Full Committee Discussion of Draft Coverage and Reimbursement Report
Facilitators: Cynthia E. Berry, J.D. and Reed V. Tuckson, M.D.

DR. TUCKSON: We're going to move now until 12:30 to start and then we'll reconvene after lunch and continue our discussion on the draft report on coverage and reimbursement. As I mentioned in the earlier comments, and to make sure also that our new members are well aware of the history of this, we determined last year that coverage and reimbursement of genetic tests and services was a high priority, requiring in-depth study, and we started working on it as a result in our March of '04 meeting.

We gathered perspectives on the issues from experts in the public and private areas. We appointed a task force to investigate these issues more deeply, and that task force held a meeting last September and developed policy options. At our October meeting we reviewed the draft report and made significant headway in our deliberations about the proposed recommendations. We have also engaged -- and I will tell you that staff has been terrific. We have gone to experts far and wide and reviewed every line of this report from every possible way, and the report has grown I think considerably in sophistication, precision and so forth. So the staff has just been really terrific. We've really worked them very hard.

You have the latest document or version of this in Tab 6 of your briefing book. Again, that document is considerably different than where we started and is really moving forward, I think, to really becoming the document that we had hoped for. In addition, some outstanding issues with regard to genetic counseling services became identified through this process. A small work group was formed to gather additional information on those issues, and we'll be re-hearing a report from that group later this afternoon.

I'd like to thank Cindy Berry for her leadership on this issue, as well as Emily WINN-DEEN, Debra Leonard, Marc Williams, Francis Chesley from AHRQ, Muin from CDC, and Steve Phurrough from CMS.

I also want to acknowledge Suzanne Goodwin and Amanda Sarata. I've already commented on their extraordinary work.

Cindy will now review the changes that have been made to the report over the past few months and then lead the discussion as we further refine the draft report, and then get it ready for gathering the public comments. So again, even after we've gotten this as tight as we can possibly get it tight, then of course it goes out for public comment, and we'll get some more input. But I will tell you, this has got to be really letter perfect as it goes out there because it will gain a lot of attention.

So with that, let me turn it over to Cindy.

MS. BERRY: Thank you, Reed.

I also want to echo Reed's comments with regard to staff. This report is an enormous undertaking, and Suzanne, Sarah, Fay, and Amanda just really performed heroic efforts, and I'm not exaggerating. I mean, really when you think about all of the input, all of the comments, having to deal with all of our edits and comments and put this together in a thoughtful way, it really was nothing short of heroic. So I want to thank them and recognize them.

To start, we can go over what this session is going to try to accomplish today, and that is to review the report thoroughly. In the course of putting together this report, as Reed mentioned, the issue popped up with regard to genetic counseling. We all instinctively knew that that's the type of service we think is beneficial and should be provided and should be reimbursed appropriately and should be covered, but we all sort of leapt to that conclusion. So we thought it would be useful in the context of this report to have some background work done that would support our conclusions. So that work was done by this working group, and we will be briefed by them.

The other purposes of our session today is to go through each barrier to access for genetic tests and services, and then proposed recommendations, most of which you've seen before in earlier iterations of the report, and then ultimately we want to reach a consensus on the recommendations so that we can finalize to the extent that it's not a final-final report but final before being issued for public comment, finalize the recommendations, and then formulate a plan for gathering public support on the recommendations that we agreed upon.

The report itself is really designed to identify the problems of coverage and reimbursement that genetic tests and services are facing and that limit accessibility and integration into the health care system. The report is designed to describe the current state of play, what are the problems, what are the barriers, and then to offer recommendations for how we can address these specific barriers. Then the ultimate goal, of course, is to improve access to and utilization of genetic tests and services by ensuring appropriate coverage and reimbursement.

This slide identifies how the report is structured. As Reed mentioned, it's in Tab 6 of the briefing book. These are the different sections. Previous iterations of the report had the overview of the U.S. health care system as more of an introduction to the report. We moved that into the appendix and restructured the report from the last version you saw in a way that makes a little bit more sense. It addresses the specific issues and barriers and recommendations together.

I should lay out the ground rules here for our discussion. I was going to bring with me a whole arsenal of air guns and water guns and pistols and all kinds of probably horribly politically incorrect weapons in an attempt to keep us focused. So what we decided we were going to do -- this is kind of a congressional thing here with this light. Twenty minutes for each recommendation. What we'll do hopefully is spend a little less time on the recommendations that we already analyzed at our last meeting, because we went through a lot of that, adjusted the report and came up with some revisions. So hopefully we won't have to spend as much time on the recommendations we discussed previously.

The idea would be we'd have 20 minutes per recommendation. If we don't finish, then we'll move on to the next one, and any time that we have left over at the end, we'll go back to address that recommendation that we didn't reach consensus on. Hopefully this will keep us focused. We want to make sure that all of our comments are very precise, directed to the specific barrier and recommendation that we're considering, and we'll just ask everyone to keep that in mind as we move forward because we really want to get through all of the recommendations so that we can finalize this draft of the report.

With that said, the first barrier, evidence-based coverage decisions, we did discuss this at length at our last meeting. Hopefully all of you have had an opportunity to review the recommendation as it has been revised. I would ask the committee to provide us with some input individually as to whether you think this recommendation captures adequately the committee's position on this matter, and then specifically to ask -- can everyone see that?

You have also in your books, and I should call attention to that -- is that in the folders or in the briefing books? -- the actual recommendations so that you can have them in front of you if you can't see them up on the slide.

But we discussed having some sort of group or body to develop a set of guiding principles with regard to which types of genetic tests and services should be covered, and when, and one of the questions and one of the issues that we talked about the last time was the EGAPP as a possible entity. Do we want to recognize them in this specific recommendation and suggest that they be the body, or do we want to keep it vague so that the Secretary could come up with some other entity?

I'll turn it over to the rest of the group. Debra?

DR. LEONARD: Well, having gone to the evidence-based review meeting of the EGAPP, I think we at least need to bring to the attention of the Secretary that the EGAPP working group exists and that it may be appropriate for filling this role. It's pretty much doing exactly what is stated in that first paragraph, looking at analytical clinical validity and clinical utility.

DR. WINN-DEEN: So would your request for that be taken care of by paragraph 2, which specifically calls out the EGAPP work group?

DR. LEONARD: Yes, and you might just want to say that the EGAPP work group is in the CDC, because it's not stated in there where it's from or where it's originated out of.

MS. BERRY: Do you think maybe as a mention of the EGAPP's mission and work as sort of an example but not necessarily designating them specifically in the recommendation, would that do the trick do you think?

DR. LEONARD: Right now the EGAPP process is in a two- to three-year pilot project status. So I think at least -- now Muin walks in after we've been discussing this for a while.

MS. BERRY: Muin, timing is everything. We're talking about the very first recommendation that's in the coverage and reimbursement report, and that has to do with tasking some sort of body to develop guidelines and principles with regard to what types of genetic tests and services should be covered and when. One of the discussion points that you were involved with the last time had to do with EGAPP and whether we should specifically designate them as that body or whether we should mention them in an illustration, or whether we should not have any reference to EGAPP and keep the recommendation more vague and leave it up to the Secretary to decide what the appropriate body would be.

DR. KHOURY: My advice is to mention them as an example but not charge them with things. Examples of these efforts are being done within the Department, and the Secretary will decide what he wants to do and convene the agencies to work together.

MS. BERRY: Ed?

DR. McCABE: Yes, that could be. You could take what you have and just say the EGAPP work group is an example of such a body. So it would be very easy to amend that second sentence of paragraph two.

MS. BERRY: And then take out the part about it may be an appropriate body to be tasked. We don't reach that conclusion?

DR. McCABE: We could say this is the kind of body that could be tasked. So again, it's an example, it's a possibility, but not tied directly.

MS. BERRY: Does anyone have any other comments? Debra?

DR. LEONARD: This is rather specific, but in the third line you say genetic tests always should be covered. I just don't like the word "always." It makes me nervous. So just to parallel the next statement, categories of genetic tests should be covered, should not be covered, and which fall into uncertain gray zones. Can we remove the "always"?

And then at the end of the second paragraph, I didn't understand -- well, that's going to be changed anyway, but I didn't understand what the last word, "raised," was. I think that can be dropped from the sentence and it will still be okay.

MS. BERRY: Any other comments on the first recommendation?

(No response.)

MS. BERRY: All right. We'll move on to the second one.

Barrier 2 had to do with the influence of Medicare on private plans and the fact that Medicare often is the model for private health plans in determining coverage of benefits. We discuss in the report the fact that genetic technologies are such that they may not be widely used or appropriate for more senior populations, and therefore Medicare is probably not the best model for private health plans that cover other populations.

So the next recommendation, this recommendation simply encourages private health plans to make their own coverage determinations about genetic tests and services rather than using Medicare as a model, and to a great extent I suspect that is already going on, and this is sort of a statement of that trend, I would say. But it's a recommendation nonetheless that addresses a perceived barrier, and we'd like to open it up for comments to any potential changes to that recommendation.

Emily, and then Reed.

DR. WINN-DEEN: Well, as it's written, it's talking strictly about Medicare. So if you intended this recommendation to be that Medicare is not the appropriate example, then I think we need to substantially rewrite this paragraph, because right now it's really referring to mixed local/national coverage decisionmaking, which is a Medicare process.

MS. BERRY: No, you're up one.

DR. WINN-DEEN: Oh, I'm sorry.

MS. BERRY: Reed?

DR. TUCKSON: Well, I think that your explanation of this section was different from what I got from what it says. So if you're trying to get at -- first of all, I think we benefit more in health care when things are more consistent rather than not. I mean, when you have mass confusion with everybody doing different things, if the evidence is there, the science is there, you want to try to get folks on the same page. Otherwise it makes it very difficult to navigate through complexity.

