U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY

Sixth Meeting

Monday,
February 28, 2005

Grand Ballroom Salons A-B
Marriott Bethesda North Hotel and
Montgomery County Conference Center
5701 Marinelli Road
North Bethesda, Maryland

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PROCEEDINGS (8:37 a.m.)

DR. TUCKSON: Good morning.

I was not worried about there being snow, and then I checked with Francis. Francis gave me the thing again, because he's got a computer with the weather thing on it. But we're going to press through today because we really do have an awful lot to accomplish over the next two days, so we'll do our best. If it looks like tomorrow is going to be bad, we'll worry about that as we go along and try to be sensitive to people. But right now I think we'll put that out of our mind and focus on the agenda as it's before us.

Let me just say that the public has been made aware of this meeting through notices in the Federal Register, as well as announcements on the SACGHS website and listserv. I really want to thank everybody that is here in person, but also I do want to make sure the committee members are aware and are appreciative of the webcast.

I didn't realize this, Ed, you didn't warn me, but emails come in during the process of the meeting. So there are a lot of people out there who are actually paying very close attention to what you say. They're okay with me, but apparently it's you. So just be aware that there's a lovely interaction from people back and forth, and we appreciate that.

Also, for those who have sent emails asking about the meeting minutes from October, those will be up shortly. We do know that those hadn't gotten up from our last meeting, but they will be, I'm assured. So I just want to make sure that those who have asked about that are aware.

I want to welcome two new people to the committee. We are very pleased that Dr. Joseph Telfair has joined us from the Department of Maternal and Child Health, the School of Public Health at the University of Alabama at Birmingham, where he is an associate professor. He holds a Doctorate of Public Health from Johns Hopkins and an M.S.W. and M.P.H. from the University of California at Berkeley. His work is focused on health care access issues for the poor, rural, multicultural, multiethnic populations, as well has been a very strong advocate for patients with chronic diseases, particularly those with sickle cell disease.

Dr. Telfair is also serving as the SACGHS liaison to the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. We thank you for taking on that role. We will hear about that committee's work some more today, so we are very appreciative of that.

Joe or Joseph? How would you like to be called?

DR. TELFAIR: Either one is fine.

DR. TUCKSON: Well, Joe, welcome aboard and we thank you for being part of this.

We are also pleased to welcome Father Kevin Fitzgerald, who joins us from the Department of Oncology at Georgetown University Medical Center, where he is the Doctor David Lauler Chair in Catholic Health Care Ethics, as well as a research associate professor. Father Fitzgerald received dual Ph.D.s in both philosophy and molecular biology from Georgetown University. His research on oncogenes has most recently focused on tumorogenesis of the MLL and the MLL2 genes. Father Fitzgerald will be participating in this meeting as an ad hoc member while the processing of his appointment papers is completed.

But, Kevin, you are fully on board here and we're going to expect you to work just as hard as Ed McCabe. There is no grace period.

We are pleased that Dr. James Rollins will represent the Centers for Medicare and Medicaid Services.

Thanks a lot, Dr. Rollins.

As well as Dr. Willie May, who is representing the Department of Commerce for Dr. Semerjian.

Dr. Melissa Fries will represent the Department of Defense for Colonel Martha Turner. I think she must be on her way.

Kim Zellmer will be joining us later today. Chris Hook can't be in person but will be participating by teleconference later this morning and tomorrow morning, and Joan Reede is, unfortunately, unable to attend this meeting.

Well, as you know, Mike Leavitt was approved as the new Secretary of Health and Human Services, sworn in on February 11th, 2005. Let me just say that I want to express my own appreciation for former Secretary, Tommy Thompson, who was very gracious and very helpful and received our committee's reports I think with great interest and responsibility, and we hope that he is doing well. But we are very pleased now to welcome the new Secretary of Health, Michael Leavitt.

As you know, he's former governor of Utah and served most recently as the administrator of the Environmental Protection Agency. We're trying to go through the process of getting on his schedule. It hasn't happened yet but I'm sure it will soon, and we'll have an opportunity to update the Secretary on the work of this committee.

Well, behind you on the chart is the strategic plan and our study priorities. I put that up there again just to remind you that this committee is very focused on its agenda. Once again, I have to give acknowledgement to the leadership of Ed McCabe, and as I take over now and continue the stream of activity, I want to make sure that we keep in front of us what we have agreed to do and we always understand what it is we are responsible for trying to complete.

Last March we did identify these 12 issues that we thought warranted various levels of attention by the committee. In August of 2004, we did submit a resolution to Secretary Thompson on genetic education and training, which is the second dot there. By the way, genetic discrimination, the number-one item on the list, we will of course be spending a great deal of time with today, and we'll talk a little bit more about that. But we did submit the resolution on genetic education and training which made nine recommendations aimed at ensuring the adequacy of genetics and genomics education for all health care and public health professionals.

The next one on our list is patents and access, and as you know, we received an extensive report on that at the last meeting and we are awaiting the latest developments from the National Academy of Science and their work, and I think we left that last discussion assured that this is moving forward with thoroughness and deliberateness, and I think we need to see what they deliver back to the process.

The overall oversight by the federal agencies stays on our minds, and that is one that we track regularly and consistently. Then there is the vision statement report, which of course we have also submitted to the Secretary, and it will be one of the main items on the agenda when we have the opportunity to meet with Secretary Leavitt.

In 2004 we sent a letter to the Secretary expressing concern about the potential harm to consumers from direct-to-consumer marketing of genetic tests and services, requesting HHS to collect data on the public health impact of the DTC marketing, and to collaborate with the Federal Trade Commission on the monitoring of such advertising. We have sent this forward to the Secretary as well. That is in your briefing books. I believe that letter is there. For those who are monitoring us through the Web, you can find that report on the website.

Let me just see what else we have on the list. The coverage and reimbursement is obviously the subject of today, large population studies tomorrow. Pharmacogenomics, we have a task force. Emily Winn-Dean chairs that, and we will be coming to that. We didn't have time in the agenda for today and tomorrow, so that is an issue we'll be coming back to visit very soon. I mentioned the direct-to-consumer.

Access is an issue that cross-cuts all of the other issues, and I think that we view the coverage and reimbursement issue to be a key issue for access. So we will be hitting that mark as we do the coverage and reimbursement discussion.

The public awareness and understanding issue is one that I would like just to take 10 seconds to put in front of the committee. I still, at least as one observer, am concerned about how well the public is prepared to understand the issues that are before them with this new revolution, integrating it into the personal health care decisionmaking, the counseling activities and so forth. I'm not going to ask for any action on that issue today, but maybe by tomorrow we might think about whether or not we need to convene at least some kind of a discussion with the best folks in the country and in the government who are thinking about this issue of what are we doing to educate the public.

I just know every single day in terms of the world in which I'm working and living that the individual American is expected to integrate extraordinary amounts of information as they take on more responsibility for their health care decisions. The last item on that agenda says "genetic exceptionalism," and clearly the issues of genetics are so intertwined now with so much of the health care system, and whether or not the public is adequately being prepared or other steps can be done, whether through elementary school, junior high school, high school education, whether it is through the kind of pamphlets and education that the government puts out as a normal course of what it does, I'm not sure, but I just think we need to start thinking about that as an issue. But at the end of the day, we've got to stay focused on what we have in front of us, and I don't want to take us too far afield. So I will leave that there and see if, at the end of the meeting, people have any thoughts.

Well, let's go straight to the agenda that we now have, and you will see that at the very beginning of your booklets. We will start the meeting with an update on our efforts on genetic discrimination and what has occurred since October. As you are, I'm sure, all aware, there have been a great deal of activities since October. So there will be a full committee discussion in light of those activities on our next steps, keeping in mind that the goal of our discussion is to determine what is the appropriate steps that we should take as a committee to push forward and add our own unique opportunities to add value to protecting against genetic discrimination, or in this case as we also understand, equally important, the fear of genetic discrimination in employment and health insurance through federal legislation.

We will spend this afternoon considering coverage and reimbursement, the in-depth high-priority issue that we ranked the highest, which has been the focus of much of our work over the past year. We will review a revised draft report on the issue, developing a consensus on 12 recommendations that have been made and discussing strategies for gathering public comments on the draft report. During our deliberations we will be briefed by the Genetic Counseling Services Work Group, which was formed after our October meeting to respond to our request for evidence supporting the value and effectiveness of genetic counseling services.

We also classified large population studies as an issue warranting in-depth study. We need to learn more about large population studies and what scientific, public health, ethical and policy issues they raise. We're devoting five hours tomorrow to an exploration of the issues associated with such studies. By the end of the 10 presentations we have organized on this topic, we will need to determine what next steps, if any, we wish to take. So again, we'll need to determine what next steps, if any, we need to take.

In addition, as we agreed at the last meeting, we'll begin hearing updates and briefings on three other important issues that we need to be aware of. First, following the genetic discrimination update this morning, we will be briefed about the National Health Informatics Initiative. This topic was introduced during our discussion of the Surgeon General's Family History Initiative at the October meeting, and we want to consider how genetics, genomics, and family history information will be incorporated into this broad initiative. While we certainly did focus this and got into this through the Family History Initiative, I think that the events are moving so rapidly now in the area of health information integration that it will have very broad implications for every part of health care, and I think it is important for many reasons that we hear and listen carefully to that report.

After the NHII briefing we will hear a report on the newborn screening recommendations that have been made by the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children, which is a report that has been of great interest to many.

Tomorrow afternoon we will be briefed about a collaborative public/private effort to promote quality laboratory testing for rare diseases. This briefing resulted from a specific request by CDC for feedback from our committee on their efforts. So due to this very full agenda, as I mentioned, we will not be having a session on pharmacogenomics at this time, but we will be looking forward to that coming forward.

Public comments sessions are always appreciated. This committee is committed to great respect for listening to the public, and as such as we have public comment on both days of our meeting. Seven individuals so far have signed up to provide testimony, so that is just terrific and we're pleased about it.

Finally, I'd like now, in closing out this part of the meeting, to have Sarah Carr give us the reminders of all of the very serious rules that you are under. You can barely breathe without being in trouble, so watch out.

MS. CARR: Thank you, and good morning, everyone. I'm actually only going to talk about two of the rules today. One is the conflicts of interest screening process and the need to be attentive to conflicts of interest during the meeting.

As you know, before every meeting you provide us with information about your personal, professional, and financial interests. It's information that we use to determine whether you have any real, potential, or apparent conflicts of interest that could compromise your ability to be objective in giving advice during committee meetings.

While we waive conflicts of interest for general matters because we believe your ability to be objective will not be affected by your interest in such matters, we also rely to a great degree on you to be attentive during our meetings to the possibility that an issue will arise that could affect or appear to affect your interests in a specific way.

In addition, we've provided each of you with a list of your financial interests and covered relationships that would pose a conflict for you if they became a focal point of committee deliberations. If this happens, we ask you to recuse yourself from the discussion and leave the room.

Lobbying. Since we're going to be talking about congressional affairs and legislation in a minute, I did want to remind the committee that as government employees, and you're special government employees, we're prohibited from lobbying, and thus we cannot lobby, not as individuals or as a committee. If you lobby in your professional capacity or as a private citizen, it's important that you keep that activity separate from the activities associated with this committee. Just remember that this committee is advisory to the Secretary of Health and Human Services. We don't advise the Congress.

We appreciate your attentiveness to these two rules and all the others that apply to you, and we appreciate how conscientious you are about them.

DR. TUCKSON: Well, with that admonition to be attentive, and with the reassurance that we're all special --

(Laughter.)

DR. TUCKSON: By the way, let me just ask, does anybody on the committee have any opening issues, anything you want to put on the table early or anything before we launch into the agenda?

(No response.)

DR. TUCKSON: Well, with that, let's turn then to Agnes and to Cindy, who will take us through this very important first part of our meeting, with an update on genetic discrimination.

MS. MASNY: As Reed had mentioned, there has been a lot of activity from the task force, as well as legislative action that's been happening, so we wanted to update you on all these activities. Cindy and I will be splitting the presentation.

Just as a recap, the genetic discrimination has been noted as one of the highest priority categories for our committee's work. In the past already two letters were sent to Secretary Thompson supporting federal genetic non-discrimination legislation and Senate 1053 in particular. The committee, in our October session, held a specific session on genetic discrimination to gather the public's perspective on the magnitude, the scope, and the impact of genetic discrimination, and most specifically we tried to address the issue of the fear of genetic discrimination in society. We received testimony from members of the public, health care providers, and other stakeholders.

So what we're going to be presenting today is some of the legislative activity that has taken place to give you an update on the report that we are to put together that's to go to the Secretary, and as Dr. McCabe had indicated at our last meeting, we wanted to make it about telephone book size, and then to update you on the fact-finding efforts that have been going on with the stakeholders, and this is the specific part that Cindy will present. Then as a committee we will discuss what steps we would like to take next.

So these are the members that have been on the Genetic Discrimination Task Force, and also I just wanted to point out the work of Amanda Sarata and Sarah Carr, who have been working extensively behind the scenes, along with all the task force members.

So for the legislative update, as you have seen in your packets that you got, your briefing books, the

Genetic Information Non-Discrimination Act of 2005, Senate 306, has been introduced earlier this month. It was sponsored by Senator Snowe, co-sponsored by Senators Frist, Gregg, Kennedy, Enzi, Jeffords, Dodd, Harkin, and you can see the rest there that are on the slides. This bill is nearly identical to the one that was passed by the Senate in 2003. So the bill prohibits group health plans and health insurers from denying coverage to a healthy individual or charging a person higher premiums based solely on genetic predisposition to developing a future disease. It also bars employers from using genetic information when making hiring, firing, job placement, or promotion decisions.

So the bill actually has passed the Health, Education, Labor and Pension Committee earlier this month and then was debated on the Senate Floor on February 16th. Although, with all the work that has been done, we can't take credit for everything, but just to mention that there were several references from the work of the committee and its support for genetic non-discrimination legislation, as well as Secretary Tommy Thompson's response to the committee's letters that he has received. Specifically, Senator Enzi mentioned testimony of our last meeting and the testimony of Heidi Williams and Tonia Phillips, and Senator Kennedy mentioned the testimony of Heidi Williams and Phil Hardt.

So almost simultaneously to that particular action, the Executive Office of the President from the Office of Management and Budget gave out a statement of administration policy on February 16th. That administrative statement was passed out in your books for today, but just to highlight one of the aspects of it, and that is the administration favors enactment of legislation to prohibit the improper use of genetic information in health insurance and employment. The administration supports the Senate passage of 306 as reported. The concern about unwarranted use of genetic information threatens access to utilization of existing genetic tests, as well as the ability to conduct further research. The administration wants to work with the Congress to make genetic discrimination illegal and provide individuals with fair and reasonable protections against improper use of their genetic information. So this has all been very, very positive, and we've been very excited about this movement itself.

Then the next day after the administration policy was issued, the bill was unanimously passed by the Senate.

As far as the House goes, no bills have been introduced to date on genetic discrimination. In the last

Congress, even though the Senate passed 1053, several bills were introduced in the House but none of them moved forward. The committee is hopeful that the Senate bill is going to be introduced very soon in the House.

As far as the update on our report goes to the Secretary, at the conclusion of our public testimony and the roundtable discussions that were held in October 2004, the committee recommended that we take several actions, and one of them, the first, was to compile the testimony that we heard, and the public comments that were received by the committee, and relevant scientific articles, to submit them to the Secretary. This was what I was referring to, our telephone book sized report to the Secretary.

Then to gather information from stakeholders, and to facilitate a meeting of the stakeholders. Some of these stakeholders were the Genetic Information Non-Discrimination and Employment Coalition. That's GINE. AHIP is the America's Health Insurance Plans, the Chamber, and the Coalition for Genetic Fairness. We did receive testimony from one of the groups, but we wanted to have further input from all of the stakeholders to be able to get perspectives on all of the issues that they had.

Then lastly, our third job was to facilitate an analysis with the Department of Justice and the Equal Employment Opportunities Commission of the current law that we had in terms of protecting the public against genetic discrimination.

So here's what has been happening. The task force held a call in late November to further develop a work plan and carry through on the outcomes that we had decided upon at the October meeting. The task force found that the broad testimony received from the providers and other stakeholders pointed out the range of perspectives on this issue and really did need a deeper analysis. So the task force worked out a three-part structure for the report to the Secretary.

The first of them was, of course, the public comments. Prior to the October meeting, the committee had solicited the public comments and received a significant number of responses in addition to the 14 testimonies and public comments received during the October sessions. All of these comments have been compiled in a document. The task force also concluded that the testimony of the seven patients that presented to us was so compelling that we should take excerpts and highlight them in a DVD. So what you have in your briefing book is you'll see that you actually have the script for that DVD, and that's something that we would like to discuss further in our discussion points.

Secondly, the second component in the report to the Secretary will be the stakeholder analysis, and this is looking at all the stakeholders' positions, their points of agreement and disagreement, and where consensus possibly can be reached. Cindy Berry will be going into more detail on the fact-finding from the stakeholders' meetings.

Then the third component that we were given to work on was the legal analysis, and that is actually being prepared by a committee, our committee staff, with technical assistance from the Office of Civil Rights, and the Centers for Medicare and Medicaid Services, the Department of Justice, Department of Labor, and the Equal Employment Opportunities Commission. All of this work is actually to help us to inform the debate about the accuracy and completeness of the current legislation that we have.

Now I'm going to turn it over to Cindy so that she'll give us an update on the fact-finding from all of the stakeholders' opinions.

MS. BERRY: Thank you, Agnes, our fearless leader.

Fact finding. This component of the report really centers around the different perspectives and opinions of the variety of stakeholders, and we wanted to consult with as many groups as possible to really get a good feel for what their view is on genetic non-discrimination. We know in Washington, while this issue is a high priority for this committee, there are a variety of viewpoints. People come at this issue from different perspectives, from the employer perspective, from the health insurer perspective, from the consumer perspective, and we really wanted to get a very deep understanding of these different views and gather much more detailed information that could be compiled into the report.

So we conferred with the U.S. Chamber of Commerce, America's Health Insurance Plans, and the Coalition for Genetic Fairness, and we'll report to you on each of those conversations. Starting first with AHIP, America's Health Insurance Plans, they shared a copy with us of a letter that they sent on February 22nd to Chairman Boehner of the House Education and Workforce Committee, and Chairman Barton of the Energy and Commerce Committee. This letter is in your table folders, and it outlines in greater detail AHIP's position on genetic non-discrimination legislation.

You have the letter before you, but I'll highlight just a few of the key points. AHIP expresses opposition to genetic discrimination, stating that consumers should be protected from discrimination based on genetic information. In the letter AHIP also expresses support for protections established by HIPAA, the Health Insurance Portability and Accountability Act, and indicates that S. 306, the bill that just passed the Senate, would not undermine important quality improvement and disease management programs. That was a positive statement with regard to that bill.

The letter goes on to state that AHIP is committed to continuing to play a constructive role in the ongoing debate on this issue and urges Congress to address the issue at a deliberate and thoughtful pace.

Next we turn to the U.S. Chamber of Commerce, and as you all know, the Chamber is a large business federation that represents millions of businesses, state and local chambers of commerce, and business associations across the country. Their mission is to advance human progress through an economic, political and social system based on individual freedom, incentive, initiative, opportunity, and responsibility. We talked to the Chamber about their position on genetic discrimination, and they outlined for us some general points, and then more specific issues with regard to the legislation at hand.

The Chamber believes that employers should be able to make decisions based on genetic discrimination in cases where the employee is an imminent threat to the workplace or the employee, and they gave us an example. That example would be an employer needing to reassign an employee working with a particular hazardous material if the employee has a genetic predisposition that makes it likely that the hazardous material poses a greater threat to the employee. So that is one example where the Chamber said they probably need to have, from the employer's perspective, a certain amount of flexibility to protect even members of their own workforce.

The general concerns that the Chamber outlined for us are listed on the screen there. Basically, there is no record of employers discriminating, or no widespread discrimination in the workplace that's been documented, so they feel that the goal of any legislation should be focused on reducing employee fear of potential discrimination. They are also concerned about the possibility of increased liability and frivolous lawsuits. Thirdly, the Chamber contends that current law does provide appropriate protection of confidentiality of medical information, including genetic information.

The Chamber outlined for us specific concerns as well, in addition to the more general concerns that we just went over. First, they feel that damage provisions in the law, in the statute, should be limited to equitable relief. They believe that one federal standard should apply and should preempt different state and local laws. The definition of "family" should be limited. Lastly, they feel that the study commission should be truly independent and not housed within the EEOC.

Next we spoke to the GINE Coalition, and this is a group of employers, trade associations and professional organizations. They have on their steering committee the Chamber, the Society for Human Resource Management, NAM, HR Policy Association, College and University Professionals, and the Association for Human Resources. We asked them about their position on genetic non-discrimination legislation.

They contend that there is no appreciable evidence of genetic discrimination in the workplace. Their focus is on employment discrimination, not health insurance discrimination, and they too have concerns about unintended consequences, unnecessary regulation, and excessive litigation.

The Coalition for Genetic Fairness strongly supports federal genetic non-discrimination legislation, and their mission is to educate congressional policymakers and staff about the importance of implementing legal protections in this area and passing non-discrimination legislation at the federal level.

I won't go through all the members of their executive committee. They're up there on the slide. But they are looking to broaden their existing membership to include patient groups that address not only rare diseases but also common complex diseases such as cancer and heart disease. They're looking to expand the membership in the provider community to include umbrella provider organizations. They are currently working, of course, with the American Academy of Pediatrics, but they want to go beyond that specialty society and focus on broader groups as well, and they're looking to expand into industry so that the business community is represented in this coalition as well.

Their position on the genetic non-discrimination legislation is that it is important because of the need to have predictability for consumers and providers. They feel that the lack of federal legislation in this area creates an unfriendly climate for companies trying to develop new innovations in this area, and they feel that patients and providers must be willing to participate in research supporting the development of new products, and that the lack of federal legislation thwarts that goal. They feel that employers would benefit from predictability in this area, and they are not convinced that current law provides sufficient clarity or protection.

They also contend that the remedies available under existing laws are murky and not necessarily limited as they are under S. 306. So they actually feel that the federal legislation as portrayed in S. 306, the bill that just passed the Senate, would provide a greater deal of clarity for employers, as well as for consumers. They have been embarking on a variety of legislative efforts. They've been very supportive of S. 306. Senate Majority Leader Frist and the Health Committee Chairman Enzi are advocating for this bill, and the Coalition's efforts have been an effort to support passage of this bill, not only in the Senate but now as the action shifts over to the House.

They are in discussion with a number of key senior House republicans regarding introduction of the Senate bill. I think their hope is that a republican will step to the plate and serve as the lead sponsor, along with Representative Slaughter, who was the Congresswoman who was the lead in previous Congresses on genetic non-discrimination legislation. I think their goal also, as it was articulated to us, is to have the Senate bill introduced in the House as opposed to having a different House version. The idea would be that this would streamline passage of the legislation so that you wouldn't have competing versions and then have to have a prolonged conference.

They are going to be working with the House Energy and Commerce Committee, the Education and Workforce Committee, and I do believe also the Ways and Means Committee, unless someone has figured out a way to draft a bill to avoid that committee's jurisdiction. But that was one of the difficulties in the last session of Congress. When a bill is referred to three different committees, it's kind of hard to get it going through the entire process.

I will stop here and Agnes, I believe, will lead us in a discussion of next steps.

MS. MASNY: First, I guess before we go on with any of our discussion on the next steps is to hear if we have any questions from the committee members about the work that has been going on, if you'd like us to further elucidate what was presented.

Ed?

DR. McCABE: Yes, I just would like to commend the task force on your excellent work. Clearly, you've been doing a lot of work on this very important effort, and I hope that that work leads to greater success in the House this year than we've had in the past. Thank you.

MS. MASNY: Hunt?

DR. WILLARD: Just a question, and you may or may not be able to respond, about the letter from America's Health Insurance Plans. I'm torn in trying to read between the lines whether this is actually a generally supportive letter on their part or whether, when we read phrases like "It's critically important for Congress to take time to consider the implications," whether in fact they're more in favor of a stalling and a slowing down the process in the interest of obtaining further information but clearly not in the interest of driving this to passage in this session. Any insights from the task force?

DR. TUCKSON: I've been sort of on some of these calls, and let me just make first of all a general observation. I want to echo Ed's sentiment to the committee, and also to the staff who have been working this. There have been some very intense, I think very specific and detailed conversations with each of the stakeholders that you've heard there. I think one of the things that's hard to gauge in the PowerPoint slides is a sense of the subtleties and the nuances of where different constituencies are really coming from.

There's no question, at least from my listening to those conversations, the sense that people really do, on all sides of this issue, understand the need for moving legislation forward. Where I think people are really concerned, as the PowerPoint indicated, is around the unintended consequences, and particularly the legal exposures, and that's just another issue. If there was some way of divorcing, of having the conversation about the legal stuff separate from some of the genetics stuff, this thing would be a lot easier. It's not as if you can sense from anybody involved in this process that they don't want to see the fear of discrimination gone away. I mean, I think people get that.

The issue is what do you do about the unintended? So that's the subtlety. The way I read the letter from AHIP, and I'm not in a position to speak for them but just in listening to the conversation with them, it seemed to be that what they are looking at are the same things that our committee is looking at doing, which is the legal analysis around the adequacy of current protections in that same kind of trying to get clearer about what things sort of exist now.

