DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Third Meeting

Tuesday,
March 2, 2004

Congressional Ballroom I-III
Bethesda Marriott
5151 Pooks Hill Road
Bethesda, Maryland

IN ATTENDANCE:

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C O N T E N T S

P R O C E E D I N G S (8:05 a.m.)

DR. McCABE: Good morning, everyone. You'll notice a book at your places this morning, courtesy of Drs. Collins and Guttmacher and the New England Journal of Medicine. Alan, do you want to make a comment about this?

DR. GUTTMACHER: Well, it's also courtesy of Dr. McCabe, since he wrote one of the chapters. This is the compendium. Some of you will have seen the New England Journal ran a series over about a year of articles about genomic medicine, basically aimed at the academically-oriented clinician, trying not to talk about what will this do for us in 30 years, but what do you actually need to know when you walk in your office tomorrow kind of thing, and was put together into a book which I think was published last month, and Francis, in an attempt maybe to win your favor for what we were voting for the priorities -- I'm not quite sure whether this is a bribe or not.

(Laughter.)

DR. GUTTMACHER: Thought it would be nice for everyone to have copies of it. So there you are.

DR. McCABE: Well, thank you very much.

I'd also like to take a moment to welcome Dr. Reed Tuckson. I mentioned yesterday that Reed was tapped to serve on the NIH Blue-Ribbon Panel on Conflict of Interest Policies, and they've been meeting simultaneously with our meeting here in Bethesda.

Reed, I know you're only going to be able to stay a couple of hours, but we're really glad to see you and appreciate that you were able to break away from you very busy schedule there protecting all of the federal civil servants, including ourselves, from conflicts of interest.

DR. TUCKSON: Well, I apologize to the committee, but I was given special dispensation from Sarah. So before this was allowed, we had to go through Sarah and she said it was all right.

DR. McCABE: In addition, Reed has been appointed to serve as the Secretary's Advisory Committee on Genetics, Health, and Society liaison to the HHS Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children, which has one heck of an acronym.

(Laughter.)

DR. McCABE: This advises the Secretary about the application of universal newborn screening tests and other technologies, policies and programs aimed at reducing morbidity and mortality in children with or at risk for heritable disorders. This is really an important committee that will be doing work quite relevant to ours and I think it's important that liaison has been appointed and we appreciated you taking that work on, Reed.

The HRSA ex officio will also help in this regard as will staff-to-staff contacts, which are already strong. Reed, we congratulate you on both of these appointments and pleased that you will be our representative.

DR. TUCKSON: Thank you.

DR. McCABE: We'll begin this morning with public comments. We have two individuals who have registered to provide public comments. Information has been passed out to you at your places this morning.

Our first public commentator is Dawn Allain, who is President of the National Society of Genetic Counselors.

MS. ALLAIN: Good morning. I am Dawn Allain, President of the National Society of Genetic Counselors. NSGC represents approximately 2,000 master-level genetic counselors who practice in a variety of medical specialties, research centers, and biotechnology companies.

NSGC recognizes that in order to realize the full benefit of genetic technologies, clinical genetic services must be integrated into current health care delivery models. This morning, I will present two issues that must be addressed to achieve this goal as well as to facilitate improved access to genetic services for American citizens.

First, NSGC feels that inadequate coverage and reimbursement for genetic services is a significant economic barrier to providing adequate genetic health care. This is a direct result of four factors. First is the failure of third party payers to recognize clinical genetics as a subspecialty in routine health care services.

Although the American Board of Medical Subspecialties formally acknowledged medical genetics as a subspecialty, many health plans and payers do not provide a listing of genetic practitioners within their plans. This suggests that genetic services are not yet appreciated as standard or routine medical care. Additionally, some third party payers continue to deny coverage for genetic services by claiming that they are experimental or because counseling services are deemed non-essential.

Third, CMS does not currently recognize genetic counselors as allied health care providers. This prevents facilities from billing for genetic services that are rendered by a board-certified genetic counselor. The combination of these problems frequently means greater out-of-pocket costs for consumers or consumers forgoing services entirely.

Finally, while progress has been made in developing current procedural terminology or CPT billing codes for genetic diagnostic tests, as pointed out yesterday, CPT codes are still lacking for the genetic counseling and evaluation services that precede and follow most genetic tests.

This system shortfall continues to make it extraordinarily difficult for genetic clinics to bill for services. As a result, genetic counseling services are frequently considered to be non-reimbursable and there is growing concern among genetic professionals that genetic services will be reduced unless the financial impact of providing services can be mitigated. If genetic service providers positions are eliminated due to inadequate or non-existent reimbursement, this will only serve to worsen access to genetic services, particularly for clients in underserved populations.