If you mean that, for example, pediatrics is not covered by Medicare, therefore there is a need for that not to be lost, then I think we should talk about pediatrics. But I'm not sure that we want to imply that it's best for everybody to sort of do their thing. I mean, I think we're trying to line these things up so there's some evidence-based consistency. So I'm not sure. I guess where I'm at a loss is what is the actual intent here.

MS. BERRY: Well, the idea, for example, that Medicare has a screening exclusion. In the private sector, however, plans often, as you know, do provide those types of services to their enrollees, and want to, and see a lot of benefit in doing that. So we shouldn't let Medicare dictate or hamper the private sector in determining what might be worth covering because Medicare is subject to statute that is very hard to amend and subject to congressional action, which as we heard from this morning takes a great deal of time.

So that's the idea, that it would be wonderful if everything were consistent, but Medicare has its own quirks and problems that we just want to make sure don't handcuff the private sector and prevent it from moving forward with coverage and reimbursement in this area. I hope I've captured it properly.

Ed, did you have a comment? And then Emily.

DR. McCABE: Well, I was thinking that you could just take what you've said and add it to this, arguing that standardization would be ideal, and then referring back perhaps to proposed recommendation 1 to look to for guidance in the standardization.

MS. BERRY: Emily?

DR. WINN-DEEN: I thought it might also be informed by putting some very concrete examples, such as the fact that children are often screened for genetic disorders and don't really fall under Medicare's purview. I'd also like to see us specifically mention the issues of -- I'll call it preventive medicine, of identifying risk factors early in life so that you can do something about it, which will benefit Medicare in the end maybe but is not going to be something that they're going to pay for up front. A lot of the issues in genetics are going to fall in the private payer arena, and thus somehow we need to get the private payers working together and standardizing how these things are going to be done in sort of the same way that Medicare works through local coverage and national coverage decisions.

MS. BERRY: Ed?

DR. McCABE: And if you wanted a reference for that, at the risk of being self-serving, there was a compendium of the New England Journal genome articles that was put together as a book, and there is an article in there by Khoury, McCabe and McCabe on screening. So there is that information, but I'm sure probably Francis could find a copy of that book laying around for you to look at.

DR. COLLINS: For which I received no royalties let me point out.

(Laughter.)

MS. BERRY: Any other comments on this particular recommendation?

(No response.)

MS. BERRY: So I think we need to adjust the language just a little bit to recognize the points that Reed and Emily and Ed made. Talking about standardization would be ideal, but recognizing some of the limitations of Medicare, and cite a few specific examples, and then lead into the recommendation as it's written. Does that adequately capture the consensus of the committee?

(No response.)

MS. BERRY: Any other comments?

Yes, James?

DR. ROLLINS: I think that it's equally important not only to stress the fact that because of the statutory regulations Medicare can only provide certain services. But also I think that if you take a look at the Medicare population, 85 percent of the Medicare population is 65 and older. I think if you take into consideration population characteristics, that might explain one reason why Medicare population genetic testing might not be as appropriate as opposed to another patient population group, such as private payers, where they may have a whole spectrum from newborns all the way up to the geriatric population. So I think the regulatory as well as the patient population needs to be taken into consideration when looking at that proposal.

MS. BERRY: Okay. Any other comments before we move along?

(No response.)

MS. BERRY: Hearing none, barrier number 3. I think Suzanne could use some of our additional guidance as to rewording that recommendation. I sort of summarized it but didn't provide any specifics on wording.

DR. WINN-DEEN: My suggestion would be "genetic tests and services in pediatrics and those with a prevention component," so as to specifically mention pediatrics, "should be considered with respect to the benefits that they can offer the populations they serve." Then in the second sentence I think we need to say something about Reed's comment about encouraging standardization of coverage decisions among private carriers.

MS. BERRY: Reed, did you have any specific language to lead in there?

DR. TUCKSON: I don't have good enough camera-ready language. But I think what I'm sort of trying to get at here is that, again, is that what we're encouraging is these principles that we've been talking about, along with best scientific evidence, that all of these things are made available so that we can get to a database and a set of guiding principles that will hopefully give us better standardization across public and private insurers to the greatest extent possible without stifling progress and innovation because of the federal concerns, the federal process.

So I'm just trying to get at a process that gets you to using best principles and an available, standardized database that allows you to be able to really assess these new technologies so that you can then begin to get people working together to make the best and right decisions without being caught up with the inherent limitations of the federal process.

MS. BERRY: Do you want to have a lead-in? Do you say something like "While standardization across public and private payers would be ideal using" whatever, then lead into the rest of it?

DR. TUCKSON: That's it. As opposed to sort of saying, which is what it says now, what you said I like. So you do it as a lead-in. But basically the goal is that we want health care to be more simple rather than more complex, more based on best science and best principles. So it should be easier, not harder. It should be more consistent, not more divergent. You don't want to drive everybody nuts. So with that as a goal, there should be available the tools necessary to achieve that to the greatest extent possible.

DR. LEONARD: Cindy, they make their own coverage determinations relevant or relative to their populations served. I'm taking up James' statement, because really the major difference is that genetics is going to be most useful not for people over 65.

MS. BERRY: Does that do it? James, do you think that does it? It doesn't specifically come right out and talk about it, although the body of the report talks about the screening exclusion and the population and all of that. Do you feel we need to have it in the recommendation itself, or do you think this recommendation is sufficient?

DR. ROLLINS: As long as we include something in reference to populations served or as we have here, populations served, because our population is a little bit different than populations that are going to be served by private insurers.

MS. BERRY: There is the disabled component for some folks who may be younger, under 65, and I think that's referenced in the report. So really the lion's share of the people served by Medicare are 65 and older. That is addressed there.

Debra?

DR. LEONARD: Rather than saying "Medicare's lead," could we say "following Medicare's coverage policies"?

DR. TUCKSON: I think we're getting close here on this. "Although standardization of coverage decisions using best scientific evidence across public and private sectors is ideal, private payers should be" -- I almost think "should be supported with necessary information to make their own coverage determination about these tests and services relative to the population served and not be limited to only following Medicare's policies." They're not now limited, but it's the idea of having this stuff available for people to do what they need to do.

I don't want us to solve a problem that isn't there. Private payers make their own coverage decisions. They're not limited by anybody. They do what they need to do. So the question is how do you have available to people the information that they need that helps them to make better and more intelligent decisions? It's the information base.

MS. BERRY: Muin?

DR. KHOURY: What happens if you just finish the sentence "to the population served," period?

DR. LEONARD: And can we put a reference to recommendation 1 after "although standardization of coverage decisions using best science"? See recommendation 1, yes.

MS. BERRY: Are we there? By jove, I think we've done it. All right.

Let's move on to number 3.

DR. LEONARD: Cindy, I know we need to march through the recommendations, but I have a global question.

MS. BERRY: Yes.

DR. LEONARD: We called this "Coverage and Reimbursement of Genetic Tests and Services," but we changed the definition of genetic test midstream. Are we really only talking about genetic inheritable tests now, or are we also talking about genomic tests? Because when we started this, genetic test was defined as genetic and genomic inheritable and somatic. Now we've changed that, which I think is appropriate to have a genetic test defined as an inheritable change. But this committee is also tasked with looking at genomic testing and applications. So right now as these recommendations are standing, we're only talking about testing for inheritable traits.

MS. BERRY: It's page 17 of the draft.

DR. WILLARD: It specifically addresses somatic mutations.

DR. LEONARD: Right, and it calls those genomic tests, not genetic tests.

DR. WILLARD: In the box "What are Genetic Tests?" they're subsumed under the wording "genetic tests," second paragraph from the bottom.

MS. BERRY: We don't appear to be distinguishing in the recommendation. In the report on page 17, all of the definitions and sort of the scope of what we're talking about are laid out. It's really just a definitional section. Do you feel, Debra, that we should be more precise in the language used in the recommendation?

DR. LEONARD: I am just concerned about what are genetic tests. That first paragraph now says "A genetic test is an analysis performed on DNA/RNA genes and/or chromosomes to detect heritable genotypes, mutations, phenotypes or karyotypes." So we've taken out the somatic part. I just want the committee to be aware that now when we refer to a genetic test as defined in this whole report, we are only talking about heritable tests. Later on we define genomics as the broader sense of heritable and somatic.

MS. BERRY: Ed?

DR. WILLARD: It doesn't define genomic. I would just delete the adjective "heritable" in the second line, because in fact the box is internally inconsistent and conflicts with itself over and over and over again. But if you get rid of that word "heritable," then it stands correct. A genetic test detects genotypes, mutations, phenotypes and karyotypes associated with disease without bias

as to whether it's inherited or not inherited, because the examples that are given throughout that box argue on both sides.

MS. BERRY: Ed, did you have a comment?

DR. McCABE: Well, I was going to respond more back to the recommendation, not to the definition. So I can hold that. I mean, in the recommendation we can make a genetic/genomic the way we did in the bottom box related to technology. So if we said genetic/genomic in recommendation 1, that takes care of Debra's issue. I think we should pursue Hunt's comment. Would that take care of your concern, Debra?

DR. LEONARD: If it's just genetic/genomic, yes.

DR. WILLARD: Then I have the concern about the word "heritable." We're putting our names on a box that is internally conflicting. We either mean inherited mutations only or we don't mean inherited mutations only, and we need to decide that and make sure the text reflects that decision.

DR. LEONARD: You're talking about the reference to RAS mutations in stool for colorectal cancer?

DR. WILLARD: Well, in terms of the writing there, yes. But I think in general, as I read through this draft report, I would personally be uncomfortable saying that this report only applies to inherited conditions, and someone else later will have to come up with another report for somatic mutations. I don't see the value of that approach, as opposed to saying we're covering both.

DR. LEONARD: I agree, but there's been a longstanding controversy as to the definition of genetic tests that goes back to SACGT, where genetic test was defined as heritable and somatic, and many people who did that had problems with that when you lump those together and can't separate them out by any means of definition, because many of the ethical/legal/social issues that are associated with heritable testing, a genetic test as defined as inheritable, are not necessarily associated with somatic testing. So having a definition of a genetic test that leaves it as inheritable or for an inheritable change is useful, because then you can distinguish it from a genomic test.

Did this get changed? Because we did define genomic as the broader heritable and somatic. Did that get taken out in this revision of the genetic test definition box?

MS. GOODWIN: That's the second box on the bottom of page 17 regarding genetic and genomic technologies.

DR. LEONARD: So maybe Hunt is right, that this third paragraph in the upper box is more relevant to put down in the genetic/genomic box rather than leaving it up in the genetic test box, since RAS mutation analysis for colorectal cancer wouldn't necessarily be considered a genetic inheritable test but rather a somatic test.

MS. BERRY: Would it be all right if it's left there and we just delete in the very first paragraph the word "heritable"? So a genetic test is performed on DNA, blah blah blah, to detect genotypes, mutations, phenotypes, take out the word "heritable," and then further on down there is a

discussion of both inherited and acquired. Does that improve the consistency? Does that address the problem?

DR. WILLARD: That was my suggestion earlier, so it certainly addresses my problem. But the issue of SACGT and whether there's a prior very narrow definition of genetic testing that some people like, we'll have to decide whether to retain that or broaden it.

MS. BERRY: Agnes?

MS. MASNY: I would favor the broader definition just because I think that the boon in genetic tests is actually going to be with the somatic mutations and the heritable diseases are much more rare. But I think that the use of genetic tests for things already available on the market are genetic tumor expression profiles to help actually give a risk category for women who may be more likely to recur in breast cancer is going to be available. I think that if we don't address this now, then we'll be behind the eight ball when those types of tests come out.

DR. WILLARD: My own sense is that the public at large -- that's a great example -- the public at large would view that, I think, as a genetic test. They're not going to look for a footnote that says, well, it's not really a genetic test because it's not strictly speaking –

DR. LEONARD: But that is a genetic test, because it's looking at the genetic make-up of the woman that influences the risk for breast -- the response –

DR. WILLARD: It's the expression of genes in the tumor.

MS. MASNY: Only in the tumor.

DR. WILLARD: Some of which may be modified, no doubt, by constitutional genotype, but we don't know the answer to that yet, and we certainly don't know the answer in a given case.

MS. BERRY: Well, I'm wholly unqualified to make any kind of determination here, other than to maybe ask if -- I know, Debra, you're concerned about it. The rest of the group, is there a preference in terms of broader versus narrower definition? I think we've got the recommendation down okay, but this relates back to a definition and a problem with the language that folks have identified, and I'm wondering if we can reach, if it's not an absolute unanimous consent, at least majority rule here in terms of whether we go broader or narrower.

DR. FITZGERALD: I'm intrigued a little bit, Debra, by what you were talking about. I grant you that there are certain differences in the ethical issues that can be raised, whether it's a heritable or a somatic mutation, but it appears to me to be the intent of this language to set a baseline, and I'm not sure it would be inappropriate to set a broad baseline and to say at least for heritable and somatic, we want to group everything together here. Then if in the process of dealing with the policies that are coming out about genetic testing or genomic testing one wants to say yes, then one has to take additional things into consideration for heritable conditions, that may be necessary.

I'm just wondering, is it still that relevant a distinction in the policy realm? I mean, I understand that we can have great ethical discussions back and forth, but in the policy realm does that distinction still have that much traction?

DR. LEONARD: Yes, because how this committee defines a genetic test may influence how CLIAC defines a genetic test, and if they have pre and post testing requirements that are relevant to a truly inheritable genetic test, those could be imposed on somatic tests as well, like leukemia translocation testing or other types of genomic tests that are not truly inheritable genetic tests, like documentation of informed consent and other types of -- it does have implications for policy.

DR. FITZGERALD: For CLIA is what you're worried about in particular.

DR. LEONARD: Can this be solved by just having a genetic test as an inheritable test and a genomic test as the broader one, as Ed had suggested at the last meeting?

DR. WILLARD: I just don't think outside of this committee room that that would have broad acceptance. It would be confusing and would be subject to misinterpretation, whereas you can take the broad definition and you can refine that by referring to a genetic test for an inherited condition, a genetic test for an acquired condition. So you can always modify the broad one later, but to just declare at the level of definition something which is not broadly accepted I think would cause us some difficulty.

MS. BERRY: Willie, and then Ed.

DR. MAY: I guess scientifically I think I agree with Hunt. But if you think about the commonly spoken English language, when people hear the term "genetics," they usually associate it with something that's inherited or heritable. So I wonder if you wouldn't confuse the general population with a more broad definition.

DR. McCABE: And Debra mentioned this, but I'll just lay it out a little bit more. I think what we're really dealing with is turf issues. So that everybody is clear why these definitions are important to certain individuals, it's because there has been somewhat of a conflict between the genetic testing community and then the pathology testing community over where the border is between what is done by whom, and that border has for the last 15 years been drawn that the genetic community does inherited testing, the pathology community can do inherited or somatic, but definitely the genetic shouldn't be doing the somatic.

That changed a little bit with the Joint Board on Molecular Genetic Pathology that allows both communities access to the entire range, including even molecular microbiology. But that's the sensitivity to what may seem a bit arcane to many people sitting around this table.

DR. LEONARD: We can take this up later, but it even the title and as we use the words "genetic test" throughout this thing in all the recommendations, it has implications for how we define the genetic test in this box on page 17.

MS. BERRY: Why don't we break for lunch, but if I could impose upon the folks who know the most about this and are the most sensitive to it, if you could scribble something on a piece of paper and see if we can work on some language behind the scenes, and then when we come back to this recommendation we'll put that up and see if that does the trick, rather than spend more time on it, because I think there's a bit of a debate such that it will prevent us from reaching a consensus on it. Debra, Hunt, Ed, if you can –

DR. McCABE: That's good, because Debra and I actually spent a bit of time with back and forth between the last meeting and this meeting. So I think it's important to have Hunt and perhaps

somebody else who might be interested who was not a part of crafting this, since it still is up in the air, and maybe not involved in the arcaneness that we have been.

DR. WILLARD: I'd be happy to do it.

MS. BERRY: Reed, should we break?

DR. TUCKSON: We start back at 1:30.

(Whereupon, at 12:35 p.m., the meeting was recessed for lunch, to reconvene at 1:30 p.m.)

DR. TUCKSON: Thank you for reconvening in a timely way. Are we back on the webcast? We are? Great.

Welcome back to all those who are joining us on the webcast. We had a marvelous lunch. Hope you did as well.

With that, let's go back to Cindy and move forward on the next recommendation on the reimbursement policy committee. For those that are on the webcast, we are moving through a series of recommendations. We've covered number 1, number 2, and we are now on number 3, with a 20-minute per category time limit.

So with that, Cindy.

MS. BERRY: All right. The clock is running.

Barrier number 3 had to do with the reality of a national and a local system in Medicare for determining what would be covered, a national and local coverage decisionmaking process. The recommendation number 3 addresses that and says basically that this mixed approach is reasonable and appropriate. There are some disadvantages, and we encourage CMS to move forward with the implementation of a provision in the most recently enacted Medicare prescription drug act, which requires a plan to be developed to evaluate new local coverage decisions to determine which should be adopted nationally. The idea would be to ensure greater consistency in Medicare coverage policy.

That recommendation is now up on the screen, and I'll put it open for discussion in terms of any revisions and edits that folks may want to recommend with regard to this recommendation.

James?

DR. ROLLINS: CMS currently has a process in place where they currently do review local decisions, and if there is significant inconsistency, then a national coverage decision more than likely will take place. So as I said, we currently have something which addresses this recommendation.

In terms of the wording, this might be a wordsmithing issue, but in the third line it says there are several disadvantages. I would prefer the word "issues," only because in the following sentence it says "while not suggesting changes in the current system." So I think that "issue" is probably a little more appropriate. That's all. But as I say, yes, we do have a process in place where we do

look at local decisions, and in case there is a significant amount of inconsistencies, then a national coverage decision will more than likely take place.

MS. BERRY: Is that process identical to what's contemplated by Section 731 of the MMA, or does CMS intend to do something more, broader, different, to respond to that provision?

DR. ROLLINS: I would have to see what that section specifically says.

MS. BERRY: Would you have any problem with us leaving reference to that provision in there, or do you feel like that's –

DR. ROLLINS: I have no problem with leaving it in there, but I do notice that you did not make this recommendation specifically for genetic testing, and maybe you don't want to.

MS. BERRY: It references genetic tests and services in the first sentence. But do you feel like it should be repeated again down below?

DR. ROLLINS: Oh, I didn't see it up there.

MS. BERRY: Okay. Emily?

DR. WINN-DEEN: I just had a sort of point of order question. Are we allowed to directly recommend to CMS, or do we have to recommend that the Secretary, in his oversight capacity over CMS, do something?

MS. BERRY: Ed?

DR. McCABE: My understanding of the process is that we're advisory to the Secretary. So it would have to go to the Secretary to then move from the Secretary's office to CMS.

DR. WINN-DEEN: So maybe we just need to add that in the wording a little bit, change that, instead of directly recommending to CMS.

MS. BERRY: "Recommends that the Secretary encourage"?

Hunt?

DR. WILLARD: Just on the line 3 wordsmithing, I'd say there are several aspects of rather than issues to.

MS. BERRY: Any other suggestions, comments?

(No response.)

MS. BERRY: We haven't really done a formal vote, Reed, Do you want to do that with each recommendation, or should we just move on in the informal way we've been doing?

DR. TUCKSON: I think in the interest of time, let's just do it and move on, and then we'll just take a formal sense of the whole aggregate.

MS. BERRY: All right.

Yes, sir? Sorry, Joseph.

DR. TELFAIR: Just for a point of clarification, do you need, after the third sentence, do you need a "such as" for an example of what one of those issues might be, or is that clear in the text?

MS. BERRY: I think in the text it goes into some detail.

DR. TELFAIR: Okay. That was my question. I'm looking at the page.

MS. BERRY: We're looking for it right now. I mean, there is a discussion of the issue broadly. What I can't remember is if there's a specific example. But there are different jurisdictions that have different coverage policies with regard to the same procedure or the same service, and I don't know if there is a specific example that's mentioned in the text. I can't remember.

DR. TELFAIR: I guess if there is a summary to be made, an executive summary, that in the executive summary you do use an example, a such as. It would just make it clearer to the broader base of readers.

MS. BERRY: It would be on page 29, in that section. So perhaps we can identify it, or staff can help us identify a particular example that illustrates this point, and we wouldn't have to revise the recommendation but the text itself would contain a very specific example.

Ed?

DR. McCABE: Or it could be at the bottom of page 28 also, where it says there are conflicting LCDs. We were given examples, and I would suggest to maybe make that a sidebar so it stands out, just an example here, or two.

MS. BERRY: Any other comments? Suggestions?

(No response.)

MS. BERRY: Okay, barrier number 4. This is the screening exclusion in Medicare, the fact that the Medicare statute is pretty stringent in terms of preventing coverage of screening tests and services for risk assessment purposes. So the recommendation that's included under barrier number 4 -- we'll put it up there in just a second -- it's hard to get it all up on one screen. This was discussed at our last meeting, and we did include on page 31 of the report at CMS' suggestion a specific example of a test that's currently excluded from Medicare coverage but that actually is relevant to the elderly population that CMS serves. So that's in the report as an example.

I'll give everyone a second just to re-read this recommendation so that you can go over the details of it and then we can talk about some edits and suggestions. You'll recall from our discussion the last time, it's one thing for us to say that preventive services, including predispositional genetic tests and services, should be covered under Medicare, but that really would require a change in the statute, unless we were successful in some of these other ideas, and working within the current system I don't know if it will fly or not. But we did talk about ways around the statutory restriction, one of which is hitting it head on with a change in the law itself. It would require congressional action for Congress to add a benefit category for preventive services.

Absent that, the fallback would be that CMS would issue a national coverage decision stating that family history constitutes a medical justification for a test being reasonable and necessary. This is kind of a -- I don't know how to characterize it. It's a little crafty I guess I would say, and I don't know if CMS would be able to do that, but this is an idea that came forward and that we talked about a little bit the last meeting as a way around the statutory restrictions that we face and that CMS faces.

Hunt?

DR. WILLARD: The craftiness doesn't bother me at all, but the question is whether just saying family history is too vague and therefore not of great utility. I mean, for example, in the colon cancer community, in the breast cancer community, there's been extensive study in order to come up with very rigid guidelines and criteria that say you need so many first-degree relatives, and absent that you need so many more second-degree relatives. So just saying "positive family history" would not be adequate. One member in the family with colon cancer does not mean you are likely to have an inherited form of colon cancer, and the same for breast cancer, and the same for any of the common disorders that we're beginning to move towards.

So my concern is that every one of those is going to require a set of criteria drawn up by an expert group of specialists who, on the basis of data, in order to say exactly how deep a family history has to be.

MS. BERRY: Joe?

DR. TELFAIR: I actually had a similar question but with a slightly different slant to it. I guess my question would be in the previous pages you talk about using clinical evidence, the criteria for evidence-based decisionmaking. So I was wondering if you go with this family history, or even personal history, is there enough evidence there to suggest that? That was my question, similar to what you're saying. But it seems to me that even trying to bypass this, you still come back to the point of needing evidence to justify the decision that's being made. It may be a time issue. You can think about having to do that, but you may need to wait. This may be premature is what I'm saying, in terms of a timeline perspective. It may be something you have to go back to later on, because there doesn't exist right now enough evidence for everything that may come about to use that justification, or do you need to wait until there's a reasonable body of evidence to do that?

I'm just kind of bringing up a lot of questions that I suspect those who may look at this may come up with similar types of questions. So I would be concerned about that. You might want to think about making a recommendation to look at this from the perspective of evidence that's there with some proviso to come back to it.

MS. BERRY: How about if we said something like, and I don't know if this does the trick and I think we had some issues earlier on about defining adequate scientific evidence I think in other parts of the report, but just see if this captures what you're saying, that "CMS should issue national coverage decisions stating that in the presence of adequate scientific evidence, family history constitutes medical justification." In other words, recognizing at the outset if and when the science supports it, family history could be considered.

DR. TELFAIR: Well, my concern is particularly with adults. With children I can understand, because you can get that pretty readily. But with adults in terms of who is covered, you may not have that knowledge, even on family history. There may be not enough people who know

enough about what their family history is. It's more the fact that people are more ignorant of their family history when it comes down to these types of issues than they are knowledgeable about it, and I think you would sort of be boxing yourself in or limiting the number of people who could actually be covered if family history, which is self-reported in a lot of ways, unless someone knows them well, then that's it. So the family history issue, besides the other thing, seems to be problematic to me.

MS. BERRY: Ed, did you have a comment?

DR. McCABE: I guess I would come at this a little bit differently. First of all, I think the addition that you made about in the face of evidence, I think that would make sense to add. But I think part of what the intent of this recommendation is that family history become something that is routinely performed. I see that one of the bigger problems is not arguing about the scientific evidence and how many people you need, but I think it's also just getting family history as part of the personal history, because without an incentive to gather the family history, the physicians are going to continue not gathering family history. With all the studies that have been done looking at practitioners, family history is an area that is extremely poorly performed.

So I see that part of this is to just get the concept of inclusion of family history as part of personal history.

MS. BERRY: Joseph?

DR. TELFAIR: I guess that's not the point I was actually making. I understand your point, but my point is that from the perspective of the client that you're asking the family history of, the physician could be very cognizant of the need to get the history, but it doesn't mean that the clients themselves can actually give an adequate history, because they may not know.

MS. BERRY: One of the objectives of this recommendation -- and correct me if I'm misstating it, everyone who has been involved in drafting this -- is that we undoubtedly recognize that not everyone has that information at their disposal, and that's kind of like the access issue that we were talking about earlier today. One of the flaws is that there are people who just have no insurance, they have no coverage, they have no access to the health care system. So obviously, many of our recommendations aren't going to benefit them either, but to the extent that someone does have Medicare coverage and may be able to provide a certain amount of family history, and that does say something to the physician that we probably should do a test here, that Medicare could maybe have the flexibility, CMS would have the flexibility to cover those screening tests and genetic services in those instances, recognizing that it won't help everyone, but it might make a little dent in the problem.

I don't know if you feel comfortable with that or if there's further change that you would recommend that might be more precise and might make this recommendation more impactful.

DR. TELFAIR: The only concern that I have, to me it's still a time issue. I think that one of the real benefits -- actually, I'm speaking more from the ground level at which I work -- of this kind of thing is the level of education that you do for the general public. The more educated they are, even in a simplistic way, about these issues, the more able they can participate in the process. To me, that's where it's falling apart, that you're asking for both sides to participate in the process, and one is significantly more knowledgeable about it than the other side. Until the other side is

adequately educated and can get into their own way of thinking in general, it's going to be difficult. That's all I'm saying.

I think it's a committee decision, but I agree with you, it will probably benefit a small number of people. Maybe over time, the more that's done, the more people are educated, they need to know their history, then it will change, and if that's built in there some way, that you have some kind of education part every time a practitioner sees it to really encourage people to go and find out more about their history, go and ask more, those kinds of things, I don't know if that's under our purview or not, but if we're trying to get at this, we need to be thinking about that because that's the society part of this, as opposed to just the testing part.

MS. BERRY: Emily?

DR. WINN-DEEN: So I'll do the counterpoint to that, which is do you think if this was a carrot out there, that you could get your testing covered if you could provide evidence of family history, that this would serve as some motivational reason for physicians to take the time to do a family history? CDC has now put some nice tools together to let people sort of do this on their own that they could be referred to, go home and do this and bring it back to your next appointment. So I'll do a Sam Broder quote: "Don't let perfect be the enemy of the good." I don't want to say that we shouldn't use it at all because it's not perfect today, but at the same time we're trying to get it covered on the basis of that, we can also work on the other things, which I think this committee has done in the past and continues to support in the future.

DR. TELFAIR: Well, I have a comment, but I'll wait my turn.

DR. FITZGERALD: I guess maybe I'd like to see this, rather than being an either/or, be a both/and kind of thing, and perhaps that could be addressed by saying instead of in the absence of legislation, even just changing that to until such legislation is enacted.

DR. LEONARD: Or in addition to legislation.

DR. FITZGERALD: Or in addition to legislation. But I'm getting the sense that in the absence -- I see the idea of having this as a carrot. What I don't want it to be is an escape clause that says, oh, okay, we won't do the legislation but we'll give them this, because I think the other is extremely important. Therefore you would say we definitely want this, paragraph 1 and 2. In the meantime or in addition, we'd certainly also want the fact that family history is an incredibly underutilized tool, and we would like that, too.

MS. BERRY: Is adding "in addition to legislation," does that –

DR. LEONARD: Maybe it should be "more immediately."

DR. FITZGERALD: Yes, something like that. Put a temporal piece to it.

DR. LEONARD: More immediately, the Secretary should direct CMS, because obviously legislation would take time.

DR. FRIES: Should we add anything in this to discuss the benefit of counseling about the family history? I'm going to pause at two scenarios. A person comes to their physician and says I have a family history of breast cancer. My mom died of breast cancer and I know that Medicare will

cover BRCA1 testing, and therefore I really want to get this test done. And the person says yes, there's a family history that's right there, so we're going to go ahead and cover it. And they say oh yes, my grandma, I know she had ovarian cancer because she had her uterus out.

Now, in just that sort of superficial view, that would certainly seem like adequate family history. But when you take a more elaborate family history, the mother had breast cancer at the age of 70 and the grandma actually had cervical cancer, and there's no other family history of breast cancer, and the likelihood in that that this person is in fact a mutation carrier is very slim. Therefore, we've spent resources based on family history alone that are probably better used for something else.

Now, I wonder if maybe in addition to this, or perhaps I'm missing the point here, we should say that there should be some component to counseling as a discussion of the family history importance.

MS. BERRY: We do have in the report a couple of things. There's a section on genetic counseling, and then under "Broader Issues" there's provider education and training, and then public awareness. Some issues are discussed there that I think touch on some of the points that you just made. What you just brought to our attention I think cuts across all sectors of health care, not just the public sector, not just Medicare. So I'd probably put those in the broader categories unless there's a way that you think of that we should address it most specifically in Medicare, in this section of the report, and any changes to this recommendation, or do you agree that perhaps it's something that –

DR. LEONARD: But wouldn't this be addressed by "in the presence of adequate scientific evidence" or "evidence-based medical practice" or something? I mean, you take a family history and the patient is saying that her mother had breast cancer, but the good medical practice, evidence-based medical practice says that you get the report, the surge path report if you can, you see what age it was, you go through the criteria that are used for breast cancer BRCA testing and not just use the family history.

So I think by having that in the presence of adequate scientific evidence or whatever that is, that you use family history in the context of evidence-based medicine.

DR. FRIES: And I would say that that's ideal, but I would say the reality is that it would probably not be that, because many practitioners do not have that scope of knowledge to recognize what is important and what is not and may not have the time to go back and do that research. Clearly, that's an education point, and I'm probably splitting hairs in this. But I just wonder if there is perhaps a role for wording. Would you say "in the presence of adequate counseling and scientific evidence"? Or have we created a monster here? I'm willing to shut up if you feel –

MS. HARRISON: As much as I'm an advocate for counseling, I think trying to appreciate that family history is something all physicians need to be able to do, they need to be able to do it well, and I think we need to focus our efforts on ensuring that physicians are doing it well. In the case where you're talking about possible BRCA1/BRCA2 situations, we would hope that that would be a more limited group of folks that would get to a genetic counselor to really flesh that out, as opposed to the person who is saying my mother developed diabetes, in which case that may focus to glucose testing more often than others.

So that's what I'm thinking this is getting to, although maybe I'm mistaken, and that's why I don't necessarily feel that we need to put in genetic counseling here. Plus it's also addressed I think later in the document in an adequate fashion.

MS. BERRY: James, and then Joseph. Did you have something? Okay.

DR. ROLLINS: Just a few points. Medicare does not have a national coverage decision for BRCA testing. That's something that's done at the local level. In terms of reasonable and necessary, that's the criteria that we would use in terms of covering something which does have a benefit category. If you look at that specifically, family history is something which is excluded from reasonable and necessary. So even though we may recommend that CMS cover a genetic defect because of a family history of the condition, it's something which we do not have the authority to do. So even though it may be stated, we still cannot do it. That would have to be authorized by Congress for us to even consider that.

MS. BERRY: Is that in the statute or is that in the regulations in terms of excluding family history?

DR. ROLLINS: That's in the statute.

DR. TUCKSON: Let me be sure I understand. A number of us are confused. You're saying that Medicare coverage decisions are local, not national.

DR. ROLLINS: No. I said that in that specific situation, for the coverage of BRCA, for breast cancer, that's a local medical decision. That was made at the local level. We do not have a national coverage decision on BRCA testing. So in the situation where it –

DR. TUCKSON: That's not because of statute. That's just an anomaly of –

DR. ROLLINS: They were given the authority to review the literature, and based on that –

DR. TUCKSON: That doesn't make any sense.

DR. ROLLINS: I understand.

DR. TUCKSON: Does it?

DR. ROLLINS: But if you remember, most of the Medicare decisions are locally made decisions.

DR. TUCKSON: I see. They have different human beings in Wyoming than New Hampshire?

DR. ROLLINS: I can't say.

MS. BERRY: Joseph?

DR. TELFAIR: Well, maybe as sort of a middle ground recommendation here, I understand that it's coming up later around genetic testing –

(Beeping sound.)

MS. BERRY: Finish your thought and then we'll move on.

DR. TELFAIR: I'll try to be brief. It seems to me that the major point, particularly in the first paragraph, is suggesting that there's genetic tests and services. So maybe one of the things to do in terms of getting providers is to get providers to think about referrals for genetic counseling and testing if the evidence warrants it. In other words, if they see something based on their own diagnoses and the history taking, that you may need to talk to someone else about this. I guess I'm just thinking that a lack of education on the recipient's part can contribute to also being problematic. It seems to me that maybe one of the things here is that in light of the current evidence, you can also say a recommendation that it's in their purview to recommend for genetic testing or education as part of this recommendation. I'm trying to rush because I know we're out of time.

MS. BERRY: What we were trying to do with this is dance around the statutory constraints for the Medicare program. So the recommendation is inadequate insofar as it's not going to address all of the things that we would like to see, like we would want to make sure that the provider be well educated and that there would be appropriate referrals, all the different steps that we would like. This recommendation will fail miserably. I think it's very targeted to address this one problem in the Medicare statute that prevents CMS from covering some of these tests and services.

So I don't want us to get too caught up in worrying about all of the things that we would recommend in an ideal world. We're really focused on this one barrier, this one problem that CMS has to deal with and that we constantly also have to deal with. So that would be my response. I hear exactly what you're saying, and please bring this up again, because as we go into the other recommendations that directly address that, we want to make sure that we get those recommendations right, because they will definitely have an impact on whether this report will erase these barriers.

James, and then I think we have to move on.

DR. ROLLINS: CMS does not have a preventive benefit category. If we had a preventive service benefit category, I think that a lot of this would fall under that. Unfortunately, since we don't have it, that is something that perhaps the Secretary can make a recommendation to Congress that you get. A lot of the things that would benefit would fall under a preventive service benefit.

MS. BERRY: And that's the first part of the recommendation there in paragraph 2. So that's what we want the Secretary to do, exactly what you just articulated, James, that the Secretary would urge Congress to establish this new preventive benefit category for CMS. That would be, I think, our top choice, because that would most directly guarantee that we could get some of these things covered. The second part of the recommendation is a little squishy, but this was sort of again to try to dance around the statutory restrictions that CMS has.

I think we need to wrap this up and move on to the next recommendation, but does anyone have any specific -- I think we're pretty much in agreement that the first part of the recommendation is important and should stay. The second part, we've been playing around with the wording. Do we want to keep this recommendation in there or do we want to take it out entirely, or are there some last minute wordsmithing changes that folks would recommend?

Debra?

DR. LEONARD: Just a wordsmith since we are talking about predictive and predispositional testing. In the third paragraph, the end of the third line into the fourth line, it says "testing reasonable and necessary in the treatment and diagnosis of an illness." If someone is sick, this isn't a problem. So "in the treatment and diagnosis of an illness" has to come out of there, because this is predispositional. It's supposed to be when there isn't illness.

MS. BERRY: Does that track the statute? Is that why that's in there?

MS. GOODWIN: Sorry. This last paragraph would be in the absence of a preventive services benefit category. So it would have to be limited to diagnostic testing.

DR. LEONARD: But I thought the argument here was that you could use family history rather than direct symptoms as a reason for doing testing.

DR. WILLARD: Right, because that's a genetic test.

DR. LEONARD: I know, but "in the treatment and diagnosis of an illness" has to come out of there.

DR. WILLARD: No. A woman with breast cancer, absent a family history, you wouldn't run out and do a BRCA1 test if she was 70 years old, would you? So this is not preventive; this is diagnostic.

DR. LEONARD: Is there a problem with doing a genetic test in the presence of disease symptoms in a Medicare-covered person?

DR. ROLLINS: When a person has disease symptoms or signs, it's a diagnostic test. We would cover that. We would not cover screening tests even with a positive family history of the disorder.

DR. LEONARD: And that's what we're trying to change in this. That's my understanding of this third paragraph.

MS. BERRY: Ed, and then Reed, then we have to move on.

DR. McCABE: So when we come back to it, I think we might want to think about splitting this into two, because I think part of the problem is that the first two paragraphs deal with this benefit category for preventive services, which is extremely important, and I think the third was a way of trying to work within the current system to accomplish an end, and I think part of the problem that we're having is mixing those two together.

So I think that perhaps you could make it a new recommendation 5 and move the other numbers down to make it a little cleaner.

DR. TUCKSON: And mine is just a question. I like that idea, by the way. But given what we're trying to do, does CMS, have they in terms of our conversation with them -- I don't want to put Jim on the spot. I don't know what's the politics here. Has CMS said that they're fighting us on this or are they eager for the spirit of this to occur? Because at the end of the day, why doesn't

CMS just give us the language? I mean, it seems to me that we're trying to figure out how to solve a problem for which we are not -- I mean, people live this every day. So are we at odds with CMS on the spirit of what we're trying to change and achieve?

DR. ROLLINS: I think that CMS is in the spirit in terms of doing the right thing, but in order for us to cover preventive services, we currently do not have that.

DR. TUCKSON: Right, got it.

DR. ROLLINS: And because of that, you've got to go through the legislative work to achieve that goal. If we were given a preventive services benefit, I think a lot of these things being requested could be accomplished.

DR. TUCKSON: But more specifically, then, we will go ahead and ask the Congress to give that -- doing it the right way. Absent that or in the interim, the secondary strategy -- and Ed I think disengages those appropriately -- the secondary strategy -- is CMS unable or unwilling to want to see a secondary strategy, an intermediate strategy occur?

DR. ROLLINS: I would say unable. I would not say unwilling.

DR. TUCKSON: Would you be unable finally, then, to provide some guidance as to how the existing remedies that you may have, such as this kind of thing, can you help us to phrase that given you've got all these technical people around there who know how to say this? We're trying to do it, and we're not pros at this.

MS. GOODWIN: This actual recommendation, maybe not the language exactly, but someone from CMS had suggested it to us in the earlier draft of the report. So that's where this came from at least.

But can I follow up with a question for you right now? The language is the Secretary should direct CMS, and you seem to be suggesting that the directive would not necessarily come from the Secretary but would need to come from Congress?

DR. ROLLINS: It would come from the Secretary.

MS. GOODWIN: So the language here is sufficient?

DR. ROLLINS: Yes.

DR. TUCKSON: It seems to me finally, then -- Cindy, if this doesn't help, then let's come back to it later. But it just seems to me that we ought to just, outside of the meeting, just have James and those appropriate people from CMS revisit this language, tell us the best way to recommend how to plus this gap in the interim while we're waiting for the ultimate intervention by Congress. If you guys just tell us how to do it and then we get there, unless the real issue, which I think we need to be aware of, is CMS doesn't want to do this. Therefore, that's a different kind of recommendation that goes to the Secretary.

DR. ROLLINS: I would say that CMS is not willing to do that. I think that they just do not have the authority to do that.

MS. BERRY: All right. Let's move on to the next recommendation. We will go back and consult with CMS on that one. I think we're close, and we have done it up until now. We have consulted with folks over there, and they've provided us with some guidance, and I think we can fine-tune it and then put it in the next draft of the report.

Let's see, where are we? Recommendation number 5. This has to do with Medicaid and the fact that all the different states have their own, because it is a state-based program even though there is a federal partnership component to it, each state has its own Medicaid program, designs its own benefits, and on top of that has budget requirements that create some instability in terms of coverage for all services, of course, but genetic services in particular. So this next recommendation really isn't a mandate in any way. It's really urging the Secretary to provide information and guidance to the states so that when they make their own coverage decisions and they determine how they're going to structure their own Medicaid programs, they have the benefit of the best and latest and most thorough compilation of information so that they can make their own determinations.

Then the second part of the recommendation has to do with grants. To the extent that there's money available, that grants could be issued from HHS which encourage the states to cover these types of services.

Reed?

DR. TUCKSON: By the way, whenever we say should disseminate information about existing evidence base, we should also include what we did in recommendation 1 about the guiding principles, because it's sort of how do you think it through in addition to the evidence, because I think states will need more than just the evidence. We ought to give them everything we possibly can in order to help them think this through, I would hope.

This idea of providing states with grants, I'm trying to remember what that program is now. The feds are providing the states with grants that encourage this now? Because it says continue. I'm not sure I remember if they're doing it now. What I'm worried about, obviously, is in the reality of the fight just to maintain any Medicaid support right now, which is a big issue. I want to be very careful that we're not asking for something that's a little silly. It's never silly, but unrealistic is what I'm trying to get at, given what's going on out there, just trying to hold on to basic coverage.

MS. BERRY: There are grants. I don't know any specifics in terms of grants that pertain solely to genetic services. So absent that information -- Ed, do you know?

DR. McCABE: HRSA has a history of this. You heard about newborn screening for sickle cell disease today. That got its first move from about 15 states, as I recall, up into the high 20s, low 30s, with a round of HRSA funding, and then it moved with another round of HRSA funding into the region where it currently sits. So without those grants to state health departments, we would be nowhere with that. So that's an example where it really did benefit individuals within the states, and it was grants to states.

DR. TUCKSON: But it's not through CMS.

DR. McCABE: No, it's through HRSA, but it doesn't say. It just says HHS.

DR. TUCKSON: Okay, I got it. Thank you.

MS. BERRY: While Reed is working on some language to address the point that he made earlier, does anyone else have comments on this recommendation?

Debra?

DR. LEONARD: So we will be referencing recommendation 1 in this as the way that we get this evidence-based information?

MS. BERRY: I don't know if you intend for direct reference to recommendation 1 or just to incorporate some of the language from recommendation 1.

DR. TUCKSON: Just the idea of the principles, that's all. So you're providing the evidence and the principles that identify criteria to help determine which tests should be covered. So you're facilitating them with information as well as principles. You've giving them the science and the principles. If we thought that was important in the first recommendation, I don't want to keep things that they could use on the shelf. That's all. So here are things that you should be thinking about as to why these are important for you to make these local coverage decisions. It's science and other things.

MS. BERRY: How about "and coverage principles"?

DR. TUCKSON: That's fine.

MS. BERRY: I don't want to put –

DR. TUCKSON: "And the identified principles."

MS. BERRY: Does that do it?

DR. WINN-DEEN: I don't think that's what he meant at all. It's how did you get to that decision. So what were the guiding principles that you used in your thinking through whether or not something should be covered.

DR. TUCKSON: So if I'm sitting there at the state and I am trying to think about should this genetic test be covered in my local Medicaid benefits, I've got a gift of the scientific evidence now made available, and then I've got a way of thinking about that evidence around a set of principles that sort of say here is how to help to shape your thinking about whether or not you should cover this. You don't have to invent the thinking, the rationale, the analysis grid, but it's being delivered to you.

MS. BERRY: But we don't have that, or we won't have that.

DR. WINN-DEEN: For verification?

DR. TUCKSON: But when it's available, we're saying in number 1 you're going to make that happen, right?

MS. BERRY: Right. But then until that happens, we don't want to hold up the Secretary --

DR. TUCKSON: No, no, no. So when it's available, you'll get back to them as well.

DR. WINN-DEEN: So if California has thought this all through and they want to share it with Oregon, they would share it with Oregon. And then when Oregon has thought it all through and they had some other concerns, they could share it with Idaho.

DR. TUCKSON: Exactly.

DR. WINN-DEEN: And you would eventually get some pretty critical thinking where the states had gone through a series, and then at that point maybe all the states just say, hey look, these three or four or five states really thought this through and let's just do it.

MS. BERRY: What if we take out "the" and "guiding coverage principles developed by other states and" whoever this body is in recommendation number 1?

DR. TUCKSON: Or you could say "and other supportive information such as guiding principles and other state experience," something like that. "Guiding principles that serve as the basis for coverage." In other words, we're basically saying we want to provide to the states as much support as possible that helps them to make intelligent, well informed, rational decisions.

DR. WILLARD: Now I think you can delete "see Recommendation 1." You've explained it fully. You don't need that.

MS. BERRY: Any other comments? Does that do it? Do you want to leave it sort of vague that way, not saying who is developing the guiding principles? Do we need to specify that we're talking about other states or HHS through this unnamed body, or do we just leave it the way it is? I guess theoretically it could be principles developed by health plans. Leave it this way?

Any other changes, comments?

(No response.)

MS. BERRY: Let's move on to Recommendation 6. This is in the billing and reimbursement category section of the report. Barrier 6 has to do with CPT code modifiers and the fact that modifier codes are necessary. This recommendation again dealing with the CPT modifier codes provides or suggests that health providers and health plans should work together to reach a consensus on this and that a private sector group should be organized to assess the impact of the modifier codes on claims denial rates, and specifically identifies the Genetic Test Coding Work Group as an entity that was involved in developing the modifier codes and that they might be an appropriate group to perform these tasks.

Joseph, and then Debra, we'll need your guidance too on this, because I know you've got some history here and some background that would be useful I think to the whole committee.

Joseph?

DR. TELFAIR: Mine is just a question of clarification. It seems that all three sentences are just one thing, because you also separate that out as different. I mean, I'm wondering if you really need "also." If this is the problem and this is the recommended solution, using this group, you don't need "also." It's a wordsmithing thing.

MS. BERRY: We'll take that out. That makes sense.

Debra?

DR. LEONARD: It's very interesting now seeing these recommendations out of the context, and I really think that they do have to be able to stand alone almost, because they may be looked at in that way. I think we need to say what modifier codes we're talking about in this first sentence, so modifier codes for molecular test CPT codes, but they're the molecular CPT codes. They modify the molecular CPT codes. That's fine.

Then in the second sentence, you say "an appropriate private sector group should assess the impact of the modifier codes." I think we also have to say "the extent of use and the impact," because right now they are not being used. So one thing to assess is are they being used, and then if they are, the impact that that's having.

Then the other question is are they having the desired effect, because we don't want to say what we want the effect to be. I mean, hopefully it's reducing denials of payment for molecular tests, but I didn't know if there was some reason we weren't being that specific. I mean, we could say "the effect of reducing denial of payment or other effects."

And just a wordsmith. If you took out the "also," you have to capitalize the "And appropriate."

MS. BERRY: Hunt?

DR. WILLARD: My concern here, and it goes back to the question Reed asked earlier, is who is fighting this? Because it's an open question. The goal is not simply to reduce denials. The goal is to have appropriate denials, because we have to allow for the fact that occasionally denials are appropriate. The way this reads, it's simply we want to maximize revenues regardless of –

DR. LEONARD: It's actually whether the communication of the additional information that these modifier codes were intended to provide to payers is useful. So it's really the information, because right now, since any kind of molecular test uses the same CPT code, it's really whether this additional information is useful to the third-party payers that you're doing a Factor V Leiden test versus an HIV viral load test versus a BRCA1 test. So it would be nice just to find out if it's having any effect at all.

DR. WINN-DEEN: Debra, could you also clarify whose group the Genetic Test Coding Work Group is? Is it an HHS agency?

DR. LEONARD: No, it's not. It was CAP/ACLS. It was a bunch of professional and laboratory organizations basically that used these CPT codes. It was not an HHS working group.

DR. WINN-DEEN: All right. So I guess the question is, then, how does HHS -- I mean, does HHS have the authority to designate a non-HHS group as something that can follow up on its behalf?

DR. LEONARD: Probably not.

DR. McCABE: That's what I was going to say. I would urge us to focus on things that we may have some leverage against and focus on what we can do with the Secretary, because if we go in

with a recommendation that is not within the Secretary's purview, I'm worried it weakens the other recommendations. I understand the importance of this, but I think we need to focus on what we are charged with doing.

DR. LEONARD: This thing has morphed over time as we've been working on this document, because the modifier codes were approved, and I actually don't remember the original purpose of this. I know I edited it in the last revision to be more accurate for the fact that these things exist, but they are not being used currently because some insurance companies are saying if you use them we won't pay you, and others are saying if you don't use them we won't pay you. So we don't know what to do with these codes. So they're just kind of sitting there even though everyone thought it would provide more information to payers about what the test was about.

So I don't even remember the original purpose of this recommendation and whether we still need this recommendation given that the codes exist. Hopefully somebody will figure out how to use them.

MS. GOODWIN: The recommendation initially was to encourage AMA to adopt the modifier codes, but now they're adopted.

DR. LEONARD: So I don't know that this is relevant, even.

MS. GOODWIN: This was added, actually, based on changes.

DR. LEONARD: Well, it was changed from the original getting the support for the codes, but now the codes exist. So I modified it in the last editing to reflect the fact that we don't need them to recommend this. It's happened. But now we have them, we don't know what to do with them.

MS. GOODWIN: The second sentence of this recommendation was actually a holdover from the last draft in terms of actually -- where it says "assessing the impact once implementation has taken place." So I think there may still be a need, if the committee agrees, to have that done, to make sure that now that the modifier codes have been adopted, they actually have the impact that they're intended to have.

DR. McCABE: I think we could accomplish that without making a recommendation to the Secretary, because I don't think the Secretary is going to accomplish that. I would think that if we look at proposed Recommendation 7, which then says look at how CMS is using the modifier codes, you could, if the committee felt that this was important enough to do so, have a group, including whatever that group is called, the Genetics Work Group, come and report on whether these things are being used and how they're being used. So I think we could accomplish what we're trying to do within the scope of our charge, and we could do it related to proposed Recommendation number 7.

MS. BERRY: Is a consensus developing that perhaps we don't need this recommendation, that perhaps we can delete it? Leave the background that's in the body of the report, because it does talk about this issue. We certainly don't have to have a recommendation for every single issue that's identified in the report, and we don't want to recommend something that's not worthwhile or something that the Secretary can't implement. Is that the suggestion of the group?

DR. LEONARD: Ed, would you take something like that middle sentence of the now-standing Recommendation 6 and add it to 7 so that CMS looks at how Medicare is using these modifier codes? Since if Medicare does, other payers may also follow.

DR. McCABE: Sure. You could say something to the effect that CMS should review the impact of modifier codes on claim denials, or I don't know whether that would be something that CMS would do if recommended. Again, we can't recommend to CMS, but we can recommend to the Secretary that CMS look at it. But I would either include it that way or not include it at all but make a footnote to ourselves that we need to re-address this at a future meeting.

DR. TUCKSON: It seems to me that again as we look at this, there are two issues that are being described here. One is, is there the appropriate coverage and reimbursement philosophy that allows you to reimburse for services? The modifiers in the CPT codes was simply a language by which someone communicates that which they have done. So the only thing, at least from my understanding of this, that really counts around the modifiers is is the language sufficient enough to explain to the people paying the bill what the clinician actually did? Whether or not you pay for that or deny the claim is a coverage philosophy issue, not a modifier issue.

So it's simply a matter of whether or not you have the right language that tells you what have you done at enough level of specificity for someone else to interpret it. "Oh, I got it, you did this for this reason. I'm clear." Now I can say does my claims policy allow me to pay you for that. So I think what we're really trying to get to -- all that to say that I'm sort of where Ed's position was, which is unless there is something that comes up down the road, now that we know we have language that can describe what a clinician does in this area, the only issue is if down the road we find that that language is obsolete and needs to be updated. But right now we have no evidence of the need for that, and so I don't think we need to make it as a recommendation.

DR. LEONARD: The only problem is that the codes aren't being used. So the codes now exist, but they're not being used.

PARTICIPANT: The Secretary can't do anything about that.

DR. TUCKSON: That's a different issue.

DR. LEONARD: Right. So we have the language, and no one is speaking it.

DR. WINN-DEEN: So do we need to give them some foreign language education or something? I guess my question is, since we have the right to make comments about things that are under HHS, should we sort of limit our comment on the appropriate use of modifier codes to monitor whether they are now being appropriately disseminated and utilized within Medicare and Medicaid, recognizing that there still are issues in getting all the private payers on board but sticking to our sphere of influence, so to speak? Rather than going back into let's just have something that says we should, as a follow-up item, monitor whether Medicare and Medicaid are really taking this on and using them as they were intended, which is to provide better communication between physicians and payers.

MS. BERRY: Do you think we should limit it to Medicare and Medicaid? I mean, do you recognize that there are other issues that private -- the original recommendation included private payers.

DR. WINN-DEEN: Right, but in terms of follow-up, the only follow-up that we could probably do would be in terms of monitoring whether things are being accepted and used. The first question is are they being used, period, by Medicare and Medicaid. The second question is if they are being used, is it improving from a health care provider point of view their denial rate, so that now they feel like they are getting paid when they've done a legitimate service.

MS. BERRY: And who would do the monitoring?

DR. WINN-DEEN: I guess the question I would have is is there someone who has oversight over CMS to see if new programs are properly implemented within the CMS umbrella of organizations.

DR. ROLLINS: I can't address that. I don't know the answer to that question. But are we restricting this only to Medicare and Medicaid?

MS. BERRY: It didn't start out that way and now it seems to be moving that way.

DR. WINN-DEEN: The only reason I'm doing that is because from a monitoring for compliance point of view, we can recommend to the Secretary that they do things within the Secretary's purview. We can't tell him to go monitor whether Blue Cross or Kaiser is doing it, but we can ask him to see if Medicare and Medicaid are doing it, and if so, what's the experience been. That's all.

DR. TUCKSON: Maybe one way to do it is -- doesn't CMS have a seat on the CPT editorial board where all this stuff is hashed out? I'm just thinking that CMS has a seat.

DR. ROLLINS: We do have a representative on that committee, yes.

DR. TUCKSON: So maybe one way to do this is simply for -- we can urge that the Secretary's representative on the CPT editorial board make this issue a priority for the CPT editorial board to assess the use of the modifier and its effectiveness at being able to have appropriate reimbursement for genetic tests.

DR. LEONARD: I don't think that's something the CPT editorial board does.

DR. TUCKSON: The CPT editorial board is the place where these codes –

DR. LEONARD: Where codes are approved.

DR. TUCKSON: And also there is a continuing update of what's going on with the use of CPT codes. They don't just put the codes out. They also have regular conversations. We can double-check on that offline. But the CPT editorial board is a place where, once the codes are in, they are always rechecking them, re-looking at them. They issue something called the CPT -- oh, gosh, a manual which continues to update how to best use codes. They're very involved in the implementation, not only in the setting of.

DR. McCABE: One of my colleagues at UCLA is on that editorial board, so I'll step out and see if I can get that clarified.

MS. BERRY: Given the limited coverage by Medicare of genetic tests and services, how much information would we glean by monitoring whether Medicare uses the CPT codes?

DR. LEONARD: Well, here you have the broad definition of genetic test, because these CPT codes are used for inheritable, somatic, infectious disease. Any kind of nucleic acid-based test uses these, and these modifier codes address all those different areas of nucleic acid-based testing, not just inheritable, that may not be as utilized in the 65 and older age group population.

MS. BERRY: We've got just under two minutes left to go on this recommendation. I'll put out before the group two ideas. One is to simply delete this recommendation entirely. The second we've been spending a fair amount of time on in the latter part of this discussion, amending it in some fashion along the lines of what we have up on the screen now, which is sort of changing the focus of the recommendation to the CPT editorial panel and monitoring the use of these modifier codes by Medicare and Medicaid.

MS. GOODWIN: Can I actually suggest a bit of modification to this? It's a bit indirect, but the Secretary, through its role in the CPT editorial panel, could encourage AMA to, through its membership on the Pathology Coding Caucus, which is described on page 36 of the report -- that body has a broad membership that includes AACC and a list of other organizations. But that might be a way to get this task done and still direct the recommendation to the Secretary but not have it take place at AMA or within HHS. It would require some tweaking of the language, but it might be a way to get a more independent organization to conduct this assessment.

DR. TUCKSON: The only thing I'm concerned about here is that this assessment is going to be very tough for some group that's not involved in this every day, because on the one hand, it's something that Hunt was getting at I think, that you've got at one level there is concern about whether payers are going to or are adequately using the modifiers. On the other end, you've got to worry about whether the providers of care are using the modifiers appropriately, because you get all kinds of mess around incorrect coding.

So you've got both sides trying to work through how they are using this language. So I'm just a little bit anxious about creating some group that's not involved in this on a regular basis.

MS. BERRY: My own view from listening to the discussion is that I don't think our report should try to chase a problem that we don't know yet exists with a recommendation. So I'm wondering if perhaps this may be a problem but it's probably not ripe yet, because I don't know that sufficient time has passed for us to really assess whether we've got a real issue on our hands. So I vote that maybe we take this recommendation out entirely, and then if the next time after we receive public comment on it we have a little bit more time under our belts, that we might revisit it, and if there is a recommendation that others might want to put forward, a specific panel or a specific entity, then we can insert that in before the report gets finalized.

DR. TUCKSON: And especially given what Debra said, that the reason we got here was because we didn't think these things existed, so there was no language to describe it, so how could anybody get reimbursed for doing it. Now we know there's a language. Now over time we can see whether or not the language works, whether the people on this side are interpreting it properly and the other side are communicating it properly. But we don't know there's a problem yet, so why make the recommendation?

DR. LEONARD: I vote for removing the recommendation.

MS. BERRY: Does anyone disagree?

(No response.)

MS. GOODWIN: Do you want to delete the recommendation? When we go out for public comments, do you want to not request public comment on this particular recommendation, or should we pose the recommendation requesting specific comments on it?

DR. WINN-DEEN: I think if we take it out, we should take it out.

DR. LEONARD: I think if you delete it, the information about these modifier codes is still in the description, and if someone has an issue around those codes or the use of them, then it gives them the grounds to raise that issue in the public comment period with suggestions of what might be added to this report. But at this point the modifier codes now exist, and I think that there hasn't been enough time to have the implementation phase of a new code have happened. So I think we should just leave the codes alone and take this recommendation out.

MS. BERRY: All right. Let's move on to the next recommendation. That would be number 7 dealing with the Medicare clinical laboratory fee schedule. This addresses the concern that has been raised on numerous occasions in previous meetings with regard to the fees being inadequate, that the costs of providing genetic tests exceed Medicare payment rates, and this recommendation is designed to address that, recognizing that lab fees are frozen until 2009, with no changes to payment rates expected statutorily in the near future.

So this recommendation is another crafty one, I suppose, designed to encourage CMS to address the variation in payment rates using its inherent reasonableness authority. That's a quick summary of the recommendation. I'll throw it open for discussion.

Where did Emily go? She's our lab fee person.

Ed?

DR. McCABE: I'll just say that I think this one definitely should stay in here. I think it is an interesting approach to this. Does CMS have any objection? Is there anything that we might be walking into with this recommendation?

DR. ROLLINS: I think this is a reasonable recommendation for them to evaluate.

DR. McCABE: If we don't use up our time on this one, can we carry it over to the next one?

MS. BERRY: Absolutely.

DR. FRIES: Could someone tell me what "inherent reasonableness" is? I have never heard of it before.

MS. BERRY: Page 45 of the report, 44 and 45. It starts on page 44. We corrected that in the recommendation that's up on the screen.

DR. LEONARD: You corrected it in the document itself, too.

DR. McCABE: I would suggest we move on if nobody has anything. This fits with the reasonable and necessary. That's where the terminology comes from.

MS. BERRY: Any other comments or suggestions? Edits?

(No response.)

MS. BERRY: All right. Hearing none, we'll move on to the next recommendation, billing and reimbursement of genetic counseling services. No recommendation.

DR. LEONARD: So do we need to hear the report from the Genetic Counseling Services Work Group, that report, before we enter into a discussion of this one?

MS. BERRY: All right. Barrier number 8, reimbursement of genetic tests. I jumped ahead. I think I need to confer with staff as to why we have this. Put on your microphone. Let's get it out in the open. We have Barrier 8, reimbursement of genetic tests, page 45 through 48 of the report, but we don't have a recommendation that's currently proposed. Is the point of this discussion to identify the problem and highlight it, and then throw it open for possible suggestions?

MS. GOODWIN: Yes.

MS. BERRY: Okay. We don't have a recommendation for this problem, which is the fact that payment rates for genetic tests don't cover the actual costs, reimbursement is inadequate and can hinder access, and we don't have a specific recommendation for the committee, but there may be recommendations that individual members want to put forward for the committee's consideration and incorporation in the report.

DR. LEONARD: I'm confused, because doesn't Recommendation 7 address this?

MS. GOODWIN: It addresses it for Medicare, but the question that we wanted to pose is whether there's another recommendation that can be made that gets at private health plans or Medicaid.

DR. WILLARD: There's a recommendation on page 45 that we skipped. Is that the one that we just skipped?

MS. GOODWIN: Forty-five. So if there is a more global recommendation regarding this barrier that can be made, we wanted to pose it for discussion. But if there is no recommendation –

DR. LEONARD: Reed, can you address it? To what extent do other private payers stay in line with Medicare reimbursement? So if Medicare reimburses differently for these molecular codes, then other payers may follow suit?

DR. TUCKSON: I'm going to be a little careful here given that I need to walk a very fine line here. I think what you're getting at is on the payment rates, my understanding of this just in the industry and not specific to my own activities is that these are variably negotiated contracts with many different vendors that get into the normal strum und drang of business negotiating contracting decisions with vendors who supply services. I think the range of permutations are probably fairly complex, and they have to do with size and scale of your market clout, the number of tests that are anticipated for a covered population. It has to do with how skillful you are at

negotiating or how many different services you may have with a particular vendor for a multiplicity of activities, some of which may be genetic basic routine garden variety stuff.

These are just pure, real-world business realities that are germane to any business negotiating with the supplier of a service. So my answer to you is probably that you will find enormous complexity and differentiality here. I think that probably categorizes it the best I can.

DR. LEONARD: Basically, the Secretary of Health and Human Services has nothing to do with those negotiations, and therefore we're walking into territory that we don't have any control over. I mean, that the Secretary doesn't have any control over.

DR. TUCKSON: As far as I understand, the Secretary is not involved in private sector economics.

DR. McCABE: I agree with you. I think it falls under the same category as one of the previous ones. The only extent to which we could make a recommendation would be the second paragraph: "Furthermore, government programs should reimburse for service codes when documentation supports its reimbursement." I think that's where you could then take some stuff out of the first paragraph that is basically the whereas. Aren't we on proposed Recommendation 8?

PARTICIPANT: No, this one behind us.

DR. McCABE: Oh, sorry.

DR. WINN-DEEN: So I personally don't see a need for another recommendation on top of number 7 which we've made, and that addresses the segment that HHS can control in terms of trying to get reasonable payments in place.

DR. LEONARD: I guess a global question in making these recommendations -- Reed and Cindy have already warned us that once this goes out for public comment, it will be scrutinized up and down by everybody. So do we have the ability to make the Secretary aware of issues that the Secretary doesn't have control over but are still an issue? So 7 could also have a final sentence that said appropriate reimbursement by private payers is also a concern, or something to the extent that this will address CMS. But there's a lot of genetic testing that's not for Medicare patients and Medicaid patients, and you need to be aware that there needs to be appropriate reimbursement across the health care system.

MS. BERRY: It's in the report, I think, and we'll have to go back and re-read it. Maybe there are some additions that we might want to make to really hone in on that. But I think that is a good way to flag an issue for the Secretary, by including in the text of the report the problem, describing the issue. We don't necessarily have to have a specific recommendation for it, but let's go back and look at the language, and then we may want to make some suggestions to staff in terms of how we might want to beef that up if we think that that doesn't adequately already flag the issue for the Secretary.

DR. WINN-DEEN: I mean, it seems like that's the appropriate place to put this discussion, is in the text. I mean, I don't think we should ignore it and pretend it's only a CMS issue. It is a broad issue, and we should say that in the text. But in terms of what we can actually recommend someone to do, I think we only have control over one piece of that, and I guess we could

encourage private payers to follow examples, but I'm not sure that necessarily some of them aren't better payers than the example we might be encouraging them to follow.

MS. BERRY: Ed, did you have a comment?

DR. McCABE: I was just going to say that running HHS I know is a lot bigger task than running a department of pediatrics. But when somebody brings me an issue about parking, which at UCLA I have nothing to do with, it doesn't do anything but make me wonder why they brought it to my attention. So I think we need to be cautious of what we put in front of the Secretary.

DR. LEONARD: And like the CPT modifier issue, it's in the text because this whole next section that doesn't have a recommendation -- I agree with Ed, we can't make a recommendation to the Secretary. But the discussion is here so that if people actually read this report and provide comments, they have the opportunity to comment.

DR. McCABE: The other thing is that by opening it up to all of the insurance industry, we have just painted a huge target on this document, which I'm not sure we want to do either.

MS. BERRY: So is the consensus that we should leave well enough alone and not endeavor to craft a recommendation that is specifically addressed to the private sector? Any objections to that approach?

(No response.)

MS. BERRY: Okay. Let's move on to genetic counseling. Here is where we needed to get some outside help. At our October meeting, SACGHS requested some information on the value and effectiveness of genetic counseling services provided by a wide range of health providers. We all knew that the services they provide are valuable and effective. We all know that instinctively but felt that we should really endeavor to get more detailed background information and scientific information, a literature review and other data that would support that.

So there was a work group that was formed, the Genetic Counseling Services Work Group. Those are the members of the work group up on the screen. The task of the work group was to provide a list of legitimate credentialing programs for genetic counseling services, inform us as to the provider types who are qualified to offer these services and be reimbursed for those services, conduct a literature review and analysis of the evidence that demonstrates the value and effectiveness of genetic counseling services and the importance of reimbursement for them, conduct a literature review and analysis of evidence that demonstrates whether licensure of genetic counselors is needed, whether and if so which non-physician genetic counseling providers are qualified to provide these services without the supervision of a physician, and whether harms are resulting because non-physician genetic counseling providers are not able to bill directly for their services.

We felt that based on all of this information we would be better able to craft recommendations that would address the genetic counseling component and make our recommendations more effective. So we're going to take some time now to hear from the Genetic Counseling Work Group. Kelly Ormond, Andrew Faucett, Judith Lewis, Judith Cooksey, all four were instrumental in putting together this report, and based on their report to us, we'll be able to then turn to the specific recommendations in the coverage and reimbursement report that pertain to genetic counseling services.

Ed?

DR. McCABE: Just as we're listening to this group present, though, this is where I had jumped ahead of the group. I think we need to cast this in light of the second paragraph. We can use some of the material in the first paragraph as whereases, basically, but then again I think we can only focus on government programs and recommend reimbursement for prolonged service codes when documentation supports the reimbursement. So I think we can do it, but I think using the discussion we've just had we should focus on what the Secretary has purview over.

I think, however, it's extremely important that we include the appendix material that has been included in the draft given to us, because I think that will provide the real information. I'm sorry to interrupt and head off our group. I just wanted the committee to be thinking about this.

DR. TUCKSON: I'm sorry also, but I just think it's important. I think that what you said is fine. I think the other thing, though, is to highlight these issues in the text, not only just in the appendix, but I think in the text is very important so that everybody understands that there is something for the public, because one of the things I think also, Ed, here is that the recommendations go to the Secretary but the report is to the public. I think that we have that obligation to that overarching thing around public education, to keep folks attentive to what the real issues are and the subtleties there. So I think if we can at least sort of say that we are concerned about, on the one hand, for example, the cost, that there's money to pay for services. On the other hand, that you don't break the bank. Just laying the issues out in the text is important.

DR. McCABE: I think the analogy is that this morning we talked about how Francis and his colleagues wrote the Book of Life, but now people are afraid to open it. If we can get past that point, we need somebody to help them understand the language in it, and that's going to be the counseling community.