I think the other area that AHIP seemed to be emphasizing was just making sure again that the use of information in service to the coordination of care for people was not violated. Other than that, Hunt, I can't tell, but I did not, at least as one person, get the sense that they were putting that in as a stalling tactic. That was not what came through at all, but others may see it differently.

DR. TELFAIR: Just a quick question. In listening to the presentation, I'll be learning more about this, but in your conversations with them, did you get a sense of -- well, a lot of times when you have this kind of discussion with them, they sort of recommend this is where we think it should go, but this is what we believe will be the case. I was wondering do you believe it to be the case in terms of will you see a change? Is this realistic? Will it happen? What did you get the sense from the discussions where people were with this in terms of their hopefulness that next steps will occur and be effective in the direction that they would like to see?

I ask that question because that's really important when you try to make decisions about recommendations, because you need to get a sense of where people believe it's going to go.

MS. MASNY: Just for the committee in general as to where --

DR. TELFAIR: Yes, for the committee in general. Dr. Tuckson said there are things you don't see.

MS. MASNY: Well, I think that's one of the reasons why some of the next steps that we have up there is that one of the things we wanted to do was actually move ahead with the report to the Secretary, but actually divide it into three separate components. Since we already have compiled the testimony from the public, that would be something that we already have that we could move forward with if we get the approval from the committee for the script for the DVD. Then to do some further investigation with the stakeholders so that we clearly present the perspectives of all of the stakeholders that are involved, and then the third component, of course, would be the legislation, so that once we get the analysis, that might even help with the perspective from the stakeholders as well.

But we don't have that completely finished, the legal analysis, as of yet, nor a complete in-depth look into all the perspectives or have that compiled because things are kind of changing all the time with the legislation.

DR. TUCKSON: I think, Joe, the other thing I would say, I guess, is that the slides, although these issues are nuanced and subtle, they're fairly specific also in terms of what those words say there. Again, I'm being very careful here, but what we did see in those conversations was a willingness I think on the part of all the constituencies that were consulted to engage in pretty serious discussion and to try very hard to get to a place of some agreement on these issues. So people are working these issues. As a result, I think the only thing that we can predict reasonably is that we will not know any more until legislation gets introduced in the House, and that people will then react very specifically to very specific parts of that legislation, and they've been very clear as to where their concerns will be.

As a result of that, Joe, I think what your question is getting at, therefore what do we understand to be reasonable next steps, I would say that in terms of trying to predict our ability to get any more consensus than you see on this piece of paper, I doubt there's anything else that we can do until the specific legislation is introduced in the House. I think that's what you're trying to get at.

MS. MASNY: Francis?

DR. COLLINS: I also want to commend the task force for the work you've done to track this issue, and for all of the consultations you're doing which are critical with really important groups that are going to have a big impact on what happens.

I confess that when I read words like, well, we need to approach this at a deliberative and thoughtful pace, that it does seem like we've kind of been doing that. If you look back at the record of what's gone on, it has been 10 years now since an article was published in Science magazine advocating for the need for federal legislation to protect against genetic discrimination. In health insurance, two years later, a similar article advocating about the workplace. Both of those articles not only pointing out the need, giving examples where discrimination was occurring, albeit not a lot of them, and also making specific recommendations about definitions and the kind of language that would be needed in effective legislation, many of which are reflected in this current bill, S. 306.

So it does seem like a fairly deliberate and thoughtful pace has been adhered to. Just the same, we still, I think, are facing an uncertain time here. I looked back, or my staff did, at the history of S. 1053, which you will remember passed the United States Senate 95 to nothing, a unanimous vote in October of 2003, and yet 12 months went by without any action being taken on that bill, not even being referred to committee. That was the only bill in the 108th Congress in a two-year session that passed the Senate unanimously and was never assigned to a committee in the House.

So that indicates to you that there's something going on here in terms of resistance, and it's not going to be trivial to overcome that. Just the same, I think we have a real opportunity this year to revisit the question, and I agree with what Reed said about the willingness of the various parties to get engaged on the specifics of the details once there is a bill introduced in the House to be discussed, and I do think timing is everything. This momentum to try to get this considered in the House is really important and not to allow that to linger on.

I do also think it's an ideal moment for the new Secretary of Health and Human Services to be quickly engaged on this issue. You reported on the statement of administration policy. It's very clear where the Bush administration stands on this, but the personal role that the Secretary takes in this could turn out to be pretty important, and whatever you decide to do, then, about next steps, I would urge you to try to do it quickly.

MS. MASNY: Thank you, Francis.

Emily?

DR. WINN-DEAN: So I guess, sort of on that same vein, one of the things that I would very clearly like to understand, and I don't know if you have the information, Agnes, or if staff does, what is the timing that we have to do before this once again just falls off as unacted on? We should work with that kind of schedule in mind. So I would urge us to try and get at least Part 1 finished today to whatever point we feel it's ready and send it on so that we don't have a lot of stuff stuck within our own committee, and then to move forward with the other two parts as quickly as we can.

MS. MASNY: So your question would be what would the timing in the House be to have a bill presented before we're going to lose the opportunity?

DR. WINN-DEAN: Before it just falls off, like 1053 did. So it wasn't acted on in a certain time period, and then it just disappears. I just personally don't know what that is. Is it this fall? Is it a two-year period?

MS. BERRY: It's a two-year period. We just started this 109th Congress, so now we don't have a full two years. Obviously, if a bill is introduced one month before the session is supposed to end, chances will be pretty bleak as far as passage goes. But we do have a little bit of time. That doesn't mean that we shouldn't necessarily take a thoughtful, deliberate pace, but we do have some time before a House bill really needs to be introduced. Keep in mind that if it does get referred to three different committees, as the last bill in the House did, that will take an enormous amount of time for hearings and markups for it to go through the regular process.

The only other way to pry it loose, and this was tried the last time unsuccessfully, but it certainly can be attempted again, is if the Senate bill is introduced in the House in an identical version and they bypass the committee process and take it directly to the House floor. That's a rather extraordinary thing to do. It's certainly been done, but it's not the kind of thing the committee chairmen like to go along with because they do like to exercise their jurisdiction over these things, and it's an important enough issue that I don't imagine that the three committee chairmen would willingly give up their jurisdiction to allow a bill like this to go directly to the floor. That's sort of a tactic of last resort.

So I would guess within this first year it would be ideal to have a bill introduced in the House to give us another year for the regular House process to go through, and possibly result in floor action.

MS. MASNY: Ed?

DR. McCABE: With that, I would urge us to move with dispatch here in terms of the report that's been proposed, and especially the DVD. When I read the script of the DVD, it really brings up the passion of the individuals who were involved, talking about how they had to hide their genetic information, how they delayed testing for 10 years because of concern about this. Twice I saw in your slides statements that this isn't a problem, there's no reason to worry about it because it's not really a problem, and yet we know it is a problem. I think I admonished the genetics community to stop publishing statements that genetic discrimination is not a problem. Those papers have been skewed, they were poorly performed, and they've done a disservice to the entire American people.

We've got to get that telephone book out there so that that can no longer be used as an excuse: No problem, therefore no need for a remedy.

DR. TUCKSON: Let me just make one other quick comment to Ed's point. Again, I really do understand how hard it is to follow this. As the chairman, I'm always trying to find ways to get the consensus and trying to find where the common ground is and making sure that we don't lose at least sight of where there are opportunities to bring constituencies together. So I'm always going to try to find those silver clouds.

If you look on the handouts on the slides on page 3 under the Chamber's position on genetic discrimination, the second bullet, because Ed sort of said it's important, does not believe employers are currently engaging in genetic discrimination, but then they added a comma and a phrase, "though it does recognize that fear of potential discrimination may warrant a legislative solution."

This is again where I want to make sure that the nuances of the words are noticed by the committee. This is an addendum that they made after the end of our discussions with them. So that phrase is important, and again I just want you to not fly by that phrase. What it ultimately means when the bill goes to the House, I can't predict. But I think Ed's point is important, but notice that that is a recognition of something there. It's a subtle point, but it's a very important point. Is it determinant? I don't know, and I don't want to overplay it, Ed. But I just want to highlight that they are looking at these issues.

MS. MASNY: Ed, do you have a follow-up comment?

DR. McCABE: Just to follow up, I think that does leave the door open a crack, or at least say that we may agree to disagree but allow things to move forward. I think we need to take advantage of that. I also think we need to point out to Secretary Leavitt, and I'm sure you will do this when you brief the Secretary, that this is a civil right. We're seeing a violation of individuals' civil rights, and I think that we also need to recognize that what they're concerned about is the litigation, the remedies as they put it.

I've said this before. If, in fact, genetic discrimination is not occurring, then what is the fear of remedy? So if they do not feel that anybody is really doing this and it's simply the fear of the American people, then it would seem to me that they should be willing to support this legislation because, in fact, there is no fear of litigation if they really firmly believe that no one is discriminating.

MS. MASNY: We'll have Barbara, Emily, and then Kevin. I mean Debra.

DR. LEONARD: So 1053 got stalled by not being introduced into the House, and we have the three committee chairs. Are the three committee chairs the same as they were in the last Congress, or have they changed?

MS. BERRY: They changed a little bit last year. Chairman Barton was relatively new towards the end of the last congressional session to the Energy and Commerce Committee chairmanship. It was Mr. Tauzin before he left Congress, and then Mr. Barton took the chairmanship. Ways and Means is the same, and Education and Workforce is the same.

DR. LEONARD: So there are several steps in the process. One is just simply getting a bill or the bill that passed the Senate this time introduced. How do we do that? That wasn't able to be accomplished last time. So how does that get influenced to happen? And then once it is introduced, can we encourage the Secretary to distribute the report to him to the committee chairs as well so that they have this phone book sized information emphasizing that genetic discrimination is happening?

But I'm very concerned about that first step. How do you get a bill introduced, and what are the barriers to that happening? Do we know that yet? Because basically we're talking about when it's introduced what we do. But if we don't get past that introduction step, it's not going to happen.

DR. McCABE: Well, I think that Sharon Terry's group is probably one of the most effective ways of getting it introduced, and that is getting a large coalition together and maybe taking their information straight to the Congress. I mean, if this is not a problem, then there should be nobody standing on the steps of the Congress when they deliver their message. But my guess is that they could get a very large group of people --

DR. TUCKSON: Let me ask the staff if they can help us. We are well aware, I believe, and I want to make sure, that the advocacy coalition is moving with some deliberate speed to use their considerable opportunities to get something in place. So I think, Debra, you're asking a couple of questions here, if I understand you. One is, is there a role that we can play in that regard? Of course, as Sarah said up front, we're advisory to the Secretary, but there is something in play right now to make that happen. Can we just ask for what we know about that?

MS. CARR: My understanding from the conversations we had with the Coalition for Genetic Fairness is that they are working hard in the House and talking to members of Congress on both sides of the aisle to try to find a sponsor of the Senate bill, and they are interested in seeing one bill introduced in that chamber, and that bill is the Senate bill. So it seems that the advocates for this legislation are very hard at work on finding a sponsor of the Senate bill, and they sound quite optimistic. Maybe it will happen. I'm not sure if anybody from the Coalition is here.

Jo Boughman, our good friend Jo Boughman. Would you like to come and tell us --

DR. BOUGHMAN: I'm a member of the steering committee of the Coalition of Genetic Fairness. Sharon Terry was not able to be here today because she has her own board meeting.

Sarah and others have, in fact, represented the activities of the Coalition I think very fairly. There have been many meetings on the Hill with staff members and Congressmen on both sides of the aisle, as you pointed out, Sarah, and we are working very hard and as quickly as possible to utilize this momentum. I think it's fair to say that we do have some optimism. We hope it is not naive optimism. But we certainly have a lot of energy moving in that direction.

DR. TUCKSON: I did get an email last night from Sharon, who is probably even at her board meeting monitoring this online. So I expect to probably get a line in a couple of seconds from her saying that everything we just heard is absolutely right. So, Debra, you might want to continue your line of questioning, but be assured that there are extremely aggressive activities to try to get something into the House.

DR. LEONARD: So it seems that in the past with 1053 that the stakeholders that we've spoken with were some of the individuals or groups that were potentially blocking the introduction. Is it possible, since we've had conversations with them and I don't see any of these groups coming out and saying this should not be introduced -- I mean, even the Chamber has said, though, it does recognize that fear of potential discrimination may warrant a legislative solution. Is it possible for us to get statements from these groups so that those could be introduced with this document so that there's something in writing about their positions, or would they not at all be willing to do that?

MS. CARR: Well, one of the next steps that we wanted the committee to think about was to have a meeting of the stakeholders, bring them all together in one room. So I think we would like to continue to work with them, and we can certainly make that request of them to actually address the specific question of whether they would support the introduction of the Senate bill in the House. But these are sensitive negotiations that are going on in the Congress, and I'm sure there's a lot going on that we're not aware of. We do have to be careful of our role. We can't serve as a platform for negotiation of a bill, by any means.

But I think our effort has been trying to focus on finding out as much as we can and understanding as much as we can the concerns of the other stakeholders so that we can inform the Secretary about those, and in his discussions with the Congress he might be more fully briefed about those issues, and perhaps in discussions with Congress might be able to find ways of overcoming the differences and bringing everyone together.

So I think what we would probably want the committee to address is whether you would agree that we should have this request of a stakeholder meeting.

I think the other thing on the table, and perhaps the most important thing right now, is whether the committee would want to write a letter immediately to the Secretary. The stakeholder analysis, the legal analysis, is going to take a little more time. As Agnes indicated, we were hoping to have all three things together because it would be the more complete way to brief the Secretary. But given the momentum, as Francis said, on the House side and things that are going on there, it might make more sense for the committee to write another -- and this is a new Secretary, a new Congress. We've said these things before. It's a new bill. But it wouldn't hurt, I wouldn't think, for us to let this Secretary know right away what the concerns of this committee are, and also sending up the telephone book, as Ed said, that and along with it the DVD, which will be a very powerful way of demonstrating the concerns that the public and the patient community has about genetic discrimination.

DR. LEONARD: I agree that that should go forward. That's just my opinion, but I do think that that should be encouraged to be distributed to -- I mean have the Secretary distribute it to whoever the important people are in the House, and the committee chairs for sure, but if there are other key people.

DR. TUCKSON: By the way, just in terms of a specific answer to your other question about getting something in writing, I think what you have in the slides is about as close as we're going to get. They did write that in the sense that there was approval for those slides and the comments made there. So that was very careful, and I think you have something in writing, probably as much as you're going to be able to get, quite frankly. I'm sort of emphasizing that again because there's been an awful lot of conversation about it.

The committee is justifiably frustrated, as Francis and Ed and several of you have said. But just know that there's been, on your behalf, a lot of work going on to try to move this thing. People have not just been sort of sitting back since our last meeting.

The last comment was that there was a meeting. I don't know whether we know anything about it, but there was a conversation between the Chamber and some of those folks and the advocacy committee together within the last three weeks. I'm not sure if we know anything about that conversation and how it went, but I do know that they are meeting offline as well. So there's a lot happening here, and I guess I'll just leave it there.

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

DR. McCABE: Yes. I would just like to second Debra's support of a letter going to the Secretary. It's in the tradition of this committee and its predecessor committee, the SACGT, that it's been the first correspondence with each of the Secretaries that we have advised, and I think that we advise them on genetic non-discrimination, and I think it would be appropriate for us to keep with that tradition. But I would also, whatever we have together, I would send in support of that, and I would think we have all of the testimony of the folks. We have the ability to do the DVD with an excellent narrator in the person of our chair. So I would support that what we have in hand we send along with that letter.

DR. TUCKSON: What would you like specifically in terms of -- and we'll find out what the expectations are for the DVD to be produced, and I think Sarah needs to let us know what the timeline is. But with that information, give us some guidance around how soon you want this. Secondly, Ed, how specific do you want our letter to be regarding sort of saying something about the House?

DR. McCABE: Well, I would look back at the letters that we've used before, but I would emphasize the need to, in the appropriate jargon of inside the Beltway, pry it loose in the House. I'm sure there's a more appropriate art form to that language, but basically to try and move it forward. I'm sure that the Secretary understands the legislative process much better than I do, but Cindy's comment about the most expeditious way of moving it forward being to introduce 1053. I think we need to put the alternatives in there, but I would trust the staff and you, Reed, in terms of what the best language is. But I think we should be as detailed in terms of what we feel the steps are that the Secretary should take.

MS. MASNY: Melissa?

DR. FRIES: What were the lessons learned from 1053 in terms of its travels through the House? Because it seems to me -- did it even make it? Did it even show up anywhere? So it never even showed up anywhere. Obviously, that's the critical point. But then what would be the strategies that we have? Any other new information? Anybody else who could provide value on how to approach differently for different strategies? Clearly, you have a frontal approach, but you've got to get past that too.

MS. MASNY: Hunt?

DR. WILLARD: I think that gets to one of the issues. Clearly, the Coalition is busy, the staff is busy, this committee is busy, and none of the questions have been questioning that. But when we first started this committee, we had a presentation from a legislative aide, if I remember, one of our first meetings, who was very helpful although frustrating, but helpful nonetheless in pointing out that this basically wasn't going anywhere, it was never going to get introduced to a committee, much less make it to the floor.

So my question is do we have any sense now that we have any friends anywhere in the House leadership where someone is tipping their hand saying, yes, this will make it, this is going to work its way through the process, or are we being stonewalled, as we were in the previous session, in which case we may have to think of a totally different strategy because business as usual isn't going to get us anywhere? Do we have any sense that we have somebody who is willing to take this on?

MS. MASNY: We have some comments from the audience.

Could you please give us your name?

MR. SWAIN: Yes. I'm Frank Swain, and I'm among the people who are working with the Coalition for Genetic Fairness. I very much appreciate this discussion. I'll try to make just a couple of remarks.

It's distracting but in our view not critical that the bill has not been introduced in the House yet. The bill could have been introduced -- last year's bill could have been introduced four weeks ago in the House, and our attempt to hold back those sponsors was purely to get a bill that is more acceptable to a broader range of people, including significant members of the House republican leadership so that the bill does not have the fate that it did in the last Congress of just going nowhere.

I would dearly like to have told the staff that we have Congressman X and Congresswoman Y as our key sponsors and they're going to put the bill in tomorrow. The Congress was on vacation last week and it might have happened had they not been on vacation. But we're hopeful that a bill will be introduced very quickly. We're hopeful that it will have bipartisan support, including support from some people that are significant and in the House republican leadership. But we're working on a moving target. We're trying to get people that will move this bill along constructively.

So it's certainly frustrating to you that there's not a bill, H.R. 1234, that you can talk about on your table this morning. If you're meeting, I can guarantee you that the bill will be introduced by the time of your next meeting. But more importantly, we're optimistic that not only will the bill be introduced but there will be constructive hearings scheduled and constructive discussion on the issues that the Chamber and others have raised that are of concern.

MS. MASNY: Joann, did you have any other further comment?

Kevin?

DR. FITZGERALD: Thank you. I was just wondering, in trying to follow the conversation, it appears to me anyway, as far as your action items are concerned, your first one says should the committee conduct a stakeholder meeting with the key stakeholders to further inform the report's analysis. Did you have any specific information in mind that you thought would be useful to have, because at least from the sounds of things, we're kind of in a Catch-22. Nobody knows exactly what the legal ramifications are going to be until a bill is introduced specifically. So that is sort of guesswork and speculation, and that can't do anything except kind of grind the whole process to a halt.

So is there anything else other than that sort of thing that the committee sees as necessary or beneficial? Otherwise, we'll just move with the action steps.

MS. MASNY: Very good point.

Ed?

DR. McCABE: Well, this is where we might use some help from people who know the process a lot better than we do, and that is is it helpful for us to have a meeting of this group, or if those meetings are already going on in ways that are a little more sensitive to some of the issues, is that a better way to proceed? I'm all for a frontal assault, but ultimately I want the bill to go through. So whatever the best way for that to happen I think is the way we should go. So I would ask Cindy or maybe Mr. Swain whether us having such a meeting is a help or a hindrance.

MS. BERRY: I think it depends on timing. Certainly, the Secretary could have such a meeting, and if this is in fact a true administration priority and they really wanted to see something passed in this area, all the stakeholders would certainly listen to the Secretary, and the Secretary could reiterate the administration's position and attempt to get some sort of consensus. I'm not sure that a meeting before our committee would necessarily move the ball forward. I don't know that the parties would change their position any. We don't really have the ability to influence legislation and can't really influence legislation directly.

So my view would be a meeting before us wouldn't be too fruitful, but perhaps if the Secretary were interested and willing, he could bring all the stakeholders together and they could negotiate and work out the issues that are currently bollixing up the process.

One other thing that I did want to mention. I think what we can do to help move things forward in a constructive way would be to provide the Secretary with all of the information outlined in these slides, and then he can make use of it in the most appropriate way. My view also is that we could go ahead with a letter right away, but I would advocate keeping the other elements of the report together until all the elements are ready and then move it forward in one big piece, because I think the legal analysis is a key component, because there are so many groups saying that current law is adequate and protects the consumer. If, in fact, that is not the case, I'd like that to be part of the Secretary's report.

I wouldn't rush the DVD and send that up, and then send some other piece up, and then the legal analysis after that. To me, that's not as effective as having one big report that addresses all of the issues of contention, give that to the Secretary, and then he can make use of it, whether it's conveying the information to the committee chairmen, or the Coalition for Genetic Fairness could make use of that information and provide it to the key sponsors of the House bill whenever it's introduced, and they can make use of it on the Hill.

So I think one big compelling package would have greater impact than sending things up piecemeal, but that's no reason to withhold the letter. I think the letter could be the first piece.

DR. TUCKSON: We're trying to get to closure, and our chairwoman here is giving us the signal. So, the details. One is the DVD. Just keep in mind that we can approve the script today, and you can do the DVD. That can get done in a couple of weeks, quick. The telephone book can be out in a couple of weeks. The legal analysis, Cindy, is a great point. I'm being informed that that's not going to be ready, and you've got to go through clearances and yadda, yadda, yadda, and it may not be until May or June for that. So as you make your recommendation, I just want to give you that data point. It may not be until May or June.

MS. MASNY: We would have one further comment from the audience, and then we're going to try to bring our recommendations to a vote.

MS. LEIB: Thank you. I'm Jennifer Leib. I work in Senator Kennedy's Health Policy Office on the HELP Committee staff. I think it's wonderful that in the last meeting and this meeting you've spent so much time focusing on this very important issue, and it was very exciting to see it move so quickly through the Senate earlier this month.

I think what would be really helpful is that we have an administration that in the last Congress and in this Congress has been very supportive of this legislation. However, other than giving that statement of administration policy, there really hasn't been any other efforts to help push this or move this legislation along in the House, and I think it would be really wonderful if you could recommend to Secretary Leavitt to really use the administration's strength to help move it through the House. We always turn to the agencies to help brief us and educate us about policies because they're the experts, so it would be great if Secretary Leavitt could look into having a briefing on the House side on the issue of genetic discrimination, showing the administration support, bringing constituents from the Chairmen's districts who have experienced genetic discrimination. I'm sure they're out there, either in the "Faces" book or just from people's personal experiences and practice in genetics.

So I think that would be a really helpful move, and even the briefing showing the DVD. I think those things need to happen very quickly as well, so I would encourage you to do that as soon as possible.

MS. MASNY: Thank you very much.

So I think we have a few things on the table right now that we could take a look at. First, I think the easiest one is just to get approval for the script for the DVD.

DR. McCABE: So moved.

PARTICIPANT: Second.

MS. MASNY: All in favor?

(Show of hands.)

MS. MASNY: Anyone opposed?

(No response.)

MS. MASNY: So we have the approval for the DVD to move forward.

Then the second would be how we want to proceed with the report to the Secretary. Do we want to send up very quickly, then, the DVD along with all of the public comments and the testimony, and possibly also the administrative statement policy that was received, things that we have in place that we could send to the Secretary along with a letter? Actually, I guess the letter would be a separate recommendation.

DR. LEONARD: In addition, we could include stakeholder information, so we could include that summary. So really the only thing missing from this is the legal analysis, which needs all sorts of approvals and may hold us up. While I understand a complete package may be better, I think the timeliness of the rest of this is extremely important so it's out there and available to be used by whoever needs it. So I think a letter plus all the public comments, the DVD, and the stakeholder analysis that's been done should be sent.

DR. TUCKSON: Don't stop the flow, but I just want to make sure staff tells us exactly on the stakeholder analysis, apparently that can't go up. That takes a little bit of processing as well. Is that what you're saying?

MS. CARR: Well, we can certainly summarize the perspectives, as we have through the PowerPoint presentation. But we want to be very careful that we portray the stakeholder interests and concerns accurately. So we'll need to go back and forth a little bit, but we can certainly make it a very high priority and do our very best to make sure we can include some of that in the material that goes to the Secretary.

DR. TUCKSON: I think the spirit of the

recommendation, Sarah -- and I just want to make sure again that we are all tracking here -- is to take the best that we can get. We have quite a lot of it done. Just give everybody one more chance quickly and get that out. But I think the clear mandate is forming that we want to get that done expeditiously. Whatever level that is, that's what it is.

MS. MASNY: Emily, and then Ed.

DR. WINN-DEAN: So I think what we can do to try and address Cindy's comments, because those are real legitimate comments, is we can inform the Secretary, send the letter, a summary letter -- "Dear Secretary, we still feel this way" -- and then enunciate to him that we have this part completed and it's coming right now, you got it with this letter. Then we have summaries of where things are with the various stakeholders. The third part, the legal analysis is underway, it's coming, and you can expect it in around, let's say, the June time frame, and then let him make the decision about does he want to wait until he has all his pieces of ammunition before he goes to talk to the House leadership, or does he want to act now.

It would arm him with all the ammunition that we have today and allow him to be responsive to whatever is happening between now and our June meeting, which would be our next opportunity to really approve something to move forward. I think it addresses Cindy's comments. He may feel that it is better to wait until he has all the pieces until he does something. That's his decision to make. We're here to advise him.

DR. TUCKSON: If I could make a friendly amendment to that. Two things. One is that we would encourage -- the legal analysis is being done by ad hoc members to this committee, ex officio. Excuse me. Those are the folks that are involved in this. So we would first make it explicit that we would ask our colleagues who are ex officio who are involved in that analysis to please move it forward. Secondly, what we can do also is in the body of the letter Emily put in to the Secretary urging the Secretary to ask those agencies to expedite the analysis, since they're in his government. So he has a relationship with those people, and we can ask him to do that as well.

DR. McCABE: From past experience with these letters, I know that if we did the letter alone, that can probably be prepared within the next week or two following this meeting. I would urge us to move that, and I was the one that proposed that we put whatever we had together. But also knowing Reed's schedule, I would guess the DVD is going to be a month or six weeks. They have to identify a production company and then do it.

How fast could these things move forward?

MS. CARR: We've actually already identified the producer of the DVD, and I think he's actually done a mock-up of a draft script. So I don't think technically it will take that long. The Chairman is going to be the narrator, and we can --

DR. TUCKSON: The Chairman is terrified of the wrath of the committee, so you can be doggone sure I'm not going to hold it up.

DR. McCABE: Well, as somebody who lives close to Hollywood --

(Laughter.)

DR. McCABE: -- I would argue that there is power in the people speaking and just looking and remembering those quotes. I also think that if it's going to take a while for the analysis, then I would urge us to try to have this out within the next three to four weeks, perhaps with the DVD that we could then send along as part of the final report. But I think that if anything is going to catch the attention of the Secretary within the next month or two, it's going to be that DVD. I understand the importance of the legislative analysis.

I would also ask -- I heard that there might need to be clearances regarding the legislative analysis, and I don't know if there's a possibility that that could come as a report of the committee rather than as a report from the various agencies, because if it comes as a report from the committee, then we don't need the clearances, because if we screw up, then it's our problem. So I would urge us to look and see if there's a way to do it as a report of the committee and avoid the clearances by the various agencies.

DR. TUCKSON: All right. I'm a little concerned about the time now, and I think we're going to have to move along. I think we have a very clear sense of the committee, so let us try to work this. The clear thing is, if I can summarize what I think you're telling us, to get this letter and the compilation of the testimony and the DVD and the urging of expedition on the legal analysis, and we'll ask about whether it can be done through us versus -- I still think it's going to be tough, but we can look at that offline. But to try to get all that in play right away.

If there is some reason that holds up any element, any of those, the DVD or any of that stuff, if there's some technical thing that we cannot foresee right now that will hold it up, then we need to use good judgment and get the letter in play so that we're moving and active. We will inform the committee if there's any glitch, but we'll go ahead and work that through, and we've got a sense of what the committee wants us to do, and we'll update you by email, if that's okay.

DR. McCABE: I just wanted to add to what you said, Reed. I think Cindy's point that we should also include in that letter a request or an urging that the Secretary hold a meeting of the stakeholders, I think that will demonstrate to me as a member of this committee whether the administration is in fact supportive of this effort or whether we're just -- well, I think it will demonstrate whether they support this effort. Thank you.

DR. TUCKSON: Does anybody object to that?

DR. LEONARD: As well as including the recommendation or suggestion that the Secretary could have briefings for the House on the issue. I think we should make specific recommendations for actions that the Secretary could take with this information within the letter as well.

DR. TUCKSON: Let me thank our chairs, Agnes and Cindy. You've done a terrific job. And we thank the committee. Thank you very much to those who provided input to our work. So thank you. That was important, and we got good work done today.

Let's move now directly to our colleague, Rex Cowdry, from the National Health Informatics Initiative, the Office of the National Health Information Technology Coordinator, Department of Health and Human Services.

There's a space right there, Dr. Cowdry. Did you have slides or anything you needed set up?

DR. COWDRY: No.

DR. TUCKSON: Good. On behalf of the committee, thank you very much. You weren't here earlier, but we talked about how important this initiative that you're doing is, and we are very eager to learn a little bit more about what you're doing so that as we go forward we can think about it generally in terms of the work of this committee, but also specifically around some activity that's moving on in terms of the Surgeon General and the NIH regarding family history initiative. So thank you so much for coming.

DR. COWDRY: My pleasure, Mr. Chairman, and it's a pleasure to be with the members of the committee.

I guess I should first ask how you'd like to handle time management.

DR. TUCKSON: Sir, we're glad that you're here, and keep to the time that we gave you. That's fine.

DR. COWDRY: Okay, rather than try to shorten it. Okay.

DR. TUCKSON: Go right ahead.

DR. COWDRY: Good. What I'd like to do is try give you all a sense of why ultimately the President decided that the time is now to move forward with this initiative. Part of it, of course, is the weight of 10 years of recommendations from various groups and committees and publications, but part of it is not just a matter of changing, reducing medical errors, for example. It is really a matter of transforming our health care system and how we organize, finance and think about health care, that this is potentially a truly, if implemented well and properly, a transformative technology.

We know that the business of medicine is in key ways the business of information, and this process of bringing information to the point of decision in a way that produces high-value care I think is our biggest challenge. We know we do a great job of acute care. We know we do great at innovation. We also know that we have problems in the areas of huge costs, efficiency and value in our system. We know that there are quality issues that need to be addressed, both things that are done that should probably not be and things that are undone that should be.

We have a problem of care fragmentation, and the key question is how you can address this, particularly in the care of chronic illnesses. Information technology is one way to integrate a system without integrating it from above. Costs, we know that we're dealing with one-sixth of the economy of the United States, and we know also that technology -- and this is of particular relevance to this advisory committee -- is a key driver of the cost increases. What we've seen in a sense is tremendous advances, but also tremendous increases in costs.

This is a major challenge to genetic and genomic medicine, or more accurately genetic and genomic medicine poses a major challenge to cost issues. Now, you all have clearly grappled as a community with key issues of ethics, of privacy, which we share in the health information technology area, with ownership of information and intellectual property rights, which is another issue that we will see bedevils us in the implementation of health IT, and in economic issues that are often just simply not directly addressed. I was actually very pleased to see the material for the report about reimbursement that goes head-on into the question of not just cost but also cost effectiveness or value, because this is a conversation that we as a society need to have more of.

We know health care market is not really a market. It is full of so-called market imperfections. It's partially third-party payments, that divorce, that incentive structure from the time of decision. It's partially the absence or asymmetry of information that we have when we as providers make decisions, when we as patients try to decide on a course of action. We lack information about quality of care from different providers.

Often we lack information about outcomes, particularly outcomes that are individually meaningful. Most notably, we lack information about price of the services that we get.

I don't know how many of you have had occasion to go recently, for example, for laboratory tests and have looked at your health plan statement that comes back that has the here's what was charged and here's what we reimburse, which is often -- the most recent one I saw was my own, something like $230, which warranted a reimbursement of $23. I felt like I was back in the bizarre, in 1969, bargaining. It is a system that is so unlike much of the rest of our economy, and in part is it an issue of information.

We have an ambivalence about technology assessment and how we put it to use. Who does it? What are the criteria that we use? And then, how does it consider individuality in the process of making recommendations? Most importantly, what's the end result of technology assessment? I think we learned in the '90s from managed care that for that to result in no as a flat-out answer is difficult, probably unacceptable.

So the question is how we can implement this kind of increasing information about outcomes, about value, into a reimbursement system that uses incentives rather than a simple no, that encourages choices based on value.

I think ultimately, from a series of six months of talking with a variety of groups about this, we and the President became convinced that health information technology is indeed a key, if not the key, to a patient-centered and provider-friendly and information-rich system of health care that really empowers patients in a way that they have not been to date, that frees us as providers to do what we do best, which is exercise judgment and compassion, not search for information, to gather information that actually flows both ways, brings information to the point of decision but also gathers information in a way that actually informs us about the kinds of resource allocation that informs guidelines based on information coming from the real world of clinical practice that gives us the kind of surveillance capacities that don't exist today, as recent headlines have shown us.

So the challenge is how to bring about this kind of interconnected system in a way that promotes value, promotes good care, and protects privacy. This is, in a sense, our challenge. Part of it is how to use it to bring about virtual integration of the health care system rather than top-down decisionmaking, and it is not a task without major challenges. I think I'll ultimately close with some of the potential pitfalls.

But let me first try to outline the kind of structure that David Brenner, who was appointed last April to be the national coordinator, has outlined in the framework for health information technology. There are different structures that we need to think through.

The first is how we build a kind of nationwide network for health information sharing. That is, how we layer on top of an existing physical network the capacity to exchange information in a secure way to authorized individuals. So one of the questions -- and I was at a meeting last week where a lot of energy was put into sort of beating down the idea of a national database that would have individuals' health information in it. No one is talking about a centralized database. That just is not in the cards. We're talking about a federated system where provider systems remain the repositories of information but there are ways to access that information with the appropriate security and safeguards.

It involves a kind of not peer-to-peer exchange of information, which is the way health information passes now, but most probably a structure of trusted hierarchies where there are basically organizations that handle information interchange, probably within geographic areas, and then can exchange information with one another. But it's those entities that will build the structures that assure that the person making the request is who they say they are and that they have the appropriate authorization to gather that information, and that the information moves in an appropriate way.

That is the second structure, the so-called regional health information organizations that to date have to some extent been somewhat larger than local regions or states, and I think there are many reasons why states are a natural geographic grouping for doing this. We know that state laws vary with regard to privacy and medical information. We also know that states are the laboratory of democracy, and I think we can see that also in the implementation of health information technology. No one has the answers about implementation. States will have very different approaches, as we're seeing in other areas of health policy, and I think that to some extent we need to encourage that.

What we don't need to encourage is the proliferation of different standards for the exchange of information, and that's one way that a major focus is emerging, both the 24 realms of standards for information that have already been developed, but more accurately assuring that when these are actually implemented, that these systems have ways of communicating with one another that are effective.

The last challenge, of course, is actually adopting electronic health records in the local provider systems. We know that larger hospitals and larger practice groups are much more likely to adopt. They're more likely to find at least the rudiments of an economic case for adopting electronic health records to get efficiencies. We also know that for many practices at the current time, implementing electronic health records is a losing economic proposition, and this is part of the issue. How do we incentivize the adoption, particularly by physicians, because that may pose the greatest challenge, of these systems that ultimately will change the way I think we all practice medicine?

Do you give people money to buy the systems? Well, none of us I think in the administration think that's an effective way of encouraging. But incentivizing use and/or ultimately performance and outcomes is the way to move this adoption process forward. There are some things that you can reimburse for gathering information, that is for use, and there are other kinds of performance measures that really only can be achieved efficiently if you have a system of reminders of electronic health information, and of decision support.

So I think those are the challenges, how we build a set of incentives, how we do this collaboratively with the private sector, with health plans, and the government as payer for health care, working together. We need to reduce risk through processes of certification of record systems. We know that one of the real pitfalls, and I'll touch briefly on that later, is that many implementations have failed to date. Kaiser, for example, is on their third implementation of an electronic health record system. This is a problem.

One of the key efforts has to be to develop a way of certifying that systems do what they are supposed to do and what they say they do. So part of that will be a certification process that's formal. Part of it I hope will also be the emergency of private sector consumer reports type of information that not just assesses the formal characteristics of the system but also looks at the actual use of the system that gathers information that can guide wise choices of electronic health records by physicians and by hospitals, but particularly by smaller groups that can't hire a major consultant that's just not feasible.

So there have been a number of strategies to provide this kind of decision support in the purchase of an electronic health records system both through the QIOs in Medicare, which now will have a statement of work that is aimed at providing support to physician practices in support of electronic health records, and similarly the regional health information organizations will have a role in facilitating adoption in a way that works.

What are the challenges and pitfalls? Number one, the one that has to be at the top of the list, is privacy and security. I think there is no question that these issues of identity -- that is, how do you know that this information belongs to this person and not that person -- how do you establish that fundamental issue of identity? How do you establish authentication? How do you know that the person making the request is who they say they are? And then, how do you establish authorization? This person is authorized by the patient to access these data. How do you establish an override system when a person who is unconscious arrives in the emergency room? So these are all key issues.

What are the characteristics of trust relationships that you have to develop? In the peer to peer level, do I trust you to have assured me that the person making the request is actually on your staff and authorized to make that request? Particularly, how do you manage it in the context of differing state laws that have very different requirements for the kind of assurances that have to be provided? Finally, there's an issue in privacy of opting in or opting out, and this is an issue for the individual, individuals who just simply do not trust information systems. What do we do about that? Do we allow total opt out? What do we do about partial opting out, though? What do we do about protection of classes of information that are widely regarded as particularly sensitive? For example, I have no problem talking about my triple bypass in a public setting. Would I feel so free about talking about my psychiatric history? Or, of direct relevance to this committee, what about genetic and genomic information?

How is that dealt with, and do we allow partial opt out so that most of the information can flow if I end up in an emergency room, but not all of it? If you do that, how do you alert the person caring for you that I've excluded certain information, so that the doctor doesn't rely on this being a complete story of my medical situation and leaves out the fact that I'm on an MAO inhibitor and therefore causes my death through drug interaction? I think these are crucial questions. Do we flag that? Do we have a way of saying this is the person's record, but certain information in terms of medications has been left off? I think it's crucial to the question of this being a system that we can trust, both trust what's in it and we have some awareness of what's not in it?

How about the ownership of information? Who owns our medical information? I think many of us believe that ultimately the answer to that has to be I own my medical information. But we also know that entities are both protective, appropriately, of our information, but also have a certain intellectual property interest in holding our information. There's a reason that many of the health information systems to date allow you to view your laboratory results online on the Web but don't allow you to import it into your own system. It is a way of building, if you will, a kind of competitive advantage, to provide information and support, but it's our information and support, and it's a way of building loyalty and commitment to this health care system. What it does economically is it makes it harder to move. It makes switching costs higher. It makes portability more difficult.

So these are all very real challenges. They result in a kind of very muddied economic picture. Why has this not moved forward on its own? It makes so much sense in terms of improving quality and reducing costs. What is the economic analysis here?

There's a very real risk that the natural endpoint is silos; that is, systems that don't communicate very well with one another, because there's an economic case for that, particularly larger silos. There is less of an economic case for sharing information. It's hard to see what the business case for that is. So we have to, as responsible payers, find a way of counteracting that, building a kind of economic case.

There's a risk of brain-dead decision support. That is, there's poor input into decision algorithms -- namely, that they come from highly controlled clinical trials but not from the real world. There are problems of how you put guidelines into a form that can actually operate in an electronic health system, how they are actually implemented. There's a problem if we don't have a system of bringing guidelines to providers in a way that is both individualized in relation to that patient but also allows for exceptions, because I can't imagine something that would be more likely to evoke a rebellion than a system of guidelines that has a kind of mandatory rather than advisory nature to it.

We have a danger of wasteful parallel systems for health information. We have a parallel system developing in homeland security, for example, for surveillance. We have parallel systems in CDC for surveillance for a variety of things, both infectious and drug related. We have FDA's surveillance systems. All of these are sort of partial, expensive in relation to the kind of information they gather, but they're what's out there. How do we assure that ultimately we end up with a system that accomplishes all of these aims and in addition facilitates research, both health services research and clinical research, without producing multiple different systems that drive providers and payers and everyone else slightly crazy?

We have a risk of a system that can't generate the kind of deidentified large-scale data that will give us real information about comparative effectiveness and cost effectiveness, that can't track outcomes, that can't identify adverse events, and that can't routinely provide surveillance.

So I think all of these are pitfalls, but they are pitfalls that we can anticipate and avoid. So I think our greatest challenges are going to be privacy and the kind of discussion that needs to go on about that, the cultural challenge of introducing value and cost-effectiveness into our health care system through health information technology, and ultimately the question of fairness, access, and cost.

I think I'll stop there to give us some time to talk.

DR. TUCKSON: That's terrific, Dr. Cowdry. Let me just ask you real quickly on this, how do you see, then, given the kinds of issues that you've raised, how we might be able to help inform the process, certainly around this idea of the genetics? You're sort of laying out two things that I see as critical. On the one hand, you're saying that the health delivery system of the future, which is soon, not way out in the future, is going to be a system that's categorized by a lot more patient-centric information, with lots of access to decisionable, actionable information to give you a total comprehensive care opportunity. So that's happening. Meanwhile, you're saying there are real issues around privacy and confidentiality of sensitive information, which is what this committee has to worry about.

So on the one hand we have folks who have chronic disease that are genetic based who are going to need coordinated, comprehensive care. On the other hand, you've got folks with diseases for which there may be some sensitivity. I guess the question ultimately is for us how do we help get into the process to inform that conversation?

DR. COWDRY: Well, I think part of it is exactly through the broader issue that you've already discussed, about genetic privacy issues much more broadly, for which the health information technology is sort of a specialized case. But I think it's useful to have sort of a range of discussions in multiple different settings about the questions of value and also the conflicting rights about information. So first of all, there's the question of what goes in the medical record and how it should unfold about the individual. Secondly, there's a question of support for processes of deidentification that really provide a way of gathering information, including family history and genetic information, and outcomes, in a way that divorces identity from that process. So it's helpful technically to discuss that.

DR. TUCKSON: Your office reports to the Secretary?

DR. COWDRY: Yes.

DR. TUCKSON: So there is a possibility there that --

DR. COWDRY: Absolutely.

DR. TUCKSON: Whose hand over here?

DR. KHOURY: Let me thank you for your presentation. I guess family history is probably one of those low-hanging fruits that this committee can work with you and the various agencies given the interest of the Surgeon General and the various public health initiatives and integrating family history into risk assessment. I think the time is right for that. It's complex because of the issues that you raised, but when you have estimates that 30 to 50 percent of the population have a family history of one or more common chronic diseases for which you can take action to prevent either disease or to manage people more, so we're not talking about genetic diseases only but the fact that people have a first-degree relative with diabetes or early heart disease or the various forms of cancer, I think the various initiatives that the Department and all of us, including CDC, NIH, and the various players will have to work together to find a way to integrate the family history information into the records and how that can be actionable.

Right now family history is part of the medical record, but it's collected poorly, nobody looks at it, it's not actionable, and it takes time to collect. The providers don't have time to collect it. The patients don't realize -- I mean, from the survey we did at CDC last year, only a third of people go about collecting information that can be used in that regard. So I would encourage this committee to take that on and work with you and your office and all of us in the federal agencies to at least begin to integrate family history into the health information infrastructure.

DR. COWDRY: It's a real challenge, isn't it, trying to figure out what a standardized electronic health record should look like. I mean, there were major fights about this, quite frankly, that different agencies had very different perspectives about, and that providers on the front line will have a very different perspective than researchers or agencies with a surveillance responsibility. Family history is an excellent idea. The actionable component of it, how do you record it in a way that actually allows you to operate on that? Well, doctors will take four times as long to deal with a system where each thing has to be coded in in relation to a particular person, and when they're paid for a 10-minute visit or a 20-minute evaluation, that's probably not feasible.

We probably can't provide in a way that's provider friendly the kind of information that CDC might want, for example, or that FDA might want in its reports. So this is going to be the kind of balancing. But ultimately, I think the North Star initially has to be the provider, because if the providers don't adopt the system, it's not going to happen.

DR. TUCKSON: Thank you.

Let me get one last question from Joe, and then I'm going to try an action step to see if we can take good advantage of this presentation.

Joe?

DR. TELFAIR: My question is just a basic one in terms of a starting point. I was wondering maybe at the macro level in your investigations, have you seen a potential area where precedent exists? In other words, at the macro level, has some small group taken on this issue and worked it effectively, or has it been that formidable even at that level that you cannot generalize it to this group? My question is where can we start? If we have the committee begin to look at this and work with you, are there any case examples where it's been successful?

DR. COWDRY: Case examples of which?

DR. TELFAIR: Where information exchange, where a lot of these challenges that you presented have been dealt with, have been approached and done effectively, maybe at the macro level that maybe can be generalized to a larger level.

DR. COWDRY: Most of them to date have sort of developed as regional organizations, for example, in Indiana, that is based on many of the institutions and is bringing in community providers. There are five states that were recently approved, which I don't have at the top of my head but should, and funded to provide the initial regional health information organizations, and I think it would actually be tremendously helpful to have this kind of input into those discussions at the state levels as well, because to some extent our initial prototypes are going to arise out of these regional health information organizations on the one hand. They're also going to arise out of what the vendors build into their software.

So I can see that there are several different fronts on which discussions would be extremely helpful, and we can certainly provide some information about implementations in various areas. Santa Barbara has had one. Boston is launching one. Indeed, Massachusetts broadly is launching one. Utah, where the Secretary comes from, he was very active and is extremely supportive of health information technology and health information interchange in a state model. So there are a number of sort of examples that are either moderately well implemented or just under way. In a sense, it's those that are just beginning to get under way that might be most useful.

DR. TUCKSON: Well, thank you very much, Dr. Cowdry.

Let me do two things, then, by way of follow-up. First, I think part of the committee's goals have been already attended to by having a relationship with you and by meeting you. I hope that you will take back to your office the interest of this committee particularly on the specific point that Muin described, which is what is the best way to start thinking about integrating the genetic-based information for family history into the electronic medical record and try to get that as a part of the national standard. So we would appreciate if you would bring that back to your agency and say that there are a bunch of very thoughtful people who are charged with advising the Secretary of Health on genetics, health and society who are making this a pretty big priority and really want to reach out. That will accomplish something today.

Number two, for the ongoing, I think we probably will be sending you a letter or some kind of way to try to get at this in a little bit greater specificity. Particularly, you can expect us to ask about who we should know about in terms of these various committees you've described, whether it's the Certification Committee on Health Information Technology that's trying to get the standards for physicians, interoperability standards and the various things that you've outlined. Which one of those places is the place that we need to drill a little deeper to try to get at this.

Then finally, what things should we worry about in terms of the confidentiality things.

Muin, if I could ask you, since you were sharp enough to raise it, and you know that you shouldn't do that around me, to try to help draft what we might send, in combination with either Francis or Alan Guttmacher -- I see you there -- given that you guys have got the lead on that family history project.

So, Sarah, we'll try to figure out how do we do that with Muin and Francis and/or Alan and get something to you, just again so you'll know who these are. Muin is CDC, and you know Francis and Alan are NIH. These are your brethren. So we can move this along. You can expect that, okay?

DR. COWDRY: Absolutely.

DR. TUCKSON: Thank you very much for your time, very excellent report. We're glad to meet you.

DR. COWDRY: Thank you. Good to see you again.

DR. TUCKSON: Can I get Rod?

By the way, for you guys, you need to look at Tab 3. It's something that we have to come back to at the end of the day. The second letter in Tab 3 is a draft of this activity. So we'll be sort of fleshing that out a little bit better now based on what we heard today. So just be aware of that.

Rodney Howell is known to all of us. He is the chair of the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children, and they're facing many of the same challenges that we are regarding access, education, and appropriate standards for validation of genetic tests. In recognition of the liaison relationship and our common interest, there's a liaison we have between these two committees, and as I mentioned Dr.

Joe Telfair is our liaison to that group. The advisory committee has been considering recommendations regarding a uniform newborn screening panel and system, and in light of the interest and overlap between the two committees, Chris Hook suggested this occur.

Chris is on the line. Is that right? Do I have to do anything? Hey, Chris, are you there?

DR. HOOK: Yes, sir, Reed. I've been listening in the last few minutes. I didn't say hello so that I wouldn't interfere with anything, but thank you for letting me call in. I appreciate it very much.

DR. TUCKSON: Well, I want you to know that you are beaming out of the ceiling. You have a celestial presence at this meeting. It's extraordinarily impressive, Chris. Thanks a lot.

DR. HOOK: Thank you.

DR. TUCKSON: With that, I'm pleased to welcome Dr. Rodney Howell, the advisory committee's chair, to speak to us about the work. You know Dr. Howell as professor of pediatrics and Chairman Emeritus with the Department of Pediatrics, University of Miami School of Medicine, a long history and considerable expertise surrounding genetics and child health.

Thank you.

DR. HOWELL: Reed, thank you very much. I'm delighted to be with this distinguished group this morning to discuss the work of the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. One of the things I would welcome is anyone who can think of a worthwhile acronym for this committee. We have not so far been successful.

I'm going to spend a mercifully brief time with you this morning, but I'd like to discuss three areas. I'd like to discuss a little bit about the environment in which this committee was formed and the environment surrounding it. I want to talk a fair amount about newborn screening and so forth, and I will obviously also talk about the charge to this committee and some of the work that the committee has undertaken.

A central focus to this committee -- and I'll talk about the charge in some detail -- has to do with newborn screening. The environment in which this committee begins its work in the area of newborn genetic testing is that there's an enormously rapidly changing technology, literally by the week, with multiplex testing platforms that have moved the whole paradigm from the classic Guthrie newborn screening test where you had one blood spot and you did one test -- that is with phenylalanine -- to a new paradigm of tandem mass spectroscopy, where you have one blood spot and you do many, many tests simultaneously on that same spot.