NSGC is currently funding a research study to analyze the cost-benefit ratio of prenatal counseling services. We encourage SACGHS to identify and promote additional companion research that will add to the evidence-based outcome data necessary to tackle billing and reimbursement issues.

In addition, we encourage SACGHS and CMS to work with genetic professional organizations and the AMA to establish CPT codes for clinical genetic services and to recommend to administration and Congress that genetic counselors be incorporated into federal statute and recognized as allied health care providers.

Second, NSGC recognizes that additional genetic testing for non-genetic health care professionals and specialty training of genetic specialists is critical. AS NSGC has testified previously, there are only about a 150 genetic counselors graduating from master-level programs annually. There are even fewer medical geneticists whose training numbers have

dropped in recent years and even fewer advanced nurses in genetics. With the demands for genetic services on the rise, this training pipeline is inadequate.

In addition, the lack of basic competencies in genetics of health care professionals is a barrier. Numerous peer reviewed studies indicate that many non-genetic service providers lack genetic knowledge, expertise, and confidence in their abilities to provide these specialized services.

An inadequate genetic workforce poses several hazards, including the potential to miss critical opportunities for preventive medical strategies. Furthermore, inaccurate genetic information given to consumers may raise undue alarm and/or prompt ill-advised and costly medical decisions, testing, or interventions.

If consumers are to benefit from the many advances in medical genetics, steps must be taken to ensure access to a well-trained health provider workforce that is large enough to handle the public demand.

We encourage SACGHS to identify novel methods to increase the number of qualified providers through genetic counseling training programs, medical genetics residency programs, and genetic nursing programs, as well as continuing to support the educational efforts targeting primary care providers and allied health professionals.

As an organization that is currently developing a strategic plan, the NSGC understands the challenges that face this committee as well as the difficulty of maintaining focus on the bigger picture. The scope of this committee's charge includes assessing how genetic technologies are being integrated into health care and public health. The top priorities you have raised both begin and end with access.

Therefore, NSGC strongly encourages this committee to evaluate achievable goals in a manner which will consistently move forward the ultimate objective of improved access to genetics as part of a global health care program. NSGC is available to support SACGHS in this endeavor.

Thank you.

DR. McCABE: Thank you very much.

Any questions? Reed, then Hunt.

DR. TUCKSON: First, thank you very much. Can you just focus on the one critical part of your comments and that was the availability now of certification of who is a genetic counselor and who ought to be allowed or is competent to be reimbursed within all the people that are going to be doing this stuff?

MS. ALLAIN: I'm not sure I completely understand. You're asking me which genetic counselors are certified and therefore available to get reimbursed for services?

DR. TUCKSON: How do you know? Thank you. Is there a clearcut certification for who it is that ought to be allowed to bill as a certified genetic counselor?

MS. ALLAIN: Well, at the national level, all genetic counselors are certified by the American Board of Genetic Counseling, but there are currently only two states that are actually licensing genetic counselors as billable health care providers and no CPT codes that are actually available for us to even bill, if we were recognized as billable entities.

DR. TUCKSON: So if someone has a certification through the American Board of Genetic Counselors, would that include then the nurses who have been trained to do that? Is that across disciplines?

MS. ALLAIN: No, that's not across disciplines. The American Board of

Genetic Counselors specifically certifies master-level genetic counselors and individuals who have gone through accredited genetic counseling training programs. There are some advanced nurse practitioners who are board certified prior to the ABGC revising its requirements for accreditation.

DR. McCABE: Hunt?

DR. WILLARD: Dawn, you raised two issues on education, one providing additional training for the non-specialists which I think, as we had discussed yesterday, we would all heartily endorse. The second one was to try to increase the pipeline, in your case, for genetic counselors but also for medical geneticist specialists.

But if you sit back and say, well, these have been on the menu now for 10 years and the consumers, meaning all those who are either in or coming into the health care scene, have already voted and they're not interested in these menu items. So in that the numbers are either dwindling or staying constant as opposed to increasing drastically.

So can you give us concrete steps that you would want us to take to increase that pipeline or, alternatively, are there other strategies to say okay, we're not going to increase that pipeline, it's static? Is there an alternative strategy we might take?

MS. ALLAIN: Well, first of all, I would disagree with you, that the amount of genetic counselors has actually maintained static. I mean, if you remember Robin Bennett's presentation at the last SACGHS meeting, we've actually grown significantly with limitations of the clinical workforce in sites for training for these students.

I think that the bottom line is that although there is funding out there available to help expand some of the already existing programs, it's extremely limited, and so what we would like to see is other avenues that the federal government can help identify areas where genetic training programs and genetic specialty clinics can apply for funds in order to enhance our services as well as enhance the training of the genetic counseling workforce.

DR. McCABE: Any other questions or comments?

(No response.)

DR. McCABE: If not, thank you very much.

MS. ALLAIN: Thank you.

DR. McCABE: And our next presenter is Dr. Joann Boughman, Executive Vice President, American Society of Human Genetics, and Joann was also a member of the Secretary's Advisory Committee on Genetic Testing, and you have a handout here, the Genetic Information Non-Discrimination Act, which the American Society of Human Genetics has been following with interest and will keep us updated on progress.

DR. BOUGHMAN: Thank you very much, Chairman McCabe.

I would like to update the committee to let you know that there has been a great deal of activity with minimal and sometimes discouraging results, but in fact, we are trying hard and with this update, hopefully we will give you the opportunity to see some actions that you might take. So I'm pleased to have this opportunity to give you the update.

As you know, the Senate passed the Genetic Information Non-Discrimination Act of 2003 95 to nothing. The 95 to nothing is significant in that this was not a Floor vote where hands were raised or voices merely said aye. The Senators asked for a roll call vote because Senators from both sides of the aisle wanted to be on record as having supported the Genetic Information Non-Discrimination Act, and inside the Beltway here in Washington that's a significant process.

On the House side, which is where our challenge is now, Representative Louise Slaughter's bill, H.R. 1910, has been introduced. H.R. 3636, a bill by Representative Stearns of Florida, has been introduced. However, unfortunately, Senate 1053 is currently still being held at the desk.

When I say that 1910 has been introduced, it has also been sent to the two committees of jurisdiction, Energy and Commerce and Education and Workforce. H.R. 3636 is a much slimmer bill. It is a shell bill, if you will, and relates only to issues in Energy and Commerce.

It's all well and good that these bills have been sent to these committees, but there have been no hearings scheduled on either one of them, and after all of the work and negotiations done in Senate 1053, our preference anyway would be that 1053 would actually be taken from the desk and formally introduced into the House and assigned to committee so it could come back to the Floor for a vote.

We have been working with a very large coalition. It is referred to as the Coalition for Genetic Fairness, and the two-sided sheet that I gave you this morning is actually an attachment to an email I received just yesterday. No, it's got text on both sides, looks like this. This is actually chaired by the National Partnership for Women and Families. This is a coalition of about 30 to 40 different organizations, including the AMA, the ANA, American Society of Human Genetics, and Genetic Alliance, and many other organizations.

To this point, we have been working, all of us together, in order to develop these strategies, and here publicly, I would like to thank the National Partnership for in fact chairing these meetings.

We've had a meeting with the Chamber of Commerce which is the one group who has suggested, with written testimony anyway, to members of the House that Genetic Information Non-Discrimination Act is not necessary. However, in our meetings with the Chamber of Commerce, this is not one of their strongest priorities. They have other issues with regard to the economy and are really remaining relatively silent on this issue.

Up through last Friday, we'd had 14 meetings in offices of representatives. There are 7 more scheduled for this week and meeting with various representatives in the House. We also had a meeting with Alan Gilbert at the White House, the domestic health affairs advisor to the president. Mr. Gilbert certainly understands the issues. He had worked on the Senate side previously with Senator Dodd, and in fact, the White House has made a Statement of Administrative Procedure, an SAP, that they are in support of 1053.

That leaves us seemingly pretty much where we were before because the logjam is literally at the desk on the House of Representatives side. We will continue our meetings, but we have developed the following more specific strategies. We have a letter from distinguished scientists that is going to be sent within the next two or three days. We will be doing a blast of emails to all ASHG members so that they could write to their members and I'll go through that in just a moment.

We also are doing with the Coalition a two-pronged approach and this is where the handout that you have. One is a release of statement and stories of cases, specific cases of discrimination. This is what we call the Faces of Genetic Discrimination Project. The Genetic Alliance and others have been very helpful in this.

Right now, our uphill battle is the statement you have a solution in search of a problem, and no longer will the statement that there is a concern out there about genetic

discrimination. That's not going to carry us where we need to go. We need to be able to present facts. We need to be able to present data, and we need to be able to show people who have actually been discriminated against who have had these challenges and are dealing with it.

So in fact, we are trying to find people who are willing to step forward, and then each member of the Coalition, each organization, in addition to trying to find individuals who are willing to step forward, we also are gathering information, harder data. Now, these are not specific data by individual centers, but if we can demonstrate to the members of the House of Representatives that there have been hundreds or even thousands of individuals out there who have declined genetic testing for fear of concern, other specific data that might be helpful, and we are gathering these.

As you can see, we need all of this information compiled and ready to go by March 10th. Then, later in March, not only are we presenting these to members of the House of Representatives, we are in the process and will be in and out of the meeting today and so on to try and garner more support because probably the week of March 20th, we're going to do a more aggressive storming of the Hill, if you will, with consumers and others and really try and bring this forward. So keep your eyes and ears open for the day that we do that.

The one other and most important issue is the follow-up by constituents to their representatives in the House and that's what the second side of this page would do. The National Partnership has graciously included their CAPWIZ email site. Now, if you've never used CAPWIZ, it really is a two-click process. You go to the website that is indicated here. There is already written a letter that you can edit at will. You put in your zipcode, your name, and then click send and that will go to your representative. It really is less than two or three minutes.

The National Partnership is doing this. ASHG will be doing this with all of their members. The National Society of Genetic Counselors, the Genetic Alliance, and other organizations will be doing a specific blast email, so in fact our members will click from inside the email, click on CAPWIZ, decide if they want to change their letter and click.

The last time around, we got about a 1,000 letters that went to the Senate. They took note. The people on the Hill, when they get a few thousand letters within a few days, they do take note. So I would encourage all of you to get involved in these issues by your concern as an independent citizen in contacting your own representative.

So at this point, that's where we are in fact from the last meeting of the SACGHS. There's been a tremendous amount of activity and not yet the results that we would like. I'd be happy to answer questions.

DR. McCABE: Thank you very much, Dr. Boughman.

Let me just remind the members of the committee, no matter how you feel on this issue, you should not send the emails while you're functioning as a special federal employee nor is it appropriate to use your title on this committee when sending those emails.

Having said that, is there anything, Dr. Boughman, that you can see that this committee could do to facilitate these efforts, given that we are on the record very strongly in support of genetic non-discrimination legislation?

DR. BOUGHMAN: Yes. I would say that in fact another letter to the Secretary to remind him that his position in the administration would go. It's very important for the Secretary to say the words to remind the president, to remind the other members in the West Wing and the other members of the Executive Branch that this is an issue out there that is of

importance because we have a very short legislative session in this election year, and we're only going to have a couple of very brief windows to get this bill on the Floor and get it passed.

The good news and the bad news is that it's an election year. The bad news is that the session is shorter. The good news is that every representative, no matter what party, can in fact make a vote in concert with the way the Senate voted, claim victory and move on. This is something that the representatives can actually bring to fruition and only the House of Representatives and every representative's vote counts.

DR. McCABE: And what's the leverage for getting it moved, released from the desk?

DR. BOUGHMAN: That is Speaker Hastert and the leadership of the House. We've been working very hard with Representative Hastert and it simply has not been raised to the level of concern at this point. So we in fact are trying to contact numerous people in his district, making comments and putting pieces into the newspapers in the Illinois area, trying everything we can to remind them on a daily basis, if at all possible, that this is an issue of import.

DR. McCABE: Other questions? Yes, Debra, then Hunt.

DR. LEONARD: It's my understanding that this bill doesn't have to go to committee, that it could go right to vote. Is that true? 1053?

DR. BOUGHMAN: It could be brought directly to the Floor. The realistic aspect, I believe. Right now, our challenge, even in our meeting at the White House, with absolute serious face, Mr. Gilbert reiterated more than once the House has a process. The legislative process must work.

Even with the encouragement that part of the legislative process would be for the administration to encourage the leadership of the House to in fact move this quickly, it could go straight to the Floor. We have seen that as a barrier that is extremely high, but it has to get released from the desk some way or another.

DR. McCABE: Hunt?

DR. BOUGHMAN: Speaker Hastert has to put it on the agenda. He either assigns it to committee or takes it directly to the Floor.

DR. McCABE: Hunt?

DR. WILLARD: Is there any value in using the visibility of this committee to ask individuals who have been discriminated against because of their genome to either provide testimony to this committee, at least in written form, in order to get it on the record as something this committee could then work with?

DR. BOUGHMAN: The timing is going to be extremely difficult and whether they would provide public testimony to this committee or in fact to members of this committee and allow others to share this. I in fact was in contact with Sarah, what was it, 3 years ago in Baltimore, a meeting in Baltimore. We did have a very impressive young woman who clearly was discriminated against. That case itself had not been brought forward and it was in part because we were able to go back and recapture that public statement that she made to the SACGT and brought it forward that we developed this Faces of Genetic Discrimination Project, so in fact every case would clearly be important and that process would be helpful. The time frame is the difficult aspect.

DR. McCABE: Certainly, Paul Miller would be aware of some of these cases because he has been the one who brought the suits before the EEOC. Many of us are

aware of individuals who have been discriminated against, some of whom have gone public already.

I think the issue is our next meeting is in June. That's really too late to have any impact on this session. That would certainly be something to think about in the future, if the committee wanted to move that way. We need to remember that our reporting structure is through the administration, but we, speaking really the SACGT, had impact before because one of the letters that I had signed that went to the Secretary had actually been used as a poster on the steps of the Hill. So I know that there's quite a bit of activity. So we can have an influence, but it's an influence somewhat indirectly through the administration.

Brad, did you want to make a comment?

MR. MARGUS: I just wanted to ask, other than the opposition to this bill and people resisting it, insisting that it may not be necessary, is there any other point they make that makes them not like this bill?

In other words, regardless of how many cases you can bring before them, why would someone be opposed to just giving people protection, and what is the other thing? I mean, is it insurance companies lobbying or what? I just don't have a good feel. I always hear the one side of it. What's their main point from the opposition? Just that it's not necessary?

DR. BOUGHMAN: The comments from the Chamber of Commerce really are fairly generic comments, that this would potentially add another layer of challenges and problems on employers with regard to insurance. There have been some discussions about concerns of one of the definitions in the bill.

Now, 1910 and 3636, the two other bills in the House, several people have problems with those two bills, but in fact, Representative Slaughter's bill, 1910, was really where Senate 1053 started before all of the negotiations process, and while it might not be as strong as some of us would like, in fact, we would be very pleased to see that version and it really is a generic no more regulation. We don't need it. We aren't discriminating. We don't need to do this. This is just more bureaucracy that we don't need to deal with.

DR. McCABE: Reed?

DR. TUCKSON: Yes, I just want to extend on where Brad was headed here. I think that one of the things that we have to, I think, be very disciplined about is being very specific about what the challenges are to getting these things done and then being able to put ourselves in a position to add the necessary information science data background that allows a persuasive argument to be made.

So I think it is important that we understand exactly who the opposition is and what their criteria are for concern, and in this case, Brad, I'm not sure, I don't think it is the insurance industry at all. I don't know that anybody in health insurance at least is against the bill. In fact, the health insurance industry signed, I think, support for the concept.

So I think it's being clear where is the problem and then what is the database that is necessary to counter the concern, and if it is, it sounds like, Joann, what you're saying is that the problem is that it is in fact the people who are purchasing health care who have their concerns.

I think if we could get from you, even though we know that you're trying to get this done between now and this term, but there's a strong chance, it looks like that it might not happen, while we're fighting this term, let's plan for the next term, and if we could get an analysis from you really with some specificity around what the argument is, then let's see

whether any of those arguments are within our domain to be able to capture credible information that would then help to debunk that and then put that forward through the Secretary.

I think those are the kind of things which we might start to narrow and focus our agenda.

DR. McCABE: Yes, the two arguments that I have heard over the last several years about this. One is a business argument, frequently a small business argument, about the cost of insurance, the cost of doing business, and the other is an argument that again if Paul was here he could address better than I could, and that is that it's all covered under the ADA. So that, we really don't need additional legislation because the legislation exists.

The problem with that is if you extend out to where people take that argument with the ADA, as we get into common complex disease and recognize that they are genetics, then we're all covered by the ADA, and in fact we have lost that safety net for the people for whom the ADA was intended.

So that, I think there are some serious concerns about pushing that, but would you be willing to consider if there is not success -- Sarah's just pointing that Matthew Bradley is here representing EEOC. I'm sorry, Matt, I didn't recognize that you were there.

MR. BRADLEY: No, that's fine. I'm not sure that there's anything I can add. The Commission doesn't take a position on legislation. We monitor what goes on. We have some awareness of cases and things like that, but if anybody wants to talk to me like during breaks or anything like that or ask any specific questions, I'd be happy to respond to the extent that I can.

DR. McCABE: But if this legislation is unsuccessful during this session and we decided to have another discussion of this and specific cases, given that some of those have been prosecuted within the EEOC, would you be allowed to tell us exactly what has already been accomplished?

MR. BRADLEY: Yes. Certainly, somebody at the Commission, if not in Commissioner Miller's office, in the EