We have made no recommendation here that Medicare cover anything specifically, and I think it is felt that in this instance it is actually going to be easier and quicker for employers to do stuff than the federal government, particularly with the prescription drug benefit on the line. They are not even acting on that this year.

So oftentimes CMS does serve as the 800-pound gorilla in leading people in coverage, particularly like transplants, but in this case employers are leading the coverage in this field and I think from the experts we have talked to that is likely to continue.

I have gone to some of these annual meetings of the managed care industry and the insurance industry and

they have annual policy meetings, they have wide-ranging topics. I am on their mailing list. Never have I seen any of these CAM topics addressed by these industries. I mean, it is just intricate, those chains.

DR. JONAS: You haven't been to the summit meeting that John Weeks puts together?

MS. MILLER: No. You can invite me.

DR. JONAS: Okay.

DR. GORDON: Okay. So then maybe what I am looking for, and I think I talked with you about this specifically, is to specifically mention federal agencies and not just put them in the implementation responsibility, perhaps back under No. 1. I just think we have to somehow even though it is implied to make it clear that we want federal agencies to be covering safe and effective CAM approaches.

DR. JONAS: I agree, and I think if you wanted one recommendation to get the federal government to at least examine which areas might have the potential for reimbursement or coverage under CAM, that you would specifically ask Medicare and Medicaid to do that, because then they would do it using the processes that

they normally apply and get it on the radar screen.

DR. GORDON: Would that be another recommendation?

DR. JONAS: I would think that is a separate recommendation.

DR. GORDON: Okay.

PARTICIPANT: I second.

DR. JONAS: I agree with you that it may be difficult to get them to do it. It won't go as fast as industry. That doesn't necessarily mean it shouldn't be done.

MS. MILLER: The reason why it is more complicated for Medicare to do this than an employer is because they have to change the statute in 1861 about who can provide services. At this point acupuncturists are not listed, massage therapists.

So it is not just a matter of coverage for them, it is a matter of also then going through this separate process within this big federal agency of deciding who can provide the services.

DR. GORDON: Understanding the complexity, I think there is still a desire to make that

recommendation.

MS. MILLER: Okay, you all want that. Can you give me the language, then?

DR. JONAS: At least catch them up with the Flexnor report.

MS. MILLER: Can we have some language here?

Ming, then Linnea.

DR. TIAN: Well, first, I second with Wayne. I think it is very important that we recommend, and Medicare and Medicaid, also the ground policy, to consider to cover CAM services provided by licensed practitioners, both physicians and non-physicians.

I think this point has repeated in the past one year and a lot of the non-physicians of acupuncturists and the other CAM practitioners mention this, that we are not included yet.

DR. GORDON: I think that point is covered now under No. 1. Wayne's is in addition.

I think you were saying something in addition, Wayne. Do you want to repeat it?

DR. JONAS: Well, I think we should recommend that Medicare and Medicaid specifically evaluate what CAM

therapies look like they may have potential for reimbursement and we might throw in there identifying what issues need to be addressed in order to move that forward.

DR. TIAN: Medicare and Medicaid should be another issue, just one recommendation separate to government policy, if I may suggest.

DR. GORDON: We have two things on the floor. We have Recommendation No. 12, then we have a new recommendation. Maybe we should address Recommendation 12 and 13 and then go to the new recommendation.

Is that okay, Wayne?

DR. JONAS: That is fine. I had just one other item about Recommendation 12. Joe mentioned that under Recommendation 10 we should take out "safe and effective" because we want them to address all the CAM, not just those.

I think the same thing would apply for No. 12, "insurance, managed care integrate information regarding CAM interventions," not just about safe and effective but also ineffective ones.

MS. MILLER: Okay.

DR. GORDON: We are on No. 12. Anything else on No. 12?

DR. JONAS: As Dean on No. 12, I have to say I disagree with removing "safe and effective."

[Laughter.]

MS. MILLER: If you didn't do that, I was going to do it for you. You have to talk to Dean on that one.

Okay, Joe?

DR. FINS: We have had this conversation in the past, and I think what we decided, and I think, which is partly why Recommendation No. 1 read the way it did, was that whatever standards were in existence to make something eligible for Medicare coverage should also exist for CAM. It shouldn't be a higher standard or a lower standard.

It was in the context of that deliberative process. If it was safe and effective, it should be funded, not because it was CAM, because there was something that was effective and safe, or not. I don't want us to get into the position where we are funding CAM preferentially over other things.

I think it is especially important to be wary

about, say, funding a supplement before you have a Medicare drug benefit. I think that is illogical.

DR. GORDON: Yes. I think that is understood for No. 1. I think the issue for No. 12 is somewhat different, and I tend to agree with Wayne more than with Dean, because --

[Laughter.]

DR. GORDON: The issue here is, people should have information about things if they don't work as well as if they do work.

DR. FINS: Right. Absolutely.

MS. MILLER: Right.

DR. GORDON: And so, if we just have "safe and effective," then we are limiting the range of information and we are not performing this as we should.

DR. FINS: Right.

DR. JONAS: But that doesn't apply to No. 13, however. "Safe and effective" should remain in No. 13.

DR. GORDON: Do we have a consensus on No. 12 if we strike "safe and effective"?

PARTICIPANT: Right.

DR. GORDON: Okay?

MS. MILLER: Okay. And then 13 is basically asking the Secretary of HHS to support the development of information programs on safe and effective CAM treatments, or interventions which can then be targeted to purchasers.

I assume this would -- I am not assuming, I am stating this would include CMS for Medicare and Medicaid, as well as insurers and managed care organizations, a wide range group, professionals, providers, the whole gamut.

DR. FINS: But Nos. 12 and 13, I am just wondering. I agree with Wayne's point, and this side of the table, about taking out "safe and effective," but does that convey that we also want adverse event information to be conveyed?

DR. GORDON: I think the same should be there in 13.

DR. FINS: Right.

DR. GORDON: Because the issue is just giving them information.

DR. FINS: Maybe in the Information section -- is Corinne still here? Corinne, yes. Do they have any

journalists-in-residence program from the trade publications? Do they have programs like that where they have visiting journalists at any of the institutes?

I am wondering if that could be something that would help get the word out into the various trade publications, and we could have journalists in NCCAM just to help with information flow as a fellowship, or something like that.

Is this an idea that you have kicked around?

MS. AXELROD: No.

DR. GORDON: Do we have a consensus on No. 13, then, as amended? Wayne, do you want to state the other recommendation, so we can have discussion on it?

DR. JONAS: I didn't write it out. Just give me a minute.

DR. GORDON: Maureen, anything else we need to go back on? We are okay at this point?

MS. MILLER: Yes. While Wayne is thinking, the intention was that all federal programs were included because they are purchasers in Nc. 1. We can either take an approach that splits them out separately and gives them a special charge, and then have another

recommendation that targets everyone else. But the intent was to not let anybody out.

DR. GORDON: Yes. I would single them out. Again, I think it is an area where we should make a specific statement because we are representing the people, who are, in turn, speaking to their government.

DR. TIAN: I agree with that. I support James's idea.

DR. JONAS: I think the wording is fine in No. 1 but, again, I think it should be split out and specified, requested that they do this.

MS. MILLER: So, am I hearing that instead of putting Wayne on notice here on draft language, that the group will take this back and split this No. 1 into two, 1(a) and 1(b), one that specifically targets federal programs?

DR. GORDON: Yes. Wayne, do you have the recommendation?

MS. MILLER: Oh, I think I was letting him off the hook.

DR. JONAS: Yes, she let me off the hook.

DR. GORDON: All right. We are going to make

it sounded like a different kind of recommendation. No. 1 really relates to safe and effective. You were making a recommendation that Medicare and Medicaid should evaluate CAM to see whether -- I was thinking you were extending the reach of that.

DR. JONAS: Well, you could do it either way. I mean you could say, are there established CAM therapies that now meet our current standards for reimbursement? Let's look at the entire field and make a decision on that.

One could add to that, or request in a report like that, that we also make explicit what criteria are needed in complementary medicine. If we assume that they are going to use the same standards that they use for conventional, then that may end up being redundant, but if we think there are some unique characteristics and would like them to look at that, then that could be added to it.

DR. GORDON: That is still slightly different from No. 1.

MS. MILLER: Yes.

DR. GORDON: Therefore, it constitutes another

recommendation, if you are going to make it.

DR. JONAS: Yes, if you were to extend it and also ask for an examination of the criteria for reimbursement in the area of complementary and alternative medicine, then that would be an additional item.

DR. GORDON: Part of what we were, I think, talking about was that we needed to demonstrate for demonstration projects the safety and efficacy of various things. We should not be here thinking about creating a whole new entitlement class, but we want the process to be evaluated and the evidence to be generated. Then it will go into the same mix.

I mean, the private sector can do whatever they want, they can establish a benefit package that includes this or not, but a federal entitlement would be under the rubric of Medicare or Medicaid, and that has profound implications.

DR. GORDON: This is a somewhat different point that Wayne's recommendation is making. It is talking about a process of evaluation, which is somewhat different than covering safe and effective, to the effect

that the evaluation presumably has already been done.

DR. JONAS: I mean, it is essentially like what we have asked in the research field, that methodologies be explored. We begin to look at research methodologies separate from just looking at particular topics, using standard methodologies.

It is essentially saying, please look at your methodologies in relationship to some of the unique characteristics, or special characteristics, of complementary and alternative medicine, and provide guidelines in terms of what is needed in order to provide benefits in these areas.

MS. MILLER: Included in the text will be a description of the current Medicare process and some discussion about how that might be fairly and equitably extended to safe and effective CAM services. If that tracks with what you are thinking about, Wayne.

DR. JONAS: Well, I assume that if they look at the area of complementary and alternative medicine, they will use the process that they have established. So that is for looking at things now.

I think what Jim is highlighting is that, if we

want them to look at the methodology in relationship to some of the unique characteristics of CAM, that we could ask them to do that also. Those are separate items, although they could be bundled. I mean, you could request them separately. They could be done together. I think probably there is not a whole lot of information about cost and effectiveness, and reimbursement issues and CAM.

DR. GORDON: So I would like to get a fix on where we are. Do we want to make a recommendation at this point, or do we want to send it back to the group to generate the appropriate wording?

Where are you with this, Wayne? Or Joe?

DR. JONAS: I think Maureen has the spirit of what we are talking about.

MS. LARSON: I would like to recommend that we put it back to the group and put it inside the text, that specific information that you were just talking about with respect to the procedures and protocols for Medicare. Then the group can consider the wording of a recommendation for looking at the methods, the text.

DR. JONAS: I mean, one of the issues that

keeps coming up in this is, how do you get things that are valued, that deal with wellness, for example, and health promotion that are very difficult to research, identify, et cetera, et cetera, but we still want them in some way, what process should be done to address, to enhance those, to bring them more up front.

So, if that is what we would like, then we could particularly ask them to do that. Let's look at your process in relationship to these kinds of aspects of CAM, and say, is what we are doing adequate for that. If not, what suggestions or modifications are there?

DR. GORDON: It sounds like what we have agreed to do is to refer this back to the group, as Linnea was suggesting, to address the issue that Wayne is raising, rather than try to come to consensus on wording right now. Is that correct?

So, can we do that, and then include others in that discussion who are interested in the topic? Great.

Thank you very much, Maureen. It was great.

[Applause.]

DR. GORDON: So the next section will be on the proposal for a central office for CAM Central, and Don

Warren will take us.

Discussion Session VIII: Coordinating and Centralizing Federal CAM

DR. WARREN: Thanks for warming up that seat for me, Maureen. We are adjourned.

[Laughter.]

DR. WARREN: I want to say that last time, that was the first time we had ever reached a consensus vote of 100 percent, and what we were in consensus about was a draft recommendation to create an office at the highest level, a CAM office.

Let me read it: "The Commission recommends that the president, Secretary of the Department of Health and Human Services, or Congress, should create an office at the highest possible and most appropriate level, with sufficient staff and budget to perform the functions that include but are not limited to coordination of federal CAM activities, federal CAM policy liaison with conventional health care and CAM professional organizations and institutions in commercial ventures, planning and convening conferences, workshops, necessary advisor groups, centralized CAM media point of contact,

and facilitation of implementation" -- that is what happens when a Southerner tries to talk fast -- "of the White House Commission on recommendations."

The reason you got all the background information when you came, is because, basically, the duties of this office, the fleshing out of the duties of this office, depends on what each one of your committees came up with, and it is still in the making. It is not completed yet.

So all the things that we agreed on in this meeting the last two days, that have the possibility of being included in CAM Central, for lack of a better word, they will be included in it.

At the last meeting, we were asked to develop functions for the office. I believe that each one of your committees has developed those functions for the office. We have five overlying proposed responsibility areas that each one of these recommendations that you come up with will be utilized into. Let me just go through those, right quick.

No. 1 was the "coordination of federal CAM activities." And what we are looking at is establishing

a trans-departmental committee of all the federal agencies that are interested or have any play in CAM and getting their input. If we can't get the input of all these federal agencies, then they are going to fight us tooth and nail, so we are looking to incorporate their activities into this.

"Conduct a baseline survey," and how many times this week have we talked about surveys? Survey of this, survey of that. Conduct a baseline survey of CAM activities in the federal sector and report it. How many times were we given a time frame to make a report? I like that.

"Provide expert advice and consultation to the Secretary on CAM." We would expect that the Secretary of DHHS would call in the head of this CAM office and consult with them.

No. 2: "Federal CAM policy liaison with conventional health care and CAM professional organizations, educational institutions, and commercial ventures. Planning and convening workshops and conferences." We had many recommendations about that. Being a federal media point of contact. That is that 800

number that Corinne was talking about. They call in, it is not a give-all-the-information thing, it directs callers exactly where to go.

"Facilitation and implementation of the recommendations," and I think this is by far the most important part of the whole operation right here is if we can't get our recommendations implemented they are fodder for the trash can.

Anybody have any comments? Fire away.

SISTER KERR: I just want to clarify that -- Charlotte -- from what you said, is it true that all the recommendations that would come out of this Commission would fall under this to be implemented? And it is not just certain ones that, well, obviously, were inappropriate for this oversight?

DR. WARREN: Let me make sure I understand you. You are saying that all of the recommendations that come out of our commission fall into this office responsibility of implementing them?

SISTER KERR: Yes.

DR. WARREN: No, no.

SISTER KERR: Okay.

DR. WARREN: All they are trying to do is work it through the system, facilitate it, get it moving, and have somebody there to prod the system.

SISTER KERR: To facilitate the recommendations?

DR. WARREN: Facilitate the recommendations.

SISTER KERR: That is what I meant. I'm sorry.

DR. WARREN: Not actually implement them.

SISTER KERR: Right. Sorry.

DR. WARREN: Just to make all the different systems work.

SISTER KERR: Thank you.

DR. WARREN: Linnea?

MS. LARSON: Just going through all the recommendations, this office is not charged with the implementation of all the recommendations. And usually, if you look at the recommendations it indicates who and what is the activity.

DR. WARREN: That is right.

Joe?

DR. FINS: Related to that question, though, how do we ensure that this person in this office, which