The problem has been around for a long time and has increased in recent years, the fact that there are large numbers of extremely rare conditions and few providers with great expertise in this area. There's new technology on the horizons that will clearly supplant even tandem mass spectroscopy.

In addition to that, there was specific legislation for heritable disorders program that established the Advisory Committee on Heritable Disorders, and also established grant programs at HRSA for regional collaboratives. At the same time, HRSA had had a contract that had been under way for some time, at this point about three years, with the American College of Medical Genetics, to develop with a large expert and diverse group, under a contract, a panel of information that would provide for a uniform panel in newborn screening. There were other parts to that contract, but that was the core part of the contract, to think of the mechanisms by which you would decide what to screen for and to recommend those long term.

The legislation that established this committee was actually a congressionally mandated committee in the Health Care Act of 2000. It established this committee, as well as a couple of other areas that I'll comment briefly about because they're relevant to this. Section 1109 directed HHS to provide screening, counseling and health care services that would be of benefit to newborns and children at risk for heritable disorders. It also authorized the Secretary to award grants for demonstration programs that we hope will be very valuable to evaluate the effectiveness of screening, counseling and health care services, morbidity and mortality caused by heritable disorders of the newborn and children.

Section 111 of that act established the Secretary's Advisory Committee that I'm reporting to you about this morning. The purpose of this committee is very extensively spelled out in the legislation. The prime purpose is to provide the Secretary with advice and recommendations concerning grants and projects authorized under these previous sections that I mentioned, and also to provide technical information to develop policies and priorities that will help the states and local health agencies provide for newborn and child screening, counseling and health services for newborns and children at risk for heritable disorders.

Specifically, and it goes down into even greater detail, to provide guidance to the Secretary regarding the most appropriate application of universal newborn screening tests, and you'll see why the ACMG report was highly relevant to that particular requirement;

technologies, policies, guidelines and programs that will effectively reduce morbidity and mortality in newborns and children at risk for heritable disorders.

The advisory committee's constitution was also further spelled out, and it said that the members should have medical, technical and scientific expertise in heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for heritable disorders; members of the public with special expertise about or concern with these conditions; and representatives from such federal agencies, public health constituencies, and medical professional societies as deemed necessary to fulfill the duties of this committee by the Secretary.

I'll go through briefly the members of this advisory committee to simply point out what they do so you'll be aware of that. This is an alphabetical list. Bill Becker is an active member of the committee and runs the Newborn Screening Public Health Laboratories in Ohio State. Amy Brower represents a major industry. She happens to also have a Ph.D. in a biologic science and happens to be the parent of children with genetic conditions that could have been detected in the newborn. Peter Coggins is with PerkinElmer Life and Analytical Sciences and, as I think many of the laboratory people are aware, that particular company has a major interest in the technology of newborn screening.

Steve Edwards, at the time this committee was appointed, was president of the American Academy of Pediatrics, and the American Academy of Pediatrics has had a long and abiding interest in newborn screening and has provided data and advice for a very long time. Greg Hawkins from the Department of Internal Medicine at Wake Forest University in North Carolina. Jennifer Howse, the president of the March of Dimes, again a large public organization that has had a major commitment to newborn screening really for many decades, and continues to have that activity.

I chair the committee, as has been mentioned. Other committee members are Piero Rinaldo, who directs the biochemical and genetics laboratory at the Mayo Clinic and arguably one of the world's experts in technology, particularly tandem mass spectroscopy, and he's been very valuable to the committee. Derek Robertson is an attorney and a parent who has been very much involved in discussions in working these areas for a long time.

The ex officio members of this committee are voting, which I gather is not common, but at least the federal ex officio members are voting. Peter van Dyck represents HRSA, and he is head of Maternal and Child

Health at HRSA, as I think you're aware. Denise Dougherty is from the AHRQ. Coleen Boyle has been appointed to represent the CDC, and Duane Alexander has been appointed to represent the National Institutes of Health. He is director of NICHD, again a group that's had a long interest in the research in this area.

There are important liaison members from other advisory committees. Jim Collins, a neonatologist, represents the Advisory Committee on Infant Mortality, and Dr. Telfair you've already heard represents this committee. He replaces the able Reed Tuckson, who began representing this committee until he was chosen as chair of this committee.

I'll talk very briefly about screening for metabolic disease. The tenets under which newborn screening has taken place really were laid out in 1968. The World Health Organization at that time released a statement that outlined kind of the general principles that you would want in a test to apply to newborns as far as screening is concerned, and those commentaries have really been in place since that time, and they basically have been used more or less by people who thought about this.

Newborn screening for genetic disease is a state administered program. I think many of you know that, but let me underline this. Although there are a lot of professional guidelines, et cetera, what a state screens for in the newborn period is decided at the state level. Ordinarily that decision takes place in concert with an advisory committee, and those advisory committees range from folks who have essentially no information on this to areas where there's extraordinary talent and depth, both in technology and the science and so forth.

I might point out last year 4.1 million babies were screened in the United States. Every state and jurisdiction has a newborn screening program, making this the most common form of genetic testing that's done today. Newborn screening has, interestingly enough, not been thought about as genetic testing, but obviously the vast majority of these conditions are genetically determined. I might point out, and we won't get into this today -- we could spend a long time on this -- most states have a program to fund this mechanism that's similar. Most charge fees that are charged back to the hospital that appears in your hospital bill or as a part of your room service. There are exceptions to this, New York State being one that doesn't charge anybody, and the State Health Department, through its various fundings, picks up the whole tab.

I've mentioned that all 50 states have had this since the 1970s. Phenylketonuria is the hallmark of this that you can detect in the newborn period, and it's been a target since the mid-1960s. Congenital hypothyroidism soon appeared, and there's extraordinary variation from state to state in this program. Again, I've mentioned the fact that technology has really changed the field because of the fact that you can identify a large number of analytes on a single sample, and the experts certainly recommend that when you look at a mass spectrum from a tandem mass readout, that you look at the entire spectrum and that you don't set the instrument so that you only see one little corner you're interested in, that you basically look at those that are done.

I might point out, one of the questions that has been posed to me frequently is should we expand newborn screening. That question has been answered, and we can talk about it as much as you like. But the point is that expanded newborn screening is moving across the country extremely rapidly, and as we stand here today 36 states currently have mass spec programs in line. I simply show this very complicated map -- don't pay much attention to it, but I wanted simply to point out that all those little stars indicate the location of mass spec labs, and those arrows indicate that certain states send their samples to other areas. There are certain private labs that have contracts. One of the most visible is Mississippi that has a contract for a private lab. Mississippi, I might point out, has the largest number of mandated screening tests of any jurisdiction in the United States today.

But if you look at that in 2004 and you look at it in January, it's changed a lot, and I might point out it's changed even since then, because my home state of Florida that is still there in green, that means that we are not screening for many things, that's now changed to purple, and it, as of February 1, is again screening for actually the ACMG recommended list.

This gives you a little more feedback into the diversity from state to state, and I might point out that there's one state, one of those square states up in the middle of the country, that currently, as we are here today, screen newborn infants for three disorders. Then you can see the other states that screen for more than eight, and usually that's the so-called 30. Again, there is one condition that the expert panel working with ACMG and most experts in metabolic disease feel should be screened for in the newborn period is probably one of the least controversial, and that's MCAD deficiency, a disorder of fatty acid metabolism that can be very simply and effectively treated, and if untreated a certain percentage of those babies clearly and unquestionably die. So there's considerable feeling that that should be screened for.

Now, MCAD can only be detected reliably with tandem mass spectroscopy, and if you adopt the idea that it should be screened for, and that's the reason I show you the states that have either mandated screening for MCAD -- some states have it mandated. Florida is now doing it but it's not yet been implemented because they're working on it, and California has found the money. They started and stopped, and now they've returned to mass spectroscopy.

This is a graphic demonstration of what people are screening for. All the states and jurisdictions screen for PKU, hypothyroidism and galactosemia. Strangely enough, there are two areas that still don't screen for the hemoglobinopathies, which, as a personal comment and not as the chair of the committee, is quite amazing to me. Then it drifts off so that just a few places screen for this, and you can see the MCAD deficiency on the right.

I will not go into this. This is very recent changes in screening programs, and I want to emphasize the fact that these programs are moving rapidly.

The committee has held three meetings which have focused on newborn screening and related technology. The next meeting is scheduled in April on the date you see here in the Ronald Reagan Building, and we certainly welcome anybody appearing for that to discuss anything of interest at that meeting.

What has the committee done? The committee has focused, as I said, on newborn screening and has seen major presentations of drafts of the report of the American College of Medical Genetics. The committee has been very positive about the premises that are set out there and felt that, because of the importance of this, that the committee would like to send a note to the Secretary as soon as the full report is available saying that the premises in there have been supported by the committee. However, the committee and its letter conveying that to the Secretary -- and I might point out it has not yet gone -- also points out that the committee has not had a chance to review the final document and will comment on the final document as it's received going forward.

Let me comment about this report, because this report has created more interest, shall I say -- I use that term politely -- than most anything you might imagine. The report is a report that was done under contract with HRSA, and HRSA quite properly doesn't release draft reports. In other words, a report is still working. Once the report is done and is to HRSA, then HRSA will post that. The report has been accepted I've been told, and it is anticipated that the entire report will be on the HRSA website by the middle of this week. Let's give it a few days. But the bottom line is the report has been accepted and it will be up there.

I might point out that folks who have gotten small parts of the report have commented about things that were not in the report. The draft report that was seen earlier by the committee was 60 pages long. The report that goes up on the website this week is 380 pages, to give you some idea of the scope of it. It's an extensive report that has involved a great number of people over the years.

But anyway, that's been a major focus, and that will clearly continue to be a focus as we review the final report of this committee.

As the committee has looked at things that are derived from this report, what do you do with these things and how do you implement them? The group decided that they would like to form three subcommittees, and I've listed those subcommittees here. There's a subcommittee that has been formed on education and training, one on follow-up and treatment, and one on laboratory standards and procedures. Now, these committees were formed at the last meeting of the group, and they are currently having email exchanges and meetings by telephone to lay out what their agenda will be and what exactly they're going to approach, and they will be reporting on their subcommittees the next time.

It is anticipated that these subcommittees, as you will see here, will identify experts all around, people who are certainly not members of the committee but anybody in the country who has expertise in these areas are likely to be asked to either be a consultant, and perhaps in time they could become a formal member of these subcommittees to work on these. But these are obviously, for everybody in this room and particularly the people around the table, understand extraordinary things that need to be done in those areas. But anyway, we expect that we will hear about that subcommittee.

The report I alluded to will be put up on an individual website, and it will be at mchb.hrsa.gov/screening. For those of you who would like to spend quite a lot of time, I would suggest that if you decide to push "Print," that you fill up your printer before you do that because of the length of the document. You've all had that thing, you decide you'll print something quickly so you can read it quickly, and you come back and your printer is out of paper. This is clearly the thing to do.

But this is the website for the committee, and at that current website all of the minutes of the previous meetings are there, along with the presenters, and I might point out there's been a very gratifying input from the public. There's always an area of public comment, and public represents parents and industry and a variety of professional organizations have had a lot of comment, and we would look forward to that. Dr. Michele Puryear at HRSA is executive secretary of the committee.

So with those brief remarks, I will end. Thank you.

DR. TUCKSON: Thank you very much, Dr. Howell. Why don't you stay there for a couple of questions? I'm sure we'll have a few.

Emily?

DR. WINN-DEAN: Obviously, newborn screening identifies individuals who have genetic disease. So have you dealt with the issue of how those individuals go on in their lifetimes to experience or not experience discrimination?

DR. HOWELL: Interestingly enough, I don't think that there's been any formal look at that. Interestingly enough, some of us have been involved in newborn screening before most of the distinguished group at this table was born. For example, when the NIH had a consensus conference on the diagnosis and treatment of phenylketonuria, one of the panel members of that committee was a college student who had phenylketonuria. So we see now adults who had these conditions, and we have a lot of sidewalk conversations, but I'm not aware of any formal effort to look at -- the biggest cadre that would be out today I think would be patients with phenylketonuria, hypothyroidism and things of that nature that were back in the general community.

DR. TUCKSON: Any other questions, and Chris, also with you on the phone?

I've got Francis, and then Willie, and then if, Chris, you want to get in, just let us know.

DR. COLLINS: Rod, I appreciate your report. It sounds like this is coming along quite nicely.

With regard to the tandem mass spec, what's the current information that's been derived from the states that have been doing this about the concern about creating great anxiety amongst parents when you find something and you're not quite sure what it means, because that's been one of the major issues about introducing this into newborn screening. With the caveat of first do no harm, are we in fact creating in some circumstances unnecessary anxiety amongst parents by a finding of uncertain significance? Is that a real concern or are people handling that pretty well? What's the preliminary data on the consequences of greatly enlarging the number of conditions that can be screened for, including many for which nothing really is known or no intervention is available?

DR. HOWELL: I think that that has been discussed extensively over the past couple of years, Francis, while this whole effort was under way. One of the recommendations that will appear in this report is to systematically look at that, because there has not been any systematic look. I'm talking about other than people talking at a cocktail party, et cetera. But I think that there are a few things that are clearly important.

There are conditions that you pick out with the tandem mass spectroscopy that we know very little about, and I think one of those is SCAD deficiency, a short-chain fatty acid defect. You pick that up. However, it is clearly known that families who have this condition, and one of the people who commented at this meeting happens to organize a group of families with SCAD deficiency, those people do have problems when they get sick. When they fast, they have problems with acidosis and so forth.

So the thing is that it has been felt by most that certainly when you pick up something you don't know a lot about, you certainly should tell the health professionals at least that you have an abnormality. But on the other hand, I think a major research agenda is going to be to follow all these people and see what the condition is really like, and that's a key part to find out what they really are like.

Let me comment about one thing, because this report has been wonderfully interesting to a lot of people. But one of the things that has to do with what has been called secondary conditions is that when you're looking with tandem mass or anything else right now for a primary condition that no one argues about, and I'll use phenylketonuria as an example, you pick up a variety of conditions related to elevated phenylalanine that are not PKU. Those have been termed secondary conditions. You are not running a test for those secondary conditions. However, if you send me back a phenylalanine that's 18 milligrams percent, as a person who is doing the diagnostic follow-up, I must study those secondary conditions, because the secondary conditions include hyperphenylalaninemia that may not require treatment. It also includes a group of conditions related to biopterin metabolism, related to biopterin deficiency, biopterin recycling.

The thing is, if you've got a child that has a biopterin deficiency, you don't put that person on a low phenylalanine diet. You add biopterin. So the secondary conditions tie into the primary conditions tightly. Then there are other conditions that you just know very little about, and those clearly fall into the category of research things that need to be looked at. But they're going to be there.

DR. TUCKSON: Let me just quickly get Willie and then Ed.

DR. MAY: I'm from the Department of Commerce, but the NIST specifically, so I have to ask you this question. Certainly, tandem mass spectroscopy is a powerful technique. You get lots of data. But there are different platforms, there are different practices of the art. So have there been any studies on the accuracy or, let's say, comparability of results that you get across all of these tests that are being performed, either qualitatively or quantitatively?

DR. HOWELL: Yes, there have been, but not to the extent you would like. For instance, there is a quality assurance program that is currently done by the CDC. The CDC does quality assurance programs, as you know, on newborn screening in general. But there is additional quality assurance programs done by the College of American Pathologists and ACMG that specifically look at some of the rare metabolic conditions.

In the regional cooperative groups that we talked about that HRSA has funded, one of the states is piloting a training and education program for people doing mass spectroscopy, and I think that's going to be a model for training other people because you obviously need people who are highly qualified. You need to keep the false positive rate as low as humanly possible, but you can't miss an affected person. So I think that quality assurance programs and the laboratory standards committee of the

Secretary's Advisory Committee I alluded to, that clearly would be one of the things that they will be focusing on.

DR. TUCKSON: Ed?

DR. McCABE: I just wanted to reiterate that since we don't know the natural history or the influence of treatment on many of these disorders, I think it brings home the need for large studies like the Children's Oncology Group, which was done for children with cancer so that we should look to follow-up studies.

The other thing is that in our table folder is the article from Gina Kolata that you sort of alluded to and many of us read, and I just want to quote one point so that those who haven't been involved in newborn screening recognize that many of us take exception to it. It's a quote from the second page. "'The majority of newborn screening tests have failed,' said Dr. Norman Fost, a professor of pediatrics and director of the program in medical ethics at the University of Wisconsin. Over the years, Dr. Fost said thousands," and I quote thousands, "of normal kids have been killed or gotten brain damage by screening tests and treatments that turned out to be ineffective and very dangerous." End of quote.

Some of us have talked about where those thousands of kids are. There were some studies early on with PKU where they were trying to figure out the treatment. The best is a handful of children, and I've been on panels with Dr. Fost at the American Academy of Pediatrics a couple of years ago, when it was only hundreds, which I still think was way overstating the case, and suddenly that's grown to thousands. These are extremely effective tests. We always need to fine-tune testing and management whenever we introduce a disorder. But I think a quote like that that is completely unfounded in the medical literature or in the experience of the clinicians does a huge disservice to a very effective public health strategy.

DR. TUCKSON: Listen, I want to thank, first of all, Rodney.

Chris, I'm sorry. Did you have any comment you wanted to make?

DR. HOOK: I'm very appreciative of the presentation, the opportunity to hear it, but I don't have any additional questions.

DR. TUCKSON: Okay, thank you.

Well, Rod, thank you again. Your committee is different from ours and separate. You're doing the work that you need to do.

I would urge our committee members who would like to ensure that your comments are introduced into the discourse to really contact Joe. Joe is our liaison and is well able to represent any concerns, questions, suggestions or guidance.

Of course, Rodney, we want to really thank you for taking the time.

DR. HOWELL: Thank you very much.

I would certainly like to underline that it would be wonderfully appreciated to have information. Ed and I have discussed the fact that we love controversy, but we do like to have the facts have some justification.

DR. TUCKSON: All right. With that, I'm running the train a few minutes late. I apologize. Be angry with me, but I'm going to give everybody at least their 15 minutes that they're due. So why don't we come back? We'll have public testimony, the first person at the microphone, at 25 after 11:00. So that means, committee, you have to be back here at 25 after.

(Recess.)

DR. TUCKSON: Welcome back. We are waiting for Muin to come back. We can't start without Muin.

Thank you all very much for your promptness. As everyone knows, public testimony is a key part of what we are about, and we're very happy that our first presenter is someone well known to us, Judy Lewis.

Judy, would you please introduce the hat you're wearing today, and please make your comments.

DR. LEWIS: Thank you, Dr. Tuckson.

My name is Judith Lewis, and while my day job is as professor of nursing at Virginia Commonwealth University, I'm here today not wearing that hat but I'm here as the immediate past president of ISONG, the International Society of Nurses in Genetics. We are an international society and we have members on all six continents. Our members are involved in the education, clinical practice and research in genetics nursing.

Today I wish to speak to you about the nursing workforce. Our country today is facing a crucial nursing shortage. While there are approximately 2.7 million nurses in the United States, it's eminently clear that this number is nowhere near sufficient to meet current and projected workforce needs. The average age of the practicing nurse is increasing, and as those of us who are baby boomers near retirement, the crisis will become even more pronounced. An even more critical shortage exists among nurse educators. The shortage of nurses available to educate the next generation of clinicians makes it difficult for increasing programs to expand to accommodate increased enrollment, and many schools are forced to turn away qualified applicants because of the faculty shortage. Again, this situation promises to worsen in years to come.

Of the nurses currently in practice, there are approximately 150,000 clinical nurse specialists, nurse midwives, and nurse practitioners who are providing primary and specialty care in areas including women's health, family health, adult health, pediatrics, and gerontology. These nurses are educated to collect comprehensive health status data, and according to the American Nurses Association's 2004 Scope and Standards of Practice, the advance practice nurse is qualified to initiate and interpret diagnostic tests and procedures relevant to the patient's current status.

All advance practice nurses hold the minimum of a Master's degree, and the vast majority of states require that advance practice nurses be certified in their specialty as a prerequisite to advance practice licensure. In addition to the credentials offered by the Genetic Nurse Certification Corporation, advance practice nurses are certified by the American Nurses Credentialing Center, the National Certification Corporation, which does women's health, the Oncology Nursing Certification Corporation, which does cancer nurses, or other specialty-based credentialing groups.

Each certified nurse must maintain continuing education and/or practice requirements to continue their status as a credentialed specialist, and we all must present evidence of current certification in order to renew our nursing license as advance practice nurses.

Right now there are five universities that provide specialty in genetics as part of the Master's programs. In addition, there are several programs for nurse clinicians, nurse educators and nurse researchers who wish to engage in the in-depth study of genetics. Increasing the number of such programs, and increasing the capacity of existing programs will serve to further enhance the knowledge of those nurses who incorporate genetics into their practice.

HRSA has program grants for schools who wish to enhance or expand programs, especially those which focus on medically underserved or rural populations and those which enhance the public health capacity. The expansion of such programs, such as the advance education in nursing grants, would help build the infrastructure of those who are prepared to meet the health care needs of our population. I have no idea how many grants just went into HRSA, but I know that each reviewer reviewed more grants as an individual than there's money to fund. So there's a huge need for qualified programs to receive funding.

Increasing and ensuring reimbursement for services for all who provide genetic services to patients, including nurses and advance practice nurses, will also help to meet workforce needs.

ISONG looks forward to working with your committee on these and other important issues to ensure that a workforce is available to meet the genomic challenge for health care. Thank you.

On a personal note, I'd just like to say how very gratifying it is to see the work that we all started in our previous lives in 1999 move forward and start to come to fruition. So I want to thank all of you for the work that you're doing, and I look forward to continuing to follow your progress.

DR. TUCKSON: Judy, you're terrific. Thank you so much. You did it in four minutes and fifteen seconds, which we really like.

One quick question, Agnes.

MS. MASNY: Judy, thank you very much for your presentation. I also wanted to ask, you mentioned about the American Nurses Association Scope and Standards of Practice, that that is a document that is put out by the American Nurses Association. Is that something that could be made available to the committee?

DR. LEWIS: It certainly can. There are basically three documents that I think are important. One is Nursing Social Policy Statement, which is the document that basically outlines our social contract with patients and with society. The second is the Scope and Standards of

Practice for all nurses that the ANA puts out. Both of those are available from the American Nurses Association. Unfortunately, my personal budget nor ISONG's budget was sufficient to provide copies for all of you, but I'm sure you can get them.

The third is the Scope and Standards of Practice of Genetic Clinical Nursing Practice, which is jointly published by ISONG and ANA, and that is currently in revision, and we're hopeful that the new document, which will actually be a companion to the major document, will be out sometime this year.

DR. TUCKSON: Yes, Ed.

DR. McCABE: I was wondering if you might be able to provide a copy of each of those to staff, though, so we'll have them for the archives of the committee?

DR. LEWIS: We can certainly work with ANA to see if they can do that. Sure.

DR. TUCKSON: Terrific. Good job. Thank you very much.

Rick Carlson, the University of Washington. Thank you very much, Rick, for joining us.

MR. CARLSON: Thank you, Mr. Chairman and members of the committee, for this opportunity. Rick Carlson, clinical professor of policy programs, University of Washington.

I want to do three things very briefly. One, tell you my perspective on reimbursement and genetic discrimination. Secondly, some experience that may be relevant to the point which I make, which will be my third point, which will be problematic perhaps to some of you, perhaps even more radical.

My perspective is this. You have been looking today and at other times at genetic discrimination by purchasers and payers, and you've been looking at reimbursement issues, also reimbursement by who. I want to shift and look at the other side, not the constituencies which you're focusing on, but rather the payers and the purchasers themselves, but from a strategic perspective in terms of the evolution of their role in the health care business.

My experience which is relevant to this is that I coined the term "HMO" -- please forgive me -- along with Paul Wood some 30-odd years ago, and have worked well over half of my professional life in the strategic and business development capacity with both purchasers and payers. In addition to that, I undertook some projects for Robert Wood Johnson starting in '01 and '02 to assess the level of knowledge among key decisionmakers and key stakeholder groups across the health care system, including primarily providers and payers, interviewed well over 600 people in small groups to assess what they knew and what they wanted to know about genetics insofar as their business was concerned. Thirdly, I have served as a consultant to biodata.org on reimbursement and market development issues over the last three years.

I mention that because the major point I want to make to you today, which has a couple of supporting arguments, may well seem quite radical to you, and that is as follows. You have been looking, again, at the constituencies and the impact that genetics has on stakeholders in the health care system. Within five years, certainly within 10 in my view, both the purchaser role and the payer role in health care will be radically transformed. Purchasers have been trying for a very long time to exit the system. This is not a big surprise to anybody.

The alignment that exists right now politically and in terms of purchasers' and payers' objectives to incrementally retreat from benefits and entitlements seems rather clear. That's not a political statement, simply an observation of what seems to be occurring. This is not an accident. The alignment is very strong for this movement for payers, if you will, to shift their business model. Most of my 35 years of consulting in this field has been with payers on the fundamentals of their business model.

My point in making this point to you today is that as you examine these questions, as you have been, and apparently, according to Dr. Collins, you've been looking at, for example, genetic discrimination issues for some 10 years, if it takes that long, the landscape will have dramatically changed around you insofar as payers and purchasers are concerned. Again, to repeat my perhaps most fundamental point, payers will no longer be providing health insurance and purchasers will no longer be paying for it within 10 years, possibly as much as five. That's a very bombastic and large point to make without any supporting data, but a few minutes doesn't provide me the opportunity to do that.

Three points, however, in support, the alignment point which I've already made, and the second point is think about it for a moment. What genetics contributes to the understanding of risks and profiling of risks is additive but powerful. When you know more about the risks associated with your member population that you're insuring, then you don't have an insurance product anymore. You have an annuity product. So what we're finding increasingly as we understand that both cancer and heart disease are now treated fundamentally as chronic problems, when you already know the prognosis of the bulk of your members who use your care, you're not insuring against accidents or untoward events. You're looking at how to manage costs for needed care for those people over time. That's where this model is going. Genetic information certainly adds to that argument, but it doesn't make it dispositive.

The third point related to this is that we have some very powerful enabling events. The HSA legislation may have seemed to be relatively innocent, but I would remind you that in 1970 a one-sentence amendment to Medicare, which I drafted the specifications for, allowed Medicare to pay HMOs ahead of time rather than afterwards. That launched a massive social experiment called managed care from which we are still recovering or experiencing. The HSA legislation has a trim tab character. Once it's there, it can dramatically economically change the landscape of the industry.

Couple that with the movement of information to the end user such that within 10 years certainly a consumer will have all of their health information at their disposal and their entire human genome on a chip for potentially as little as $10 per person --

DR. TUCKSON: Dr. Carlson, you're over by five. So if you want to just go ahead and make your last summary --

DR. CARLSON: That's my summary point, that the landscape that you are looking at as you address the questions of payers and purchasers will inevitably change, and very powerfully, over the next couple of years.

Thank you.

DR. TUCKSON: Thank you.

Anybody have any quick questions at all?

DR. McCABE: Not a question but more a comment. Maybe it's a question. I said earlier today that this was a new civil right. How does that fit in with your predictions?

DR. CARLSON: Well, in one sense I'm not sure it's elevated to a right until it's recognized legislatively. I would argue philosophically it should be viewed as a right. I would agree with that.

DR. McCABE: I would argue just in counterpoint that civil rights were recognized as a right before they were legislated.

DR. CARLSON: I don't question philosophically or otherwise that it is a right. However, I think it should be pointed out that by, in a sense, impeding the access of insurance companies to risk information, you're undercutting the actuarial model on which insurance is based. That's not an apology for it at all. In fact, I'm very much in favor of anti-discrimination legislation. But it's another reason why the insurance model is no longer supportable and will eventually disappear.

DR. TUCKSON: Thank you very much. Appreciate it.

Next is Judith Cooksey from the University of Maryland Medical School.

Welcome, Judith.

DR. COOKSEY: Thank you, Reed, and committee members.

For the past four and a half years, I have led a multidisciplinary and multi-institutional effort to study the ways that genetic services are organized and delivered in the U.S., the roles of health professionals, and emerging models of care. There is a handout that committee members have, and I'm sorry that there were just a few handouts for the audience.

Today I come before you to present a new and evolving conceptual framework that applies some of our findings in genetics care and services to an established conceptual framework to assess the quality of medical care and health care. We believe this framework for assessing quality of genetics care, if successfully developed, could be useful to this committee and others. In other words, what we're trying to present at a very draft phase is an overarching way to pull together and think about a number of the issues that this committee has discussed.

I will skip over the history, a three-generation history, of ways to assess quality of medical care but would highlight one feature and then quickly move to the applications of this conceptual framework to genetic services.

The one feature that I would indicate is one page 2. At the top of the page there's a very small schema that has structure with an arrow to process, to outcomes. What this reflects is what is now a very traditional way of looking at the quality of health care services through three domains. One is to look at the structural elements, the basic components that are needed to support the delivery of health care or, in our case, genetic services and care. The second level of looking would be to look at the processes of care. I'll give some examples of that shortly.

The third way, and some people feel the ultimate and best way, is to look at outcomes, outcomes from the patients perspective, in our instance from the family, and to some extent the community perspective, not only biomedical or clinical outcomes but also well-being of the patient, functional, physical, emotional, psychological, and social outcomes.

This concept was developed in the '60s and has been advanced with a very interesting, well designed research study in the '80s, and in the Institute of Medicine studies that have looked at safety and quality of care. What I present to you on the last two pages of the handout are a beginning model or framework for thinking about the structural elements for genetic services, or the genetic services infrastructure. This has seven tiers that are listed there, the first being genetic science, which is the foundation translated to clinical and population-based applications. The next level would be organizational resources. These are the institutions that support genetic services in all manifestations.

The third is the health workforce. The fourth is data systems and information transfer. The fifth is financing and reimbursement systems. The sixth is health services research, which looks at and studies organization, financing, delivery, access, quality of care, as well as ELSI research, the ethical/legal/social implications research. The seventh infrastructure element is policy development. I would say that the genetics infrastructure for the country now is underdeveloped in many, many areas, and you're well aware of this from the studies that you're doing. But I think that this sort of sorting out may be a useful conceptual framework as far as infrastructure. This sort of describes what is now.

For processes of care, looking at the way genetics care is delivered, the Institute of Medicine identified four process levels that really look at different arenas. The first arena and the most important is the patient/family outcomes. Our study did not look at this, but it's extremely important, and it can be studied.

The second level looks at microsystems. We sort of go from the individual up to societal, microprocesses of care. In our study we looked at this a lot. What's the patient-provider interaction, the patient team-provider interaction? There's much variation in these microprocesses, and these microprocesses vary by their sponsoring institution. As we looked at academic medical centers, children's hospitals, moving to level C, we saw that the institution supported and organized the ways that the care delivery was provided in many successful but different ways.

We saw that some institutional processes, such as state-sponsored newborn screening, early hearing loss detection and intervention, involved a series of microprocesses of care -- baby seeing geneticist, nutritionist if it's a metabolic disorder, whatever. And then the final level, level D, the external environment, which you spent a lot of time looking at, policies, whatever -- and Reed is giving me the high sign, so I will cut this short, only to let you know that this is in progress and we'd be delighted to present a fuller exploration at a future date.

DR. TUCKSON: Judith, let me, first of all, thank you. This is the second time you've had a chance to update us on work that you're doing in this area. I guess the real question is how do we see in terms of all that's available? Is it all collected, at least in terms of what you've done to this point, in an easy, accessible way?

DR. COOKSEY: We have amassed a vast amount of information. We are in the process of preliminary report writing and are moving ahead with that and hope to have that finished. Our funding has ended, and I think this sort of research, health services research, is another way to look at what do we have now and what might be coming down the pike. So we're eager to see if this sort of model is a useful framework for people to think about things, and we're trying to sort of look at our findings in this context. But we've really only analyzed a piece of the data that's been collected.

DR. TUCKSON: First of all, I just want to thank you for keeping us up to date. What I've got to try to figure out, and I think you know us well, you know what the committee is doing, you know our priority list that we showed up on the board --

DR. COOKSEY: Yes, yes.

DR. TUCKSON: I think if you would just keep thinking of opportunities in the subcommittees that we're working on to remind us of applicable issues as we go forward, I think that's probably the best way, because five minutes is not enough for you to make all the points you want to make. So if you will track with us and then insert the knowledge that you have in the places that you think it goes, we would sure appreciate it.

DR. COOKSEY: That would be great.

DR. TUCKSON: Yes, Debra?

DR. LEONARD: I was very intrigued by the outcomes information. That's a fairly old study, 1989. Is it still relevant? Are there updates? The reason I ask that is because EGAPP is looking at very practical ways to define outcomes as a basis for defining clinical utility that are broader than the strict is there a treatment, did the patient get better types of definitions of outcomes. So one of the things you may consider doing is interacting with Linda Bradley, who is heading up the EGAPP program.

DR. COOKSEY: Yes, and there are others that are looking at outcomes. We're working with the Quality Institute, and this is a beginning of much opportunity to think and to look at the information.

DR. LEONARD: Thank you.

DR. TUCKSON: Yes, James?

DR. ROLLINS: In looking at your model on page 5, does this go all one way? Because I can see how health services research actually would vacillate back and forth between financing and reimbursement, as well as policy development.

DR. COOKSEY: Yes, and this is a very new conceptual sort of putting some pieces down, discussing, thinking. There's overlap. The narrative gives a little bit of an example of sort of how process and structural issues relate. But yes, clearly research looks at those issues. Research helps inform policy around those important issues, as you'll hear about more today.

DR. TUCKSON: I'm glad you said it, James, because I had the same thought. I drew an arrow sort of making it more circular as opposed to hierarchical in my chart. So I think that's great.

By the way, thanks for all your help on our genetic counseling services work group. We really appreciate your involvement there.

And by the way, Judy, thanks for ISONG's involvement as well on that. We appreciate it.

We'd better move on. Thank you so much.

Pam Williams, University of Oklahoma. Pam, welcome and thank you.

MS. WILLIAMS: Thank you.

Ladies and gentlemen, my name is Pamela Williams. I'm a graduate student in the nursing program at the University of Oklahoma Health Science Center. I'm a student in the program that Dr. Lewis described earlier. I will pursue and I am pursuing the advanced practice nursing in genetics credential. I also am a member of the Oklahoma Bar Association. I've practiced law in Oklahoma for over 20 years.

I did not prepare in advance a statement because, having looked at the agenda, I didn't see any point in sticking my neck out at that point. When I made the decision to come up here on my own nickel, it was a decision made in pursuit of research resources. I came to your meeting today to formulate or to fine-tune my research question as it now presently stands to study the psychosocial impact of genetic testing on BRCA1 and BRCA2, potentially patients getting testing for those particular genes.

But then I heard the presentation of Dr. Howell, and his presentation was fascinating regarding the diverse opportunities to have testing done on newborns. Then Dr. Collins asked the question about the anxiety impact on parents and was surprised to learn that, as far as he knew, there wasn't any descriptive studies in that area. So my purpose in coming forth today to make this statement is to let you all know that there are nurses and nursing students in research right now wanting to know these questions, dying to know these questions and research these questions in both qualitative and quantitative methods.

As I continue to pursue completion of my current program and my Ph.D., I'm hoping that there will be funding, not just for the genetic nurses at the bench but for the genetic nurses that want to study the psychosocial and the psychoneuroimmunological impacts of this information. So those of you that do sit at the right tables and attend the right cocktail parties and sit on the other committees that make the decisions for funding in nursing research, please, if you would, make sure there's funding for us that want to pursue the answer to Dr. Collins' question. Thank you.

DR. TUCKSON: Thank you very much for coming forward. We very much appreciate it. I think in the interest of time we'll probably have to keep moving, but thank you so much.

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-Dean, 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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.)

<u>AFTERNOON</u> <u>SESSION</u> (1:35 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-DEAN: 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-DEAN: 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 yo 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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-DEAN: 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.

MS. BERRY: Andy?

MR. FAUCETT: First I'd like to thank the committee and Chairman Tuckson for giving us the opportunity to do this. It's kept Kelly and I quite busy the last few weeks.

You can go ahead to the second slide.

I just wanted to reiterate what we tried to do.

We tried to look at what are the current credentials and qualifications of the individuals who are providing genetic counseling services and focused on the non-physician providers. We tried to look at the value and effectiveness of genetic counseling services and what literature was out there, and then the importance of reimbursing for genetic counseling services, the potential benefits of that, and any documentation of potential harms.

There were two huge binders created of all the articles and the literature that's out there, and that's all referenced in the actual report. There is some literature clearly lacking in certain areas, but we did pull what was available.

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I want to start off by just talking about the organizations that are currently involved in credentialing, and this is kind of done in an historical context. Originally, everyone in genetics was credentialed through the same organization, the American Board of Medical Genetics, and that credentialed physicians, Ph.D.s and genetic counselors. Then with the creation of the ABGC in 1993, you had them taking the genetic counselors and the ABMG keeping the physicians and the Ph.D.s. In 2000, the rules for genetic counselors were changed so that you had to come from an accredited training program, so that separated where it wasn't possible for Master's trained nurses who did not attend a genetic counseling training program to be certified.

So in 2001 you had the genetic nursing credentialing commission which began certifying Master's trained nurses with a concentration in genetics, and then recently, in 2002, they started a program for certifying bachelor's level nurses.

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This slide I think is revealing because it shows who currently is credentialed that might possibly provide genetic counseling services with credentialing to back that up. As you can see, there are 1,075 physician M.D. clinical geneticists who are certified by the American Board of Medical Genetics. There are 151 Ph.D. medical geneticists. There are 1,811 Master's level genetic counselors who were either originally certified by the ABMG or currently certified by the ABGC. Then there are 39 Master's level nurses, and most of those were certified through the ABMG/ABGC in the original program, which gives you a total of 3,076. Just to point out that if you look, 59 percent of these are the Master's level trained genetic counselors.

Another important point to bring up is there have been conversations in several groups that the number of physicians is declining. There clearly is a slope, a gradual increase in the number of genetic counselors as represented. There are 466 people currently eligible to take the certification exam this year.

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One of the changes that occurred when the ABGC was created is rather than just certification, the program also created accreditation, which means we actually look at the training programs to make sure they all meet a minimum standard and that supposedly the training that you get with one program would be equivalent to the training in another program, and it also created a pathway for recertification, which currently can be achieved either by exam or collecting a series of continuing education units.

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Just a second on ABGC certification. I think the most important point for the committee in recognition of this certification is the fact that the general exam is still a combined exam with the American Board of Medical Genetics. Genetic counselors and medical geneticists take the same general exam, and traditionally the genetic counselors have scored fairly consistently evenly with the physicians. The statistics are not significantly different.

The ABGC exam in genetic counseling was

transitioned from the ABMG and is developed in cooperation with the National Board of Medical Examiners. So the level of the certification exam has remained at that same high bar. To sit for the certification exam, they must be a graduate of an accredited training program, they have to have proof of clinical experience with a log book of 50 cases, and they need both training and professional references.

Next slide.

For the accreditation process, which is when you're looking at training programs themselves, it is competency based, and the four main competency domains are communication skills, critical thinking skills, counseling and psychosocial assessment skills, and professional ethics and values.

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Under the instruction, they do have to have instruction in all of these areas, basically the principles of human and medical genetics, psychosocial theory, social and ethical issues, health care delivery systems, and teaching techniques and research methods.

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They also have to have evidence of a broad base of clinical training, which is done through a log book. They have to have a certain percentage of cases that are all supervised. This process is supposed to result in skill development, so it's an ongoing process.

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Now, prior to 1999, most of the nurses who provided genetic counseling services were Master's level trained nurses who chose to receive ABMG or ABGC certification. Since that time that's no longer available, so they have created a Master's in nursing with clinical course work, and that was done by a log book.

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ISONG was formed in 1988. The ANA recognized genetic nursing as a specialty in 1997. Then ISONG established the "Scope and Standards of Genetic Nursing Practice" in 1998, and as Judy Lewis mentioned to us earlier today, that document is in revision and the new revision will be out shortly.

Next slide, please.

They created the Genetic Nursing Credentialing Commission, which has the certification in the advance practice nurse in genetics. This does require that the nurse have a Master's in nursing. It's done by the portfolio process. The individual must show three years experience with a 50 percent concentration in genetics. They need to have 50 cases collected over five years, 50 hours of genetic content. Now, this can be continuing education, it can be college courses, a combination of those. They have to discuss four in-depth case histories, and then references from three professionals. I think the big difference here is that the nursing credential is done by a portfolio process, whereas the genetic counselors is done by an exam process, but it's similar.

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The Genetic Nursing Credentialing Commission did create a program in 2002 to begin to recognize nurses with a Bachelor's level training who provide genetic services. It is also done by a portfolio. Then there are several other nursing special interest groups who offer ways of recognizing nurses who have concentrated training in genetics and, say, oncology or women's health. But at this point we would say that the two groups who are offering Master's level certification at this point are the ABGC for genetic counselors and the advance practice nurse credential for nursing.

I'll turn it over to Kelly.

MS. ORMOND: Next slide, please.

I think now that Andy has done an excellent job summarizing the data about the training and credentialing of non-physician genetics providers, I'll switch gears a little bit to talk about the licensure and value and effectiveness data. I think the information about genetic counseling licensure is relevant in the sense that Master's trained genetic counselors are one of the few health professionals who are not currently licensed. The material in your documents really accurately reflects the state of licensure in the sense that it really is for the protection of the public from harm, and the bulk of the data about harm in genetic counseling comes from looking at physicians who are not genetic specialists and the data about their having lower knowledge levels, providing incorrect interpretation of genetic tests, et cetera.

There's very little information that's out there about non-licensed genetic counselors causing harm, and we feel that that's primarily because they are not a licensed profession and there is no mechanism to do that reporting to the public health departments. So that's been a challenge to document.

There are currently, as you know, three states that have enacted licensure, and a correction to what's written in your materials is that the only state that's enacted it is Utah, not California. So I think that's important to stress.

We are certainly very supportive of any efforts of SACGHS to utilize mechanisms such as the National Governors Association or the National Conference for State Legislators to encourage state licensure in additional states, and you can see from this slide that there are nine states that are actively working on licensure efforts today.

Next slide, please.

This slide outlines some of the potential benefits and challenges that go on with licensure, and our working group looked through a number of the sunrise provisions and talked with many of the states, particularly through Dan Riconda, who is the subcommittee chair for the NSGC looking at licensure, and we tried to look at what some of the barriers were to genetic counseling licensure. The biggest one was the issue of cost, either to the state or to the consumers in the state, and that's particularly true for states that have small numbers of genetic counselors.

In a recent set of data that I looked at for Master's trained genetic counselors, there are almost 10 states that have five or less genetic counselors, and there are probably somewhere around 20 that have 10 or less. So I think that that's an important thing when you look at reasons why states may not want to pursue licensure of these professionals.

An additional issue is a desire not to add regulation to the books, and that certainly was the issue, as we understand it, in Florida, when they passed the bill through both House and Senate and the governor decided not to sign that bill.

I would like to tell you a little bit about the benefits that we have seen anecdotally in genetic counseling licensure, and that's illustrated through the Utah experience. When Utah passed their licensure bill and enacted it, they had 14 genetic counselors practicing. They now have 24, so they have almost double the number of providers in that area, and they also provided evidence at our most recent educational conference that they presented about the number of third-party payer insurance companies who recognized genetic counselors as independent providers. They had seven out of the 18 surveyed insurers had gone from not recognizing genetic counselors as providers to recognizing them. An additional four were allowing genetic counseling billing sort of incident to the attending physician. So I think that that demonstrates on an anecdotal level that there are some benefits to genetic counselor licensure in the billing and reimbursement setting.

Next slide, please.

This lists some of the organizations that have made statements that emphasize the value of genetic counseling services, and one of the issues we dealt with in our work group is the difference between genetic counselors or people who provide genetic counseling services, and the service itself. As we talk about the evidence that's there, it's very important to try to separate those, but it's also very difficult to do it when you read the data. So I want to talk about services, regardless of who they're provided by here, and I'd like to give you some example quotations that we found documented.

First, from the National Conference on State Legislatures in 2004. "Because of the complex issues genetic tests raise for individuals and their family members, genetic counseling will likely play a more prominent role in health care as use of technology grows."

The second from ASCO in 2003. "ASCO supports efforts to ensure that all individuals at significantly increased risk of hereditary cancer have access to appropriate genetic counseling, testing, screening, surveillance, and all related medical and surgical interventions which should be covered without penalty by public and private third-party payers."

From the Great Lakes Regional Genetics Group in 1999. "Genetic counseling is provided whenever a prenatal testing procedure is performed."

From ACOG in 1997. "With regards to breast and ovarian cancer screening, the standard of care should emphasize genetic services, genetic information, genetic education, and counseling rather than testing procedures alone."

So these are just some examples that I wanted to have on record of recommendations which really reinforce the importance of genetic counseling services.

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As you can see here, we identified several states, and this is certainly not all exclusive given our limited time to prepare this, but Michigan and New York both have legislation on the books that requires an informed consent process prior to genetic testing, and in addition Massachusetts even goes one step further to require that patients who are having genetic testing be made aware of genetic counseling services and provided referrals. I think again those are some concrete examples that reinforce the importance of these services.

Next slide, please.

So getting to the evidence, as Andy has already said, we reviewed two very thick binders -- you can see a copy right here in front of you -- of how much we went through to try to examine the evidence. It's very complicated to weed your way through, and I wanted to start off by talking about some of the caveats to really breaking down this evidence.

First of all, when you read through the

studies, they include a variety of different health care providers. There are physicians, there are nurses, there are genetic counselors, there are people with all different degrees who are providing them, and often they're all providing the service within the same study. So it's very hard to break down the effectiveness of any of these particular groups. Then you add to it that we're talking about a range of clinical areas -- prenatal genetics, pediatric genetics, adult genetics. So the outcomes are very hard to ascertain.

Second, many of the studies are also including genetic testing. So it's very hard to separate the outcome of genetic testing from the outcome that may have been sort of caused by simply the service. Then the final thing is that there are so many different outcomes that are discussed that, again, it's very hard to know which ones are the most important, and I've listed up here some of them, and I'll give you some examples. Again, we included a very long bibliography in the document and tried to summarize some of the key points.

But with regard to knowledge, for example, genetic counseling services have been demonstrated to increase knowledge of those consumers who received the service at at least an equivalent level of brochures or videos or computer aids that they have been compared to.

With regard to impact on clinical services, an example would be that if a genetic counselor or genetics professional of any sort takes a three-generation pedigree, they're picking up upwards of 20 percent of additional families who may be at increased risk for some of these conditions we're screening for, so again demonstrating some value in the provider services regardless of who that provider is.

With regard to test interpretation, there's the study that most of us have referenced from the New England Journal in 1997 that looked at the interpretation of genetic test results for APC by non-genetics physicians and found that in 31 percent of the time they were misinterpreting those tests. So again, another assumed benefit of genetic counseling services by any genetic specialist would be better interpretation of tests and better ordering of tests, which was an issue that was discussed earlier.

With regard to cost effectiveness, I know this is an issue that the committee cares a lot about. We really had a very difficult time finding studies on cost effectiveness of genetic counseling services, and in particular we did not find any data that documented an explicit harm because services were not being reimbursed, and I'll talk about some of the anecdotal concerns we have in a minute. But we did not find any studies on that specific point.

We did find a couple of studies that addressed willingness to pay for genetic counseling services, and in that study they were looking at willingness of about $200 for the service. Also, the NSGC has conducted a study which we do not have the full data available yet, trying to address that in a prenatal genetic counseling realm.

Next slide, please. Next slide. I already covered all that.

So with regard to why reimburse genetic counseling services, many of these are assumptions I think the committee is already making. We wanted to point out that when genetic services really were getting going many years ago, much of the service provision was covered by MCH block grants, which may be changing in terms of their availability or amount. So when providers were sort of covered under these block grants, having reimbursement and coverage was a little less critical than it's becoming today, and as a result we're actually seeing that both nurses and genetic counselors are moving into research roles versus clinical settings, which is certainly going to impact access to these services.

Next slide, please.

This slide documents some of the current billing practices for both ISONG and the NSGC, and you'll notice that for the NSGC data it's from 2004, which is an update from what's in the document that you're currently revising. You'll see here that many both nurses and genetic counselors are having issues around billing. The minority are really reporting ability to bill, and I want to point out that when you look at the genetic counselor data, those people who are billing under their own name and the physician's name may very well be billing under the physician's name and simply documenting their own name as a way to internally track how many cases are being seen. So that may not be an accurate representation of what's really being submitted.

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We found several examples of recommendations that revolved specifically around billing for genetic counseling services, and again most of these are not specific surrounding which provider we're talking about here. Usually they're just talking about any qualified provider. Washington State, as you can see, mandates Medicaid coverage for prenatal genetic counseling and benefits. Texas, which is an addition to what's in your document, and then Aetna again being an example of a third-party payer who may have recommendations. You all have copies of these slides, so I won't go through them all.

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So in summary, our working group reached these three conclusions. The first conclusion was that we request that SACGHS recognize non-physician providers with expertise in genetics as demonstrated by being credentialed by a national genetics organization as appropriate for providers of genetic counseling services.

Second, we recommend that SACGHS advocate in all manners possible for the development of CPT codes that are specific to genetic counseling services for use by any qualified provider, and I will add that we were particularly pleased to see that in the document you were proposing a recommendation for time spent being considered as part of that. That wasn't something that we specifically discussed in the working group, though.

Finally, we propose that SACGHS support the funding of further studies to assess the value and effectiveness of genetic counseling services provided specifically by non-physicians, since that was something that was very difficult to flesh out.

Then the final slide, just again, thanks to all our working group members.

MS. BERRY: Thank you very much.

Before we move to the specific recommendations, there may be some comments and questions from individual committee members with regard to this working group.

Yes, Joseph? And then James.

DR. TELFAIR: I was glad you made the distinction between genetic counselors and genetic services, because my question all along had to do with who was providing the genetic services. I know in a lot of states, particularly states where there are so few genetic counselors, that so-called single-gene counselors and those sort of things were very targeted, are the ones providing the genetic services, and states make agreements to reimburse them through another service like genetic services and that sort of thing.

So I was wondering in your recommendation about services and your recognition about services, one, is that included as part of that? Secondly, in your recommendation, did you consider any of the work that was done looking at the efficacy of these counselors in doing the work?

MS. ORMOND: I guess I can answer that, and committee members, please feel free to chime in.

We did not specifically look at any data that only focused on individuals like a single-gene counselor, but we're obviously aware that they are providing some of the care and that the current genetics workforce is not enough in terms of numbers to do all of the genetic services.

DR. COOKSEY: Could I respond in a slightly related way but also add some comment on a discussion? I think that the role of nurses in genetics has been really significantly understudied. The literature is more limited there. We conducted a survey that we're in the process of analyzing and writing the results, and what we're seeing is that nurses in genetics come to genetics often with a nursing background in another area and often with a Master's degree or credential in another content area. Many of them are nurse practitioners, whatever. There has been a striking paucity of educational opportunities for advanced education for nurses in genetics, severe paucity of programs, programs opened up with some HRSA funding, closed, a number of graduates from these programs.

So nurses functioning in genetics have received their training through on-the-job CEUs and other programs, and I think that's one of the reasons the credentialing reflects this. There are, as Judy mentioned, I think, 170,000 advance practice nurses. The numbers are growing. Those practitioner programs have increased. So I think if the bottom-line question is who is providing services now, who is qualified and credentialed to provide services now, and what will be future workforce capacity or potential, our group has not fully, I think, reviewed the issue because of the nursing role. I think that genetic counselors are an extremely well prepared workforce to do genetic counseling, and they can function as generalist genetic counselors, which is very important, and often substitute for geneticists in many settings.

In many interviews we had we heard interpretation of tests, getting information back to a patient with a diagnosis, but I think there's a bit more to this issue. I agree with everything that has been stated, but it sort of opened up an awareness.

DR. LEWIS: And just to add to that a bit from the nursing perspective, and to give a specific example, advance practice nurses who practice as certified nurse midwives certainly are able to order and assess and educate patients around prenatal genetics. Standard of practice, there's not one of them that practices that doesn't do quad screening, for example, or triple screening, depending on the protocol. But there are lots of nurses, oncology nurses who are cancer genetic specialists, who are probably as qualified as anyone, if not more so, in terms of working with patients.

Part of what happens in nursing is sometimes the genetics piece isn't separated out because nurses deal with the human response to health and illness in a broad perspective, and for many patients genetics is one piece of the health condition that brings them to care, and the nurse is able to integrate the genetics within a scope of practice. As a women's health nurse practitioner, I'm able to help women who are dealing with issues around breast cancer, for example, within the scope of lots of other issues that bring them in, and they may not be coming in for a genetics visit, but they certainly may have issues that deal with genetics that are dealt with within the scope of their practice that's hard to separate out. So I agree with Judy absolutely in terms of that.

The other thing I want to comment on in terms of the report that I want us to be careful what we ask for, no one is more interested in accountability for practice, which is one of the things that I believe licensure does. It sets up a social contract between the provider and the state, and it's really part of the consumer protection piece. But I want to be really careful that as we do that, we don't create situations that restrain trade for other professionals who are appropriately licensed and credentialed, perhaps not even by a genetics organization but through their credentialing and certification, because I think the last thing any of us want to do is create an environment where we reduce the number of people who can provide services rather than increase them, and there are many ways in which one gets qualified, and we have to be careful what we ask people to do because we're going to scare people away if we start to get too serious.

But I certainly think any group that's providing services to patients needs to have some formal mechanism of accountability, and that's what I see licensure doing. For example, the Massachusetts legislation that's up right now, one of the things that we're looking at from ISONG is just to be very sure that that legislation doesn't exclude nurses but adds genetic counselors, and I think that's one thing we need to pay attention to.

Then one comment on the document that we got, your issues paper, the issue that came to the audience. It talks about ISONG credentialed nurses in that, and I just want to be very clear that ISONG doesn't do credentialing. It's GNCC, which is a separate organization, because it's really inappropriate for a professional organization to issue credentials. That's a conflict of interest. So ISONG has no official -- GNCC is separate and it's a separate legal entity. So I just want to make sure, as you do your report, that you're clear on that.

DR. ROLLINS: As a payer for health care services, since we've used this term "evidence-based medicine" throughout this document, I would use that same type of approach in determining whether or not a particular intervention has been shown to be effective. Based on the literature which you reviewed, you mentioned one study I think you said where they compared physicians who were not genetically trained with other persons, and I think based on that you said that the group that was genetically trained was superior in terms of demonstrating them to be more effective.

With the exception of that one, all the rest of the information seems like it's anecdotal or it's a descriptive statistic, describing exactly what's going on out there. During your research, were you able to find any evidence where maybe Master's prepared nurses were better than B.S.-trained nurses, or even genetic counselors compared to physicians who were board certified in genetic counseling? Because I know there are a lot of reports. I don't know if there was a meta-analysis done, whether or not you could do that type of research. Because as I say, based on what I've heard, I don't hear the evidence which would support that one group was more effective than another.

MS. ORMOND: I can speak to the genetic counselor piece. When we did our literature review, again, we didn't have enough time to do a complete meta-analysis. I think that that would certainly be something, particularly done by an objective group, that would benefit all of us, to really take a good look at this data. I can give you some examples of some of the studies that are out there. The one that I referred to specifically was of non-genetics physicians interpreting tests, and 31 percent of the time they misinterpreted those genetic test results. So that was one example.

There have been studies that have looked at the use of, for example, a genetic counselor taking a three-generation family history in either a prenatal setting or in an adult setting, and they have then compared that to what's been documented in a medical chart by physicians in terms of high risk for various adult onset diseases or various conditions that might put a fetus at risk, and they have found approximately 20 percent more families were identified at risk by those genetic specialists as compared to what was seen either by a primary care physician directly or what was documented in the medical chart.

So those are some examples I can give you off the top, but I do agree that the value and effectiveness data is quite hard to interpret.

DR. LEWIS: The other piece that I think we have to pay attention to when you're looking for evidence-based practice is the issue of it's really hard to randomize people in terms of who they go to, and one of the things that I think becomes -- there's a lot of individual clinician variability, but I think also sometimes patient populations, for example patients who seek care from a midwife, may be fundamentally different from patients who go to an OB for their prenatal care. So I think part of what we need to look at is it's really hard to randomly assign patients to particular providers.

DR. ROLLINS: Yes, that's true, but I think that there are statistical techniques which can adjust for all of that.

DR. COOKSEY: There's a research bias here, though. I'm trained and licensed as a physician and surgeon, and I can practice as a physician and surgeon almost to any extent that I wish, and a dentist can practice as a dentist almost to any extent that they wish. Any lesser order on the hierarchy of historic medical care in the U.S. has to prove issues that physicians do not have to prove to gain licensure or to gain reimbursement.

So what happens when a profession is trying to achieve recognition is they develop studies and they figure out how to do studies to show that a clinical pharmacist can deliver care that's adequate compared to physicians, and then they're given the additional burden of showing that they're more cost effective and they can save money and whatever.

I think those are the wrong questions to ask, and I think what this group did review extensively was the credentialing and the training programs and the literature that has been there. When a genetic counselor graduates from a U.S. genetic counselor training program and they pass the exams and do what they need to do to provide genetic counseling, they're approved by their profession to do that. I don't think comparing the studies that try to do a design to compare a bit apples and oranges, because people practice in different settings, they do different things, it's very hard and there isn't the money to do those kinds of studies. I think it's a waste of resources.

So I wouldn't criticize the commentary here on that kind of analysis. The literature, there's an extensive literature out there, but it won't lend itself to that kind of comparison because of historic and other reasons here.

DR. ROLLINS: I'm not trying to criticize the committee for the work it's done, but I thought that one of the objectives of this discussion was to look at the effectiveness of genetic counseling dissemination or the providing of genetic counseling. I thought that that was one of the functions, to look at the effectiveness. Maybe I'm mistaken.

MS. BERRY: You're correct in that we wanted to get input on who provides these services, what are the barriers to providing services, recognizing that, for example, there are not M.D. geneticists in every location, and so there are other health care professionals who are eminently qualified to provide genetic counseling services. So we wanted to get some feedback as to who are those individuals, what are the qualifications that should be held out as sort of the minimum standards, and what are the barriers to licensure and other things that were identified in this report. So you're exactly right, it was the nature of the services, the scope of the services, but also who provides them, who should provide them. The group examined those.

DR. LEWIS: You know, the other piece that needs to go along with this is every state has individual practice acts that govern the scope and standards of practice, and what I can do in Massachusetts is very different than what I can do in Virginia, and who supervises me in Virginia is very different than who supervises me in Massachusetts. So that becomes a piece of it.

But just to reiterate what Dr. Cooksey said, a pediatrician can write a prescription for medication for an Alzheimer's disease patient because a physician is allowed to prescribe medication. I mean, hopefully people know what they're doing, and I'm not speaking to that. But an oncology nurse who is dealing with patients' pain medication in many states, even though they have prescriptive authority, they're eliminated from prescribing that particular class of drugs.

So I think the differences in terms of standards of practice to which we have held a variety of professionals, and certainly non-physician providers many times, because the focus is narrower, sometimes have as much expertise. It's just that they're constantly having to prove comparability to a standard which, according to the article that you talked about, may or may not be an appropriate standard. So I think we have to pay attention to that.

MS. BERRY: We've got a couple of questions. Reed, and then Alan.

DR. TUCKSON: I'll see if I can truncate a few of these. First of all, I would be careful about the argument, though, of saying just because docs can do a lot of inappropriate stuff and waste a gazillion dollars, everybody else should be able to as well. I don't think that's quite the argument that we're looking for.

But the question ultimately becomes that I don't think that given what you've described of the state of the art right now, that we can get all of the answers to every question that we need. So at some point, if this is going to go forward in a rational way, there has to be a belief that there is some credible group of people who are not only certified today, continuing to reexamine it, continuing to look at it and that kind of thing.

So this is one of my first questions here. I think you've described that there is an inherent relationship, an agreement between the ABMG and the ABGC that sort of says we agree with each other. We're two different organizations, we're on the same page, and we believe that we'll keep looking at what we're doing together. I can't tell whether the GNCC -- does the ABMG and the ABGC like GNCC and consider that to be equivalent? Let me just start there. Are you all on the same page?

MR. FAUCETT: I think so. I think the group is too new for a lot of those negotiations maybe to have been worked out, but I would just use the example that if you go to any genetics center in the U.S. that has all the parts, they would be willing to hire any of those individuals. Usually if you look at their advertisements for physicians or whatever, that's what they're going to ask for, board certified, board eligible by ABGC or with a nursing credential. So I think there is acceptance in the profession of those three groups.

DR. TUCKSON: Good, because one of the things I try to look at in our recommendations is sort of saying that at the end of the day a person who is certified -- now, you can get fly-by-night Company L who says we have our own criteria, and it could be a scheme. So when you say certified, you're talking three organizations that all basically have some relationship and there's some credibility and some expectation that while everything may not be known today, that they will be continuing to ramp this activity up over time. That's a guesstimate, a faith.

DR. LEWIS: I would argue that the appropriate credential in nursing is a Master's degree, because the process for GNCC credentialing is so new and is so limited, and the numbers that can be accommodated and the numbers who are eligible, it's far beyond an entry into practice credential. So I would argue that the appropriate credential for nursing is a Master's degree in an appropriate clinical specialty, and certification within that specialty, because that's where the expertise is.

DR. TUCKSON: Secondly, just help me quickly understand the scope of practice issue. Is this field at this point so new that can you legitimately suggest that a person who is certified by ABMG or ABGC, whatever, that they can in fact do the whole range of counseling services? Or is it that they are good at pieces of this thing?

MR. FAUCETT: I would say the whole range. I make a clear distinction between diagnosis, which is clearly in the spectrum only of physicians, but when you look at doing genetic risk assessment, doing genetic counseling around that risk assessment, discussing the issues of genetic testing, providing informed consent, helping the person understand those tests, I think they're all equal trained and would be appropriate, and that is the standard. If you look at any of the programs that exist now in the country, that's who they use to do that.

DR. TUCKSON: Then finally, and you may not have looked at this, but any ideas now in the real world in terms of the chain of events by which counseling occurs? So the test has to get ordered, the relationship between a doctor and a patient -- and I'm trying to see where the counselor fits into the chain. So the doc says I'm going to bill you a CPT modifier that says I have done a complex intervention with Ms. Jones because I have spent time, and the language of what I've done says I have spent time counseling. Then a genetic counselor gets into the picture and says no, no, no, I've also counseled Ms. Jones. Then you order the lab test. The laboratory has genetic counselors as part of their laboratory. They build in the price of the counseling into the lab service. Then you get the interpretation. The test is done, and then somebody has to interpret it.

Help me to not be concerned that in doing something that is good, we're about to throw into the health care delivery system another bazillion dollars worth of money and thereby ultimately decrease access to care for people who need it.

MR. FAUCETT: I think if you look now at most of the academic centers or the major medical centers, it is a team approach, and I think that's one thing you can say about genetics from the beginning. It's always been a team, and everybody has a piece of that team. I think that the trick is as it expands outside the medical center, because you clearly have situations where the genetic counselor is doing all of that process in an independent role or with a perinatologist as a backup, and then you have the centers for their part of the team.

I think as far as the laboratory genetic counselors, they do most of their work with tests and things that come from physicians without genetics training. I know in my own experience that most labs love getting a sample from a genetic counselor because they know they're going to have to do a lot less with it, because again that team is working. The local genetic counselor is doing the foot work on that case so the laboratory professional will have to do less.

DR. TUCKSON: I've got so many questions here, but this is the only way I can understand these recommendations. Imagine a world that is no longer the academic -- because we're talking in the normal world of health care delivery. That's what we've got to deal with. Now, in that world, are you suggesting then that the physicians, as Judy sort of opened up the door, they shouldn't be sending them out a (inaudible) that says they did counseling. So do you do it as only the genetic counselor gets paid? How do you see it in the real world working?

MR. FAUCETT: Well, I don't want to say that the physician shouldn't get reimbursed, because I think they will do pieces of it, they'll have to do pieces of it. But I think there's a difference between being someone who does pieces of it and someone who does the entire process. I also think that you clearly -- I'm just giving you an example from the 10 years that I worked in coastal Georgia. About the half the women who were referred to me for prenatal testing, when you actually did the risk assessment, were not candidates for prenatal testing, and many women who were referred to me for some other reason, another reason for testing actually came up that was more appropriate.

So I don't think it's going to increase the numbers a whole lot. I think it will improve the appropriateness of testing ordered and the appropriateness of the results that you gain from that testing.

DR. COOKSEY: Reed and committee, we've spoken to over 200 providers, and I don't have the numbers of how many were genetic counselors, how many were geneticists, nurses in genetics, medical specialists, very few primary care physicians. That issue about not duplicating effort and not duplicating billing, I mean the billing system is broken, but not duplicating effort, the sense that we have from the discussions is that the detailed genetic counseling experience with gathering information and helping interpret and present that is generally not duplicated. It's time intensive. Physicians do not have time, geneticists do not have time. They're delighted to delegate that to someone else. This is what genetic counselors are trained to do.

So the sense that I have is that in the practice setting, people try to be very efficient creatures, and that doesn't happen. The billing is a mess, and it's hard to deal with that issue because counselors can't bill independently, whether they're --

DR. TUCKSON: The language that you just used, Judith, just in terms of describing the scope of work and the intensity of service and so forth, is that language, are you comfortable that we have language in CPT now, that the modifiers are there? I mean, can we define what that range of intense services are that should be done, thereby saying okay, somebody with appropriate license or training or certification has done da-da-da-da-da, therefore that then is a describable event that has value, and then we can talk about reimbursing it? If it's done by that person, you don't have to pay for it if somebody else does it because it's already been done once?

DR. COOKSEY: I'm not sure I can answer that question. There should be a way to bill for this defined newer service. Times have changed. Genetic counselors should be recognized as a profession. They should be licensed. Genetic counseling wasn't something that 40 years ago we thought about. The service should be a billable service. It's a defined set of services. I don't know enough about the modifiers and all that. I think we're trying to fix a broken system.

MS. BERRY: I hate to cut off the debate because we do have some folks who are sort of in the queue here. We had Alan, Melissa, and Ed who had some comments and questions, and I think we need to move along.

Alan?

DR. GUTTMACHER: Mine's a fairly brief one, I think, and that is just to make clear how poor are the data from which we operate in this area about who should provide genetic services, et cetera. Probably the most frequently quoted study is this study from Giardiello in the New England Journal in 1997. It's not only the most frequently quoted, but we rarely quote the most, to me, telling part of it. So we have heard in almost one-third, 31.6 percent of the cases, the physician's interpretation of the test result was incorrect and would have led to the misinforming of the patients.

But what almost never gets said by us in the genetics community -- I'm a card carrying medical geneticist -- is the following sentence in that same paragraph. Analysis of the use and interpretation of the APC gene tests, according to the medical specialty of the physician -- so genetic counselors aren't indicted here -- of the physician, gastroenterology, surgery, medical genetics and other specialists, showed no statistically significant difference between groups. The primary data aren't there, but that would seem to indicate that we medical geneticists didn't do any better than anybody else at this.

So we medical geneticists tend to hold this article up all the time as proof that we can't trust other people to do medical genetics, yet it's not that. It's an indictment of our profession. So that's the first point I would make.

The second one is that the few data that we have out there, almost none of them talk about what's meaningful, which of course are health outcomes. I don't want to come out as arguing against knowledge. Knowledge is wonderful, but it's only something to get us somewhere, which is to patient behaviors, to physician actions, to other kinds of things that actually improve health outcomes.

So the question for much of this, which of course is so much harder to study for all the reasons that people have wisely pointed out, but that's the reason question, do different kinds of providers, different settings, achieve better or worse health outcomes? For instance, I personally, and this is just speaking personally, suspect that some health professionals who have a less good understanding of some of the details of genetics may have better health outcomes with their patients around genetics issues because they've launched long-term relationships with those patients, they see them for other things, they see the rest of the family, et cetera. Those are the kind of data that we also don't have.

Now, as Judith pointed out, and others, it's a bit unfair to sort of apply those rules to those who are now trying to sort of get their way in under the tent when those of us who have been under the tent before haven't had to satisfy those criteria. But if we're going to start doing any of this to see what's rational in terms of health care delivery, then I think we need to realize there probably aren't gold standards out there, and we need to look at health outcomes, not just knowledge base.

DR. FRIES: I'd like to speak to that and elaborate a little bit, and also maybe answer something that James raised in regard to a specific program that all of us are probably involved with, which is the issue of prenatal screening for cystic fibrosis. In the Department of Defense, specifically in the Army, this has been a program that they have been very proactive with, and it gives us actually a means to study the effectiveness of counseling by the basis of actually numbers of tests ordered.

If we look at it, and I have stratified because all of the tests are typically done at one institution, and if you look at the distribution of tests from different institutions, I can pick out the ones that have had no counseling. How? One hundred percent of the prenatal patients are sent. The ones that are in fact given counseling have fewer tests and are sending the appropriate ethnicity, and you can actually look at this with some data across the board.

So I think that that may be a means for us to, in fact, look at the merits of counseling by outcomes. I did a study of this in one institution. People who are of the target ethnic group who in fact receive counseling, all of them do not request the testing, and I think that that is a real factor; whereas if you're sending 100 percent of your people of Caucasian descent or Ashkenazi Jewish, the cost factor for that is enormous. It means that the counseling has saved dollars, and this is a way that we can look at that.

DR. McCABE: I was going to expand on that, too. In response to Reed's question, I think probably the cost of genetic services will go up, because genetic technology is going to begin to infuse medicine. So I think that will happen. On the other hand, I think it will ramp up faster if we don't figure out a way to reimburse for counseling services for the reasons that have just been stated. We need to use this technology appropriately, not forgetting the fact that inappropriate things will be done to people. But if we're just looking at cost, it will be more cost effective if we do it right and do it knowledgeably.

DR. LEWIS: And just to add to that, if you look at pediatric nurse practitioners when they started in Denver, the issue that happened with pediatric nurse practitioners is they ended up decreasing costs because you ended up with a less expensive provider. So I think if you can get quality services with the least expensive provider, you end up maximizing efficiency.

DR. ROLLINS: And I don't want to beat a dead horse, but we were talking earlier about structure, process, and outcome, and as part of total quality management. I think also that looking at the Plan Do Check Act is something that you also would have to do to complement structure, process and outcome. It's those types of studies which would demonstrate not only the effectiveness of each individual counselor or provider of service, but as I say, longitudinally you'll also see the cost effectiveness of them too. So those are the types of things that an insurer would look at in terms of documenting effectiveness of a particular provider or an intervention.

DR. FITZGERALD: I'd like to just begin again by thanking the panel for the great work that you've done and all the energy and effort that you've put into this.

I'd like to come at this from a slightly different perspective. Let's take what I would consider to be the likely scenario, that if the camel gets its nose under the tent, people will in fact discover that this is something that's going to be highly beneficial for the health care arena, as I think many people have already begun to indicate.

Is there any study, has there been any study who looked at what is the possibility, what is the capacity right now if there's a need to ramp up the number of non-physician genetic counseling professionals from across the board? I know you've already mentioned the paucity of programs and classes, but should that also be part of something that is studied so that we look at where we are now in the training process and what would have to be done to ramp that up?

MS. ORMOND: Yes. I think this is something that's been discussed by this committee multiple times, and I'll let Judy comment on the nursing component. But I can speak as a genetic counseling program director to the fact that within the past 10 years we've doubled the number of students that we can accept into our program on a yearly basis simply because the number of genetic counseling providers in the city that I work in has also increased substantially. So if you think of this as a circular thing, the more we obtain reimbursement and coverage for the services, the more genetic counselors can be theoretically employed, which means the more people we can train to continue to meet those needs.

My sense, and I think Andy's as well from the ABGC, is that if there were backing both in terms of support and finances for these programs, the genetic counseling programs could meet that need.

DR. LEWIS: And there's certainly a huge shortage of nurses to meet the health care needs of the population in genetics and in other areas, and I think part of what we have to look at is making sure that we have the funding, the capacity, and the faculty. I know, for example, having looked at some HRSA grants recently, I believe that there was enough funding to fund fewer grants than I as a single reviewer reviewed on the national basis, and there had to be 50 or 60 of us reviewing.

So certainly the need for increased capacity for specialty programs is well documented if you look at the number of people who are qualified who are applying to programs and are being turned away, and we have a huge national shortage.

MS. BERRY: Kim I think has the last question before we break.

MS. ZELLMER: Really I just had a comment. Again, it's something that I've said before. I think that the reality is that most people don't get the genetic services that they need, and while we can sit here and say -- obviously, I think coverage and reimbursement is important, and you've got to try to encourage getting more people in the field so that that will help that. But I think the reality is most people who need genetic counseling don't get it, and I think it's a lack of knowledge in the medical community in large part that people don't get the services they need.

I think that a lot of genetic information is obtained through the Internet and through individual disease organizations. I would guess right now that most people affected with genetic diseases get information from their national organization specific to that disease and not from the medical community at all.

DR. ROLLINS: I would agree.

MS. BERRY: Okay, I lied. Hunt, and then we cut off.

DR. WILLARD: I would add only one more item to the list that I think your organizations and others will have to address from a research standpoint to try to articulate with solid data what the evidence base is that a counseling is effective. We all believe it but, as you pointed out, we're lacking a lot of the hard evidence. I think I would add to that list the approach to counseling. I mean, certainly in our text, and I know from my own experience back when I was running a department, that this issue of we spend two to three hours per patient, and that doesn't count what we do before and after, that's true.

But I've yet to see any data that said that

that's the optimal amount of time. So those of us who are in the position of managing the budgets of those units often say, well, we can't afford to have you spend two to three hours and you need to figure out how to do that in a half an hour. That's probably not the right approach either, but just because it's traditionally two to three hours doesn't mean it needs to be two to three hours. There needs to be studies designed that can carefully compare the traditional model with what actually does lead to better health care and better outcomes for the individuals who are getting that counseling.

MS. ORMOND: I completely agree, and I can say that our organization is both aware of those issues and actively trying to find ways to address them.

DR. TUCKSON: We're going to take a break right now. Cindy is still writing it, but I want to be the mean guy. We're near the end of the day, but we're going to make it. We have three recommendations around genetic counseling, and then we have two other ones, and I think those are easier. We have to get this done before this day is over, though, so we've just got to drive this thing through. So I just wanted to say to you that the break is 10 minutes, and then we'll come back in. So it's 10 minutes. So if it's 4 o'clock now, you come back at 4:10, and we'll rock and roll.

By the way, to the committee, you guys are great. Thank you very much. Outstanding.

(Applause.)

(Recess.)

DR. TUCKSON: Thank you all for coming back.

We have some announcements to make very quickly. I'm actually stalling so a couple of you all can get back at the table. But we are starting on time, as we said. I didn't say it was going to be substantive conversation on time.

The dinner tonight is going to be here in the hotel so that you don't have to go out in the slush and the mush. In addition, and I hope this is okay with you, dinner is going to be at 6:00. Thereby, you get to eat and then go read all your briefing books and figure out the answers for tomorrow without being up all night, and the good part of that is so that our talented and wonderful staff are not out here in the mush and the slush going home at midnight, which I just can't have. So we're going to eat at 6:00, okay? Cool?

Now, Cindy has to leave at 5:30, so that means this session will be over at 5:30.

Therefore, take it away, Cindy.

MS. BERRY: Okay. A threshold question I think for this group before we get into the specific recommendations is whether the working group report should be incorporated into our coverage and reimbursement report in some way, and I think it is a valuable tool and a valuable asset for us. The question is should we pull relevant information from it and incorporate it into the report? Should we have it as a stand-alone chapter? Should we include it as part of the appendix? I throw that open as sort of the threshold question, and then we can move on to the specific recommendations.

Hunt?

DR. WILLARD: I've only read parts of it as it was going through, but based on what I read I think we should redact and pull out the parts that we feel are valuable and that we agree with and can validate, and then simply refer to it but not publish it. We'd have to examine it word by word, sentence by sentence in order to decide that we either agreed or didn't agree or that it was validated or not yet validated, et cetera. So I think we should grab what we can use and should use and leave the rest in a file.

DR. FITZGERALD: Just wondering, a follow-up on what Hunt just said. If we do references, is it going to be available to the general public somehow? Do we know if it's going to be published elsewhere or by someone else, or available on the Web, on the NSGC website or something like that?

MS. BERRY: Do you know what the plans were?

DR. WILLARD: I didn't suggest we reference it. I simply said as part of this process we solicited a body of research performed by that work group and then incorporate the findings we wish to incorporate.

MS. BERRY: Debra?

DR. LEONARD: If this report is an appendix to our report, since we have other appendices, does that mean that the appendix is something that we agree with or just something that we solicited as a report? Because I feel a little uncomfortable with pulling out parts and maybe leaving out other parts that we may not think are relevant but may be relevant to other people, genetic counselors per se. So could we do it as an appendix to the report and then pull out the parts that we want to cite in our actual report?

MS. BERRY: Yes. I don't think the fact that it would be included as part of the appendix or in the appendices means that we necessarily agree with all of the statements and findings in there. So I think we can sort of do a hybrid of what Hunt suggested, pull out pieces that we think make our case and bolster the issues that we have raised in the text of the report. We could refer to the report in greater detail and have it included in the appendix but not make any statement in terms of we are adopting this report and all of its conclusions. It's more for purposes of ease for the reader, really, when going through our report, and we're referencing something they'll be able to read in its entirety if we do it that way. That's one advantage.

DR. LEONARD: I would agree with Kevin's issue that if it's not easily available or you can't find it or it's not published, and I don't know if this is publishable, then it's difficult to find. So if we put it as an appendix, since we did solicit this report --

MS. BERRY: I am wondering whether the work group members have a preference, if there is any heartburn about us including the report as an appendix.

MR. FAUCETT: That'd be fine.

MS. BERRY: Andy's on record.

Barbara?

MS. HARRISON: I think it's a significant body of work and something that we formally requested, and they did deliver. I think it would be appropriate to put it as an appendix and highlight as needed within the text.

MS. BERRY: Hunt?

DR. WILLARD: Let me be a little more transparent. My particular issue is with a conclusion sentence that says genetic counseling has demonstrated value and is effective. At least in what I heard presented, I didn't see the data for that, and I fully accept that the working group may conclude that they believe genetic counseling is effective and has demonstrated value, and that would be fine. But to make that as a conclusion when we all just discussed how the data aren't out there to really allow us to look at the evidence and say in an objective manner that that's true, I'm just very nervous about having that attached to our report.

MS. BERRY: What if we had an appropriate -- I don't know if you want to call it a caveat or a little asterisk or a disclaimer in the front of this report in the appendix basically saying that we are not adopting all of the conclusions and -- put it in the heading? Okay. Well, somewhere before the actual report that we're not necessarily endorsing it or adopting all the conclusions, but it is there in the appendix for reference purposes, and leave it at that, so that it's clear that the working group, this is their work product, not ours. We have it there for a reason but are not necessarily endorsing all of its conclusions.

Do you think that would solve it?

(No response.)

MS. BERRY: Any other comments?

(No response.)

MS. BERRY: Is there a consensus on including the report in the appendix to our coverage and reimbursement report with the appropriate disclaimers or caveats?

PARTICIPANTS: Yes.

MS. BERRY: Okay, we've gotten that. Now we can move to the specific recommendations. I'm afraid of this next one, Recommendation 8, because of our discussion earlier about what the Secretary can and can't do, and particularly when it comes to the private sector, we may run into similar problems. I wanted to just flag that with you, and maybe many of you have already thought of that.

But Recommendation 8 really focuses on reimbursement and CPT codes and instructs the AMA to get input from various providers and assess the adequacy of existing codes and, based on what they've identified in terms of inadequacies, address those inadequacies as the AMA deems appropriate. So I throw it open for discussion with the intro that we may have some trouble with this one along the same lines that we discussed earlier.

DR. McCABE: Well, I would just restate my position. I think we can include much of what is here if we focus on the furthermore and use some of the stuff from paragraph one to support the furthermore and make that government programs should reimburse for service codes when documentation supports their reimbursement, use the material in the first paragraph to argue that that's not being done. But I would take out the issues about health insurance plans and AMA and those sorts of things.

MS. BERRY: Hunt?

DR. WILLARD: I tend to agree. I think I would also carefully edit it with respect to the "should" clauses, because it's prejudging a finding which we may not be there yet, and the Secretary certainly may not be there yet. In other words, it starts off saying counseling services should be reimbursed at rates commensurate with the amount of time spent. As I said just before the break, I'd probably modify that to say the amount of time determined to be medically necessary, not the time spent, because that's an open question still. I think there were a couple of issues like that that would need to be carefully edited so we don't look like we're stating a case that we can't necessarily state.

MS. BERRY: Does that capture it, taking out "time spent"?

DR. WILLARD: I'd say "determined to be medically necessary." It's getting to the evidence base again. It's self-serving otherwise.

MS. BERRY: Now, what about the AMA part of it?

Ed suggests that we take that out for many of the reasons that we went over already.

DR. FITZGERALD: Could I just ask a more systematic question here? I understand you're following the order of the text and the order of your recommendations, but following up on the point Hunt is making, it would seem to me that if we want to do this in some kind of logical way, number 10 is the one that is getting at the research that needs to be done, the analysis that needs to be done to see exactly what the benefit is going to be, by whom, what the structure might be, that sort of thing.

So I don't know. Is it possible to reorder these recommendations and to say, look, this research needs to be done to answer these questions that have been raised. Consequent to the research, and of course following upon the data, then you go back and take the next step, what do we do next, and that kind of thing, so that we follow a more logical progression in the sense of what one would want to do next. I know it doesn't follow the text, but it might be better for the order of the recommendations.

MS. BERRY: I think it's a good suggestion. It does make a certain amount of sense. Now, some of the options you'll see here under number 10, just jumping ahead for a quick moment, we may end up deciding to delete some of these bullets under number 10, and one of the reasons would be that when we're looking at this analysis bullet, has the working group report already achieved that goal, in which case we don't need another analysis, or is there some other body, a more formal body, that should undertake such an analysis.

So why don't we hold on that? I think it makes perfect sense if we go the route of an analysis and some of the other things that are recommended in this bullet to have that be first. Let's go through, and when we get to number 10, if we decide to delete some of these, then we'll go back to that. But let's hold that because I think it makes sense from a logic standpoint.

Debra?

DR. LEONARD: Over past meetings we've had a number of discussions about genetic counseling, and I remember there being issues about genetic counselors not being recognized as allied health professionals, and therefore they couldn't get a provider identification number in order to do billing, and I don't see that anywhere in here. I don't know how the recommendations of the work group, the three recommendations, relate to the actual things that would have to happen to have genetic counselors be able to submit CPT codes and bill for their services, whether in relationship to a physician or not.

There's something that's lost here that I don't see. Did we decide that that was something that we could influence, or --

MS. GOODWIN: The recommendation regarding the provider identifier numbers was taken out because the UPIN system is being replaced by the national provider system, and it's expected that counselors and other non-physician health professionals that are able to bill any health plan directly for their services will be eligible for a provider number, and that's expected to be implemented sometime in 2006.

DR. LEONARD: Could we make some statement that they definitely should be?

MS. GOODWIN: Dr. Rollins, my understanding in communications with your colleagues at CMS is that counselors and what I just said was going to be implemented. So counselors, for instance, because they are able to bill private health plans directly for their services would be eligible.

DR. ROLLINS: Correct. What you're saying is correct.

MS. GOODWIN: You still think there needs to be some sort of statement made that they ought to be?

MS. BERRY: Ed?

DR. McCABE: I guess I would feel that in the absence of policy at this moment in time, that we should state that fact and not trust that the winds will blow properly between now and 2006. Do you have the old recommendation, Suzanne, or is it gone forever?

Can I ask a question? I don't deal a lot with a lot of Medicare in pediatrics, but there's a way that health professionals, non-physician health professionals can bill incident to. Does that system work in Medicare as well?

DR. ROLLINS: I don't have the answer to that question. I don't know.

MS. BERRY: Kelly?

MS. ORMOND: I can tell you my understanding of the incident to is that if you're billing incident to the physician, the physician has to bill only for the time that they spend with the patient. So if a genetic counselor spends, say, 45 minutes and the physician spends 5 minutes, you're billing for the 5 minutes that the physician spent, and if the physician does not spend any time face to face with the client, then you bill at that very lowest level, which is equivalent to that. So there are significant challenges to using that as your primary payment.

DR. McCABE: My question was more about whether as non-licensed -- all the people I know who do that are licensed health professionals where the licensure was a barrier to that.

MS. ORMOND: I don't believe so.

DR. LEWIS: I can tell you that advance practice nurses do not have to bill incident to in Medicare, at least in some specialties. I believe family nurse practitioners and pediatric nurse practitioners do not have to bill incident to.

MS. BERRY: Hunt?

DR. WILLARD: I'm keeping an eye on the clock here. I would suggest we delete the sentence that says specifically E&M codes, et cetera. To me that's detail and gets to the issue of before and after contact, and I can't think of any medical specialty, and I'm sure there's an exception but I can't think of them, where physicians are reimbursed for the time when the collective office staff is chasing down x-rays from five states away and all those kinds of before and after testing. So I think with absent details and specific examples of what the value added is, which I don't think would be appropriate within a recommendation, I think we're better off leaving it out.

MS. BERRY: How about the sentence before that, again essentially directing the AMA to make this assessment?

DR. WILLARD: That goes to the point Ed was making, and there ought to be a different way to phrase that because we can't tell the AMA what to do, and the Secretary can't tell the AMA what to do.

DR. McCABE: I would argue that then you could say HHS, with input from, should determine the adequacy.

MS. BERRY: So HHS, with input from the American Medical Association?

DR. McCABE: No, no. I'd get rid of the AMA.

(Laughter.)

DR. McCABE: That was not intended as a general statement but in this sentence I would get rid of the AMA.

(Laughter.)

DR. McCABE: I'm going to be drummed out of the AMA.

(Laughter.)

MS. BERRY: Now, is this something HHS as an agency is able to do?

DR. McCABE: Yes. Then I would address the last sentence, some way HHS could do research to determine whether this was adequate.

MS. BERRY: As deemed appropriate, by AMA, delete all of that.

Debra?

DR. LEONARD: Just like we're having an evaluation or recommending an evaluation of the laboratory CPT codes that exist, would it be useful to recommend an evaluation of the adequacy of the genetic counseling services codes that exist by CMS? Because I see that as a major issue that I'm not sure is specifically addressed. So it's not saying that the codes are not adequate. It's just that we're hearing evidence that maybe the codes don't go to a long enough period of time or they can't be utilized in the proper way to cover genetic counselors or other non-physician health professionals.

So could we recommend just like we did, sort of a parallel to the laboratory codes, that there be some evaluation of these codes to make sure that they're adequate for --

MS. BERRY: How would you change the language, then?

DR. WILLARD: It might work better in the next recommendation, where it just says very broadly we should utilize the full range of codes for services provided incident to a physician, and there you could say "or laboratory services."

DR. LEONARD: No, no, I'm not saying to bring the laboratory services into this. I'm saying could we write something that's parallel to. I get lost in all this wording up there in 10. I'm not quite sure exactly what it is we're saying because it's long, and the one that's for the laboratory codes is relatively concise. I was wondering if we could make the adequacy of genetic counseling codes parallel to the laboratory code recommendation.

DR. WINN-DEAN: Isn't the key thing we're trying to address here the fact that there aren't any existing CPT codes for long-duration encounters, so the top you can bill is something like an hour of interaction, and if you spend three hours you can't bill the one hour three times? You just get paid for one hour even if you've spent three hours.

DR. LEONARD: Right.

DR. WINN-DEAN: So we're trying to encourage really the creation of additional codes to allow longer duration encounters to be properly reimbursed. That was my understanding of what we're trying to do with this particular recommendation.

DR. McCABE: But I would argue also that -- I agree with Hunt. In a lot of medicine, not just in genetic counseling, a lot of areas of medicine, I like the terminology "adequacy of" because I think part of the problem is we may not be able to do business as usual. I don't think there's an evidence base that spending three hours is better than spending 30 minutes. So I would like to leave it "adequacy of" because I think the model may have to be evaluated, as well as the E&M codes per se. I would prefer not to come out and say we need reimbursement for three hours because I'm not sure that we know that we need that.

DR. WINN-DEAN: No, I just meant that that was the basic thing that we were -- that the reason this got into the book in the first place was that there was some feedback that these sessions were lasting longer than the longest available code for payment. Let's say we did determine that it was appropriate to spend two hours. Even if you determined it was appropriate, you couldn't bill for it.

MS. BERRY: The second part of the recommendation in terms of "government programs should reimburse prolonged service codes when documentation supports their reimbursement," do we want to regard this like the others Suzanne points out we did earlier, where the first one is the ideal but in the meantime, until new codes, if any, are warranted and developed, that government programs should reimburse prolonged service codes when documentation supports it? Is this sort of a fallback?

DR. WILLARD: We could simply say when documentation supports their need (inaudible).

DR. LEONARD: Is that second part needed in light of the first? Do we know the prolonged service codes that currently exist are not paid for? I don't know that

that second little part of Recommendation 10 is needed.

MS. GOODWIN: I think anecdotally we've heard that, that prolonged service codes are not always reimbursed. So this second half of the recommendation would encourage the prolonged service codes to be reimbursed.

DR. WILLARD: The second half just repeats the first sentence in slightly different words.

DR. LEONARD: Right, and it doesn't have the medically necessary part. It's just saying reimburse prolonged service codes when they're submitted, and I don't know that we want to be saying that, because whenever anything is submitted, sometimes it will be paid and sometimes it won't.

MS. BERRY: So is this the prolonged service codes that currently exist? So the second part of it really addresses existing codes, and the first part of the recommendation deals with the possibility of new codes or modifying existing codes to address inadequacies.

Ed?

DR. McCABE: I see the second as being prescriptive to CMS to look at this. The first is let's study it and see what we find. The second says in the meantime, let's pay at the rate if there is the appropriate documentation.

DR. LEONARD: So I guess the question is what is the appropriate documentation, because people must be providing the appropriate documentation now and it's not being paid. Are we going to really change that practice with this recommendation?

DR. McCABE: That would be a question for Dr. Rollins.

DR. ROLLINS: In answer to your question, I think "reasonable and necessary" should probably accompany that last statement, because that's what we would be looking for in terms of reimbursement. But you still have to get past the issue that CMS has certain constraints, and it would be the Secretary who would make that recommendation.

DR. McCABE: So I think those are important helps to us in crafting this, that it needs to be that prolonged service codes, when documentation of reasonableness and necessariness --

(Laughter.)

DR. ROLLINS: Reasonable and necessary.

DR. McCABE: So I think that's helpful, and I think the important point is that again it should be that the Secretary should recommend or should urge I think is a term that we've used before government programs.

DR. LEONARD: Does the Secretary urge or

direct? I mean, does the Secretary have the ability to direct anyone to do this, or is it just encouraging?

DR. WINN-DEAN: I would think he could urge Congress but direct CMS.

DR. ROLLINS: Yes, the Secretary can direct CMS once they have been given the authority by the Congress to do that.

DR. McCABE: But I think it's important that we put in there "government programs" and not just CMS, because there are other government programs that might be paying for services as well.

MS. BERRY: Does that do it? Do we need an intro in the second part, another one of these "in the meantime" kind of lead-ins, or is it sufficient standing on its own? I think the intent was we have the analysis but in the meantime the government should do this with regard to government programs. Do we need that or should it just stay as it? Have the lead-in?

DR. WINN-DEAN: Maybe we need them in the opposite order. This now becomes the first sentence of the recommendation. First, reimburse for the things that are there; second, investigate whether there are gaps.

MS. BERRY: Makes sense. Let's do that, flip them.

Any other comments or edits on this

recommendation?

DR. LEONARD: If those have to be separated into two separate paragraphs, are those two separate recommendations, or are they one?

MS. BERRY: I think they're all one recommendation dealing with codes. But we do have another, and it's not clear to me why we have 9 separated out from 8.

DR. LEONARD: Isn't the first sentence, now that you have "The Secretary should direct government programs to reimburse," isn't that the same as Recommendation 9, "CMS should allow health providers to utilize the full range of CPT E&M codes"? Is the full range the high-end longer ones, or is there something else that I'm missing here?

MS. GOODWIN: CMS has informed us that when genetic counseling services are provided by auxiliary personnel, the physicians are only permitted to use the CPT code 99211. They're not permitted to use the full range of E&M codes that are available to physicians and other allied health care providers. We had that guidance a few years ago and in the past few weeks have gone back and asked to make sure that that's still true and have been told that that still remains true, and Dr. Rollins is shaking his head yes. So Recommendation 9 would get at that barrier.

MS. BERRY: Does it make sense, though, for it to be a separate stand-alone recommendation? In order to address Debra's point, should all the coding issues be addressed in one recommendation? I guess it doesn't matter too much, but why is that one separated out when the other two are part of the same recommendation?

MS. GOODWIN: I think it's just the order in which the topics were discussed in the report as it is currently.

DR. McCABE: But it's a different issue. I think it's a way of dealing with the one that was deleted, because it's a definition of who is a health provider to CMS, and it may get fixed in '06, but I would not trust that that would occur. I'm going to get drummed out of the AMA, and now I'm saying I'm not sure I trust the government. But I think it's better to just write what we think we ought to have in here rather than hope for the best. So I would argue that we should say CMS should allow health providers, including those health professionals providing genetic counseling services, to utilize the full range of CPT E&M codes available for genetic counseling services provided incident to a physician.

MS. BERRY: "Providers qualified to offer" or "qualified to provide"?

DR. McCABE: Yes, something like that. I don't remember what I said, but yes, qualified health professionals providing genetic counseling.

DR. FITZGERALD: Why not just allow qualified health providers?

DR. McCABE: But they aren't qualified. That's the problem, we're trying to get them qualified.

DR. FITZGERALD: Oh, I see.

DR. McCABE: I was trying to keep it general as health professionals providing genetic counseling services so we weren't locked into one model versus another model.

DR. WINN-DEAN: Do we need "qualified," too?

DR. McCABE: Well, I put in "qualified" because I think we've heard that there are mechanisms to qualify individuals to provide these services, as opposed to anyone who claims they can provide the services. So that was the reason for introducing that, even though I know it makes it a bit cumbersome.

MS. BERRY: Debra?

DR. LEONARD: I don't mean to jump around a lot, but I'm now reading 11.5, which is non-physician health providers who are permitted to directly bill health plans, should be eligible for an NPI. Is that a Catch-22 in that if they can't bill they don't get an NPI? I mean, the way that's worded, are genetic counselors currently able to directly bill health plans?

MS. GOODWIN: Some private health plans recognize genetic counselors and other allied health professionals as being able to directly bill. So as long as one health plan or health program in the country allows them to directly bill, then they should be eligible for an NPI, and that plan does not have to be Medicare.

DR. TELFAIR: I actually have a comment, but first a question. A couple of us are wondering what is an NPI?

PARTICIPANT: National Provider Identifier.

DR. TELFAIR: Okay. Then the second thing is that under the provision in Recommendation 9, there are a lot of circumstances that counseling services are provided which are not necessarily incident to a physician, and I was wondering what about that? Is that part of the recommendation? I was trying to wait until we got to 10 before I brought this issue up because it's a bigger issue than just that, but I can wait until we get to that. We'd have to go back to modify it, but there are a number of issues mostly related to Recommendation 10. There are a good number of incidents where the request for services does not come from a physician.

MS. BERRY: I know where you're going with it, and it's critical. I think we should address it in number 10, and we are probably going to have to come back and modify this one in light of that discussion.

Ed?

DR. McCABE: Perhaps I misunderstood this one, but I read it that they could utilize the full range of CPT codes that provided incident to. In other words, I wasn't sure that we were saying that it had to be incident to, but the same codes that are provided to a physician incident to could also be provided to the non-physician health professional providing genetic counseling. If that was a misinterpretation of this, then the way to deal with it is just to put the period after "genetic counseling services" and not leave it open to misinterpretation.

MS. BERRY: We should get clarification, because I read it the way Joseph was talking about it, which is that if the services are provided incident to a physician visit or a physician service, what was the intent behind it?

DR. McCABE: But those are already available incident to. So I think the big problem is, as we heard, if you bill incident to, then you're billing only for the time the physician was in the room providing the services. So that's what I thought, and we can already do that, so there's no need to remedy that. I thought what we were doing was opening to the non-physician the same range of services currently available incident to.

If we put the period after "services," then we don't risk this misinterpretation, and I think if we leave it open to what I perceive as a misinterpretation, there's no need for that remedy since it already exists. But I just think it's not equitable.

MS. BERRY: Suzanne has edited it a bit, but I think it still reads in the way that Joseph and I were reading it and not the way you interpreted it, Ed. Look it over again and make sure.

DR. LEONARD: Shouldn't the "incident to a physician" be related to the CPT E&M codes as currently used? That's what I think Ed is saying. It's the CPT E&M codes that are used to bill services incident to a physician now should be available for all health professionals providing genetic counseling services to use.

DR. McCABE: What I would do is I would take "incident to" out of this completely and what Suzanne added. That's the way I interpreted it, and I think getting "incident to" out of there is better.

MS. BERRY: Now, how is this different from the other recommendations, then?

DR. McCABE: I think there are two issues. I think this really has to do with the qualification issues, whereas the other has to do with the adequacy of existing codes. So I see it as two different issues. We could determine that the codes are inadequate. We could fix the codes and we would still have the problem of incident to. So that's why I think one has to do with are these acceptable folks to be providing the services. That's I think what we remedy in number 10. I think in number 9 we investigate whether the codes are adequate. I think they're two completely different things.

DR. TUCKSON: So just to be sure, what we wind up doing is looking at your last point with number 10. You have to establish the criteria that allows you to be an independent biller. Then you can talk about independent billing.

DR. LEONARD: So do these need to be reversed in the report?

MS. BERRY: We're going to reverse them because I think the old number 10, as Kevin was suggesting, really belongs up at the top.

DR. LEONARD: Unless you have that, you're talking about qualified people but you haven't defined them as qualified.

DR. McCABE: Yes. We need new members to point out that we need logic in the work that we do here.

(Laughter.)

MS. GOODWIN: And is that wording along the lines of the clarification you were looking for?

MS. BERRY: Number 9 there.

DR. McCABE: I like it better before the most recent edit. I don't think there's a problem for a physician billing for genetics. I think the whole issue is can the nurses and the genetic counselors bill independently for genetic counseling services.

MS. BERRY: But it's not the physician at issue here. Can't an allied health professional, if they can't bill directly, they bill incident to a physician service, and it doesn't have to be that the physician is actually performing the work, that they are as well. So I think it's addressing the health professional, not the physician. It's just focused on --

DR. McCABE: Probably the "both" takes care of it, then.

MS. BERRY: Do you think?

DR. McCABE: As long as it doesn't revert so that we've now allowed them -- if they can bill for the full scope of their services and not just for the time that the physician is in the room, that's what I think was discussed with the panel and that's what I want to be sure is reflected here.

DR. LEONARD: My concern is can health professionals at the beginning of that sentence be interpreted as physicians, or are those non-physician health professionals? Those are the people you're talking about.

MS. BERRY: So should we say allied health professionals?

DR. LEONARD: Well, you get into problems of definition. I would say non-physician health professionals because genetic counselors currently are not defined as allied health professionals. So you don't want to use words that are going to exclude them from the cure we're trying to create.

MS. BERRY: So non-physician health professionals?

DR. McCABE: Yes.

MS. GOODWIN: Is that language correct? Because CMS distinguishes between -- well, there are physicians, but there are also non-physician providers who are allowed to bill directly, and then there's also auxiliary personnel who only may bill incident to a physician. So currently if you're allowed to bill directly, you can utilize all the E&M codes. If you're considered an auxiliary personnel, you have to bill incident to, and you're only permitted to use the 99211 E&M code. Does that clarify?

DR. McCABE: So could we include both of those groups?

DR. LEONARD: Well, I think what Suzanne is saying is that auxiliary this would not be able to apply to, right?

MS. GOODWIN: I think the wording here would apply to them. The auxiliary personnel are those that bill incident to the physician. So the recommendation as it's worded would allow providers who are billing incident to a physician to use other E&M codes besides just the 99211 code.

DR. LEONARD: I guess I'm confused as to whether we're fixing -- we're working with a definition of genetic counselors as it currently exists, or as we're hoping to fix it to exist in Recommendation 10, which is now, I guess, 8?

MS. BERRY: It will be 8.

DR. McCABE: Cindy, could we ask Dr. Rollins?

DR. ROLLINS: Non-physicians, as was said earlier, I think is probably more appropriate, as opposed to auxiliary.

MS. BERRY: Non-physician health professionals?

DR. ROLLINS: Yes, non-physician health professionals.

DR. TUCKSON: So let's be clear. I think what we're struggling around, again, is this idea of making a recommendation that fixes the problem versus making an interim recommendation while we are waiting for this moment. I think if we can just go ahead and be clear, I think that this will intellectually decide that we can say that we know we're going to move 10 up. Let's deal with the issue of this is the way it ought to be. We hope it to be this way. Then say in the interim while that is happening, there is this intermediate transitional step which we recommend being the following, and then be just done with it.

DR. LEONARD: Suzanne, why did you take out "who bill independently" rather than leaving the "incident to a physician"? Because if they bill incident to a physician, they now can currently use the full range, no? Am I missing something here?

MS. HARRISON: I guess going to the discussion of how we're going to frame this toward where we're going or where we are, I just really want to see the incident to go away. I think the problem here is that the genetic counselor is stuck with having to bill under a physician, and the goal would be that they would not have to, the genetic nurse would not have to. Unless we can put something in here to say in the interim or say more immediately or something so that it's understood that this is not our end goal but is something that is okay in the meantime, then fine. But I just want that reflected somewhere.

MS. BERRY: What if we added "and who currently bill incident to a physician" as a way to recognize that we're talking about what people have to do right now but not making a statement as to whether we think how it should be in perpetuity? Take what out?

MS. ZELLMER: (Inaudible.)

MS. BERRY: Because I think only those who bill incident to are the ones having the problem. They're not able to use the full range of CPT E&M codes. So they're the ones facing the most immediate problem right now.

DR. WILLARD: Then the word "currently" works okay without prejudging what we think the ultimate solution should be. So I understand why you, Barbara, and your colleagues want to be able to bill by yourselves, but I don't think this committee necessarily comes down on the side of that because we don't have the information and we don't have a dog in that fight, as they say. Right?

MS. HARRISON: But if we're making the argument -- well, I guess we have to get to 8. If we want to make the argument that there are other people that are qualified to do this work, then those people need to be able to bill for their services.

DR. WILLARD: Either directly or incident to. A priori, it shouldn't matter. It matters to you guys for professional reasons, but it doesn't matter to this committee, at least not this person on this committee.

DR. McCABE: I just think if you leave the incident to in there, you've got to in the body make it clear what the intent of this is, that it's really, the way I read it, to open up the possibility of billing for the full scope of services provided whether a physician is in the room or not.

MS. HARRISON: And I just want to also throw out there that there can be times when, with genetic risk assessment, that kind of thing, where it may be appropriate that there's not a physician involved.

MS. BERRY: Barbara, does this, keeping in mind the concerns that you raised, does this recommendation as it's worded work for you, with maybe some appropriate clarifying language in the text?

Barbara, and then Joseph's got some concerns as well.

MS. HARRISON: Let me read it more carefully.

MS. BERRY: Okay.

Joseph?

DR. TELFAIR: If the point is to make a distinction between those who are in situations where they bill incident to a physician and those who are in situations where physicians are not involved, then this doesn't do it. You need an "or" in there to separate out. Where you have "and," it should be "or," not "and," because "and" is inclusive. "And" means that they are qualified and they are currently billing.

MS. BERRY: Right.

DR. TELFAIR: So I'm saying that it doesn't make a distinction that there are two separate --

MS. BERRY: No, it's not. In this recommendation, it's focused on one group, and these people are qualified but they're also forced to bill incident to.

DR. TELFAIR: So this one is only dealing with that single group, not both.

MS. BERRY: Yes, it's one group.

DR. TELFAIR: Okay. I'm sorry. Never mind.

DR. TUCKSON: So let's just try something a little daring here. I'm watching the clock here. We've got a half hour. Let's just go to number 10 and let's just state what we want the ideal to be right now. Let's get that locked and then come back in and say okay, in the interim, this now defines the reality. I think we keep going back and forth between the ideal and the real. We've got it 90 percent of the way, so let's pause there and say where we think this thing ought to go and then come back and say in the interim, and then we lock this one in. How about that?

MS. BERRY: So this will be moved up. So this will be the first recommendation under the genetic counseling section of the report, number 10, which is going to be number 8.

MS. HARRISON: Just real quick, is this going to change the order in the report?

MS. BERRY: In the text of the report.

MS. HARRISON: I mean, this 10th recommendation was on page 52. The other was on page 49, and we actually changed it now.

MS. GOODWIN: We can combine all three recommendations so that it falls at the end of this section. So the order of the text will remain the same.

MS. HARRISON: Okay.

MS. BERRY: I think one question to throw out there to help guide us is the first part of the recommendation focuses on an analysis of who is qualified to provide genetic counseling, under what conditions, under what supervision. Do we feel that that is a worthwhile effort? Has it been rendered moot because of the work group's efforts, or are there still gaps that justify this type of recommendation?

Hunt, and then Joseph.

DR. WILLARD: I think we spent an hour saying that we didn't have the data that we needed, despite the fine work of the work group. So I think this is very much still needed.

MS. BERRY: Okay. Joseph?

DR. TELFAIR: I would concur, because one of the things that the work group, in its fine work, did was actually present only one part of the story. The other part of the story has to do with what I keep bringing up, which is that there are a number of people who provide genetic counseling services who do not go to these formalized programs, and they are not even reimbursed directly. Some are reimbursed through HRSA grants, some are reimbursed through the state side of Medicaid, some are reimbursed through private insurance and care, and they're usually attached to a single condition of one type or another. I cite as examples cystic fibrosis, hemophilia, hemoglobinopathies, and metabolic disorders.

There are Master's trained persons involved, but nine times out of ten, particularly in rural areas, there are usually those who are trained specifically to provide counseling and education for those particular conditions, and are reimbursed maybe not directly but indirectly through other means. I think we as a committee need to take into account that that is a big reality when we're trying to make recommendations related to reimbursement.

MS. BERRY: What about the point that came up during the review of the working group report and efforts that the data really just doesn't exist, and they've been through a literature review, and they've conducted a pretty thorough -- but what is the analysis going to look at if it's not already out there?

DR. WILLARD: The analysis is research. It's the research and subsequent analysis is what's needed. There's not an analysis of prior research.

MS. BERRY: Okay. So then we should clarify the language.

DR. WILLARD: To me, the analysis is sort of all encompassing. But if it isn't obvious to you, and therefore may not be to the Secretary --

MS. BERRY: So you would say "further research and analysis."

DR. FITZGERALD: Would it be appropriate, with the working group's concurrence, to use some of their language? Their third recommendation was to support the funding of further studies to assess the value and effectiveness of genetic counseling services provided specifically by non-physicians, which would include your single-disease counselors. So that's one of their recommendations. We could use that recommendation, if that's okay, and then if you want piggyback onto that the intent to recognize non-physician providers with expertise in genetics. The idea is we're going to do this analysis and see are there indeed non-physician providers with expertise in genetics that should be reimbursed.

DR. TELFAIR: And I would agree with Kevin that you have a real (inaudible) set of recommendations.

MS. BERRY: Do we want to recommend a specific body to conduct this research and analysis?

DR. McCABE: I would argue we shouldn't recommend to the Secretary who within HHS, which group within HHS do this. It may involve different agencies, but I really think that's the Secretary's decision.

MS. BERRY: Reed?

DR. TUCKSON: I think, again, this section, as I understand what we were saying, is that we are recognizing the idea that there is a genetic counseling activity that needs to be defined but that can be independently engaged and billed for outside of anybody else's supervision. So it's different than the people that Joe is talking about in the sense of the single condition stuff that's done with a doc. We're talking about an independent function.

At least a point that I would like to argue is that we recognize that there is such a need and that there are certain people who theoretically, for lack of a better word right now, can do that function. I think the first recommendation from the work group is actually pretty good in the sense that it's saying that we do need to recognize that there are non-physician providers with expertise and who should be credentialed by a national genetics organization.

I think the way to handle who should do that, then, as an example is we had the report earlier today from the Office of Information Technology. One of the ways in which they are working to create the interoperability standards for the electronic medical record is to create the Certification Commission for Health Information Technology. The government caused it to occur, but it's a private/public sector joint venture that is creating the certification standards. On this group sits the Office of Health Information Technology, CMS, but also the private software vendors, et cetera.

So what I'm getting at is there are models by which government can cause the stimulation of a multidisciplinary group charged to create the standards that are ongoing. So I would give you all something to shoot at and disagree with, but we would call for the government to stimulate the development of a credentialing group that allows this credentialing to occur to include at this point in time the AC -- those three, and to be augmented as necessary.

So you get at this idea of saying there is this group, the charge to this group ought to be pretty specific. It ought to be to create the criteria and to continuously update those criteria based upon Recommendation 3, which is where Hunt started out as well, and that is that there needs to be ongoing studies. But I guess where I'm differing a little bit from my colleagues is if you decide that you can't start unless you have everything in order, you'll never get anywhere. So you've got to have something that gets you started.

Based on that, then we can start to move to those who have to practice with somebody, and then we can get to the interim with the other thing. Anyway, that's just something to shoot at.

I didn't give you language, did I?

MS. BERRY: No, you didn't. You were totally unhelpful.

(Laughter.)

MS. BERRY: I'm kidding.

How about, as a suggestion here, because you touched on the licensure issue which we haven't yet gotten to, you'll see in the recommendations in the bullets we've got further on down under this Medicare demonstration idea, I don't know if we want to propose a demonstration project or not, take that off the table for a second. Looking at the alternative that's presented here in the bullet, it talks about studies that assess barriers to billing and reimbursement and whatnot.

What if we combine all of that in with the first analysis? So we have here where we're talking about research and analysis to determine which health providers, blah blah blah, add to that this business about barriers to billing and reimbursement so it's all part of one study or one analysis, and then the second recommendation would deal with the licensure component which you identified. Are those two reasonable ways to attack this? Does that get at everything?

DR. McCABE: Cindy, I think what it doesn't deal with is the CMS demonstration project, which I think if we're going to work through CMS and Medicare, we're ultimately going to need that. So as long as we leave in there somewhere the CMS demonstration project piece.

MS. BERRY: So merge the two sections that deal with further research and analysis, then add the demonstration suggestion, and then the third piece would be licensure, which actually I think we need to talk about a little bit more because I did note in the report that there was some discussion about what licensure can and can't do. I don't know that there was the case made that that is absolutely critical and that there's been any documented harm to consumers when there's been a lack of licensure. So I'm not sure if we necessarily want to recommend that or whether we want to wait until the analysis is done.

DR. McCABE: A bigger problem has to do with just the structure of how we operate. There won't be national licensure. That's a states rights issue, so it's not going to happen. I don't think that's one that we should even go after, and there are already certifying bodies, so I'm not sure that we need another certifying body.

I think we need a group that just brings together the various segments of the non-physician health professional community providing genetic counseling to be even more inclusive than the panel we had to address some of Joseph's issues, to really look at how one could go about maintaining quality in terms of certification, but making sure that we're certifying all of those individuals who ought to be certified.

DR. TUCKSON: I think that's a more precise way of what I was trying to get at. I mean, at the end of the day, I think people have convinced me, maybe not Hunt yet, but they've convinced me that it makes sense that even though we don't have all of the evidence and every piece of data in yet, that the idea that a certified counselor may well in fact add some value, enough so that I'm prepared that if there were a real body that could certify that there are real disciplines here, real rigor, and that these folks are not fly by night but they actually have some training and some competence and can demonstrate at least a starter set of competencies, I'm prepared to think that then maybe those people ought to be given an opportunity to do their thing and be compensated.

I'm prepared to accept that that needs to be studied rigorously and continuously updated, and I'm prepared then to do that under the conditions that there is an organization that has some legitimacy that is actually controlling this. So you've got the CCH and the AMG, et cetera, that they can be pulled together under some umbrella that has some rigor and some discipline so that fly-by-night certifying Agency A doesn't just jump up there and say, okay, all my people are now certified, but that there's some rigor to it, some controls.

MS. BERRY: Agnes?

MS. MASNY: But I would just kind of reiterate what Judy Lewis had mentioned earlier about that. If we limit it just to a specific genetic organization that would set the criteria or provide the credentialing, then you're going to overlook the various groups that already provide credentialing for specialty organizations. From my own perspective in oncology, the oncology certification, the oncology training provides a background in genetics, and nurses are credentialed as advance practice nurses, and many of those advance practice nurses that weren't reflected here are actually providing cancer genetic risk counseling.

So when you looked at the number of nurses who were credentialed, there were only 30. But through organizations, through ONS, there's over 150 nurses who are providing cancer genetic risk counseling. So the appropriate credentialing body would be the Oncology Nursing Society. For a variety of other health care providers, the situation may be similar.

DR. TUCKSON: Maybe they could appeal to the group and let the group work it. I don't think we could ever work that level of detail out.

DR. WILLARD: I just don't see why we're even getting into this. To me it's prescriptive, potentially. I mean, let's do the analysis. We can't predict where it's going to go after that or say what if. We're going to need certification, we're going to need licensure, we won't, we will. To me it's getting way beyond where we can go with a recommendation to the Secretary.

MS. BERRY: Suzanne?

DR. FEETHAM: As part of this discussion, I think we also need to look at this saying which health providers are appropriate. Again, I think you're back to identifying descriptive studies which identify the qualities and characteristics of the providers, but I think you're opening on this whole theme of discussion a huge can of worms about scope of practice, licensure, everything else. I think you're making a better contribution if you say "to identify the qualities and characteristics of the providers," not saying you'll identify which are those providers. I just think that's part of this discussion, a track you may not want to go down.

MS. BERRY: Yes, Emily?

DR. WINN-DEAN: I agree. I don't think we should get into the whole issue of licensure in particular, but I would like to throw out to the colleagues who presented on genetic counseling to us that they maybe think about a mechanism to "certify" individuals, particularly individuals who are providing specific disease characteristic kind of counseling and who are not going to go through a full-blown Master's in genetic counseling program, but who could be certified as an officially deemed counselor for CF or sickle cell or something like that, so that those people did have some training and uniformity in the way they're providing services to the community.

MS. BERRY: We are running out of time. Do we have a consensus that we should eliminate the licensure recommendation and stick to the first two, which are the analysis and the demonstration project for this recommendation?

DR. TUCKSON: I may be the only one -- and, by the way, certification was my thing, not the licensure. If I am the lone person for having the certification group set up and then study simultaneous, if I'm the only one, then we should run me over.

DR. LEONARD: You're not the only one, definitely not.

DR. TUCKSON: Then stick to the study first, and then let the study direct what happens after that, which is I think another point of view.

MS. BERRY: Debra?

DR. LEONARD: I've been sitting here listening, and I'm really kind of upset, but I'm not quite sure how to voice what's really bothering me. I think part of it is that I have many colleagues who are genetic counselors who are professionals, and I highly value their education, their certification, and they have a certification process, and that's been described to us by the working group. GNCC and ABGC have a certification process. They've described the criteria for that, which seems relatively thorough in the training that these people have to have.

Now, you can argue that analysis is needed for the value added, the outcomes, results that genetic counselors get, but these people are professionals, and I feel that we are sitting here and discussing their professional stature, and it's insulting to them and to me, who works with these colleagues. So I agree with Reed that we should set up some process to acknowledge these people as professionals, some way of saying this is a group of people who are qualified to provide genetic counseling services, and then that body can deal with the people who only counsel for CF and Ob/Gyn offices or other ancillary groups that aren't doing a full-blown Master's.

But you have people who are highly professional, and we're talking about having to do an analysis that's probably going to take two or three more years before there's any result coming out, and they're already certified. So I would agree with Reed that there should be a certification process. Licensure, I also agree with Ed that licensure is not something -- that's a state by state basis that I don't think we can influence much. It's a whole legislative process. But the certification, so that then if these people are recognized as certified by this body, then they would have the right to bill either incident to -- I mean, then you could work on the other things that maybe need to be analyzed under this analysis section.

I am just finding the whole conversation insulting.

MS. BERRY: All the folks who were involved in putting this thing together, the intent was not to insult anyone but it was actually to face the very real situation, which is to get reimbursement from government programs or from private programs. It's not that we're questioning their qualifications and their value. It's the fact that these plans and Medicare and others do require a certain amount of proof. They don't just let anybody come in and bill for anything.

DR. LEONARD: But ABGC and GNCC are not providing that kind of proof? I think they are in their certification process. It's fairly stringent, with an exam.

MS. BERRY: I think they should be, but I think there are some programs and plans out there that apparently aren't recognizing that. Otherwise we wouldn't be faced with this problem that there are some difficulties in billing and reimbursement. I mean, that's the sense that I have, that there are some real barriers out there that shouldn't exist for these professionals who are providing these services. So whatever it takes to convince the payers, that's what these recommendations are focused on, not to insult anybody but to help them make the case so that we clear away these barriers.

DR. FITZGERALD: I was just wondering, at least in some discussions, particularly with Andrew, I'm not sure that the assessment and valuation period is going to be that long nor that difficult for the very reasons that you point out. I think there's a good bit of evidence that's out there. I don't think it has been pulled together and structured well so that it can be analyzed in a way that gives people the sense of the kind of outcome measurements that they want to have. So in that sense, I agree that whatever works is what we're trying to get at, and if it's a structure that says pull the certifying groups together under some coordinating entity, that's fine.

Let's get moving on the analysis and evaluation so that the professionalism of these people and these groups can be demonstrated to the criteria that's been used by the reimbursement agencies. Obviously, there's a gap, and I think the effort is to close that gap as soon as possible just because we know of the professionalism of these people and we've got to do whatever we can to help close that gap.

DR. TUCKSON: I think in some ways we're starting to get closer here. Maybe it is that we signal what we are attempting to do. We're saying this ought to occur. We're saying that there is a place to start so that you've got this foundation. Then we're saying that we have some critical questions that need to be answered very quickly. Then I've heard Hunt and a couple of others saying that we really want to know the answers to a couple of things here, building on the foundation that exists now. So maybe there's a hybrid in there somewhere that lets this thing move.

DR. COOKSEY: Could I just add a couple of points of clarification from about 10 years of doing workforce-related research, because there's some confusion of issues that's making this more difficult than it needs to be, I think.

Licensure is something that every identified health professional group would like to achieve. Licensure is a very political process at the state level. I have a sense that there is probably uniform sense from the committee, but you could get clarification on the issue, that genetic counselors are clearly a defined health profession, a new health profession, a health profession that has come about because of the growth and expansion of genetic services, and as advisors on that I think you could send very strong signals. I don't quite know how you'd have to do it, but if you recognize that genetic counselors are a new profession, they're not recognized with licensure, but that would strengthen the genetics workforce.

How you do that in your very tight constraint about what you can recommend to the Secretary or not, I think there's a way to do that. Licensure is political. It's somewhat costly to states. You've heard the reasons. A profession wanting to get licensure does not have to show to anybody generally that they're cost effective or anything. It's contained in general within the profession to define who is eligible to be named as a licensed genetic counselor and whatever.

I would strongly say that it would be against conventional certification or whatever to try to establish a superstructure. Certifying boards tend to be very profession specific, and you have a well established certifying board with the American Board of Genetic Counselors, and well defined credentials, training programs and whatever. That's not broken in any way. So they would easily, when they have political support or whatever within the state, become licensed. They're tiny. That's part of the problem right now, and they're a new profession that people don't very well understand, and it has to be done carefully so that, as was mentioned, you don't exclude others from the legislation.

But I think the genetic counselors can deal with that. I think what they're asking from this group is recognition. It's different than reimbursement. Reimbursement is a whole different set of rules.

DR. TUCKSON: The GNCC and so forth are not in the American Board of Genetic Counselors, are they?

DR. COOKSEY: I'm not in the American Board.

DR. TUCKSON: Does the American Board solve the problem of letting the GNCC in, as an example?

DR. COOKSEY: No, but that's a different issue that the nursing profession has to work on. But the profession of genetic counseling, getting licensure, is ready to go if this group feels that licensure is appropriate from all the evidence that you've heard and years of presentations by genetic counselors and years of cumulative experience of working with genetic counselors. I have a feeling that there's consensus that the time has come to recognize them as a profession. How you do that can be worked out, but getting a sense of the board would be useful. That's very different than reimbursing issues and proving you're cost effective to payers and whatever. Very, very different issues, but related. But you can take a step at a time.

MS. BERRY: What about this last iteration here? We wouldn't be recommending licensure. It's not really within our purview, but recognizing that there may be states that do not have licensure, that public programs and private health plans should recognize certification by someone, and I don't know if these two are the ones we want to name or do we name anyone as equivalent to licensure.

DR. COOKSEY: You're trying to merge reimbursement issues with licensure issues. I think what we were asked to sort of present evidence -- genetic counselors are a relatively new profession. They're very small, they're growing, they're extremely important to the delivery of genetic services in the country for the current and near term, and I think a statement that would be fashioned in such a way that would say the committee recommends recognition of the profession of genetic counselors, one of the few highly trained professionals that is not licensed --

MS. BERRY: The reason we're linking it is because it's a coverage and reimbursement report, and the lack of licensure or some refusal by some plans or programs to recognize certification has been identified as a barrier to coverage and reimbursement.

DR. COOKSEY: Yes, that is correct.

MS. BERRY: So that's why it's in here. If we need to delete it entirely, we could do that too.

DR. COOKSEY: It could be a two-step thing. But I guess what I haven't heard you say, and it was brought up by Debra a little bit, is what is the sense of the group around licensure for this highly trained, highly professional, needed new profession?

DR. TUCKSON: As the moderator, or whatever I am, let me stop for a minute and do a process check here. We have a challenge.

First of all, thank you. Appreciate that. Cindy's got to go. We're past the 5:30 mark. People are tired as well. You guys have worked really hard today.

Now, our challenge is that we've got a heck of a schedule tomorrow, and we've got to bring some recommendations to closure. What's the snow look like out there?

PARTICIPANT: It's snowing and it's going to freeze soon.

DR. TUCKSON: I was more worried about tomorrow morning. First of all, do we think we'll be here tomorrow?

PARTICIPANT: It's supposed to stop snowing around 1:00 a.m. or something.

DR. McCABE: We'll be here. The question is whether we leave.

(Laughter.)

DR. TUCKSON: Well, I think what I'd like to do is this. I think we'd like to start at 8 o'clock tomorrow. The question is can Cindy Berry be here tomorrow?

Are you going to be around tomorrow?

MS. BERRY: Yes.

DR. TUCKSON: Good.

The second thing is I think what we need is to have a few people try to sit today with Cindy and with Suzanne -- the Federal Register says that we can't start until 8:30 because we did it at 8:30. So let me ask this of the rules. Can we have a work group meeting to work on things, and then at 8:30 talk about what we've created? Can we meet as a committee of the whole, as a work group, and then rehearse everything we did at 8:30? We can't do that either.

MS. GOODWIN: As long as there's no decisions made during the work group discussions. If there are any recommendations, that they're discussed in public.

MS. CARR: But I don't think you can start at 8:30. I think we'll have to do it later in the day because we really have to get going on the -- don't we? Or do we have time for this in the morning? No. We have to start with large pops.

DR. TUCKSON: All right. So we have to re-look at the schedule, and we'll do that then. We're allowed to continue tonight?

MS. CARR: Yes, you can have it tonight if you want.

MS. GOODWIN: Continue the discussion right now?

MS. CARR: Oh, yes. You can continue.

MS. GOODWIN: You're just not allowed to start earlier, but you can continue later.

DR. TUCKSON: I don't think that this committee should be subjected to the tyranny of having to keep working on this right now. I think people are tired and their nerves are frayed. I think what I'd like to do is to have a small group of people try to frame the issues very carefully for tomorrow. Hunt, if you won't kill me on this, I'd like you to sit with Cindy and with Suzanne, and I would like Ed to sit for a few minutes and try to lay out the issues in terms of what are the debate points here, and at least lay out in stark contrast what we see as being the sequence, starting with the way we want the world to be and whether or not you actually have certification criteria for independent billing, what would it take to be able to make that happen.

I can't do this twice. You've got to write this down. This is it, man. The assignment is to just lay out in clear terms what the debates are, starting with if you could create certification, what would it take, what are the critical questions that have to be answered to satisfy people. Secondly is what can the Secretary recommend about that that's relevant. Third is what do you do about the folks who are not independent but incident to, and then finally what do you do in the interim. Try to lay it out in terms of what are the debate points and clarify them as precisely as possible, give us the language to choose from, and let's try to get something.

Cindy's got to go. That's what the whole problem was.

So can you all do that at 8 o'clock, from 8:00 to 8:30? You won't be here. Okay. So, Amanda, you'll be here tonight? So let's try to get that done this evening, sometime either before dinner or right after dinner. So we'll do that. Thank you.

Do you want to do it tonight or at 8 o'clock? Ed McCabe, Hunt, and Cindy. Well, Cindy won't be here. She will be. Cindy will be here in the morning. Okay, and Cindy. Who else wants to volunteer? Barbara. Can we do it at 7:30?

DR. WILLARD: In the morning?

DR. TUCKSON: In the morning. Is that okay? They keep telling me who is going to be here and who is not, so I'm getting crazy. 7:30 in the morning we'll meet right here and we'll just have it laid out. Joe wants to join that. We've got the whole committee coming. That's good.

No, I'm just kidding. So Joe is going to do it. 7:30 they'll do that. Now, then we will find some time in the day, some kind of way to work on this. We'll figure that out. What time is dinner?

MS. CARR: Six.

DR. TUCKSON: Six. Where? In the room.

You all have worked very hard.

DR. McCABE: Can I just ask, because there was another subcommittee put together that I was going to have meet briefly tomorrow morning, but you've just coopted half of us.

Debra, Hunt, Kevin and me, could we meet for 10 minutes right now, please, to talk about definitions?

DR. TUCKSON: Definitions, okay.

Dinner is right where we had lunch.

Thank you all very much. Good day's work.

(Whereupon, at 5:40 p.m., the meeting was recessed, to reconvene at 8:30 a.m. on Tuesday, March 1, 2005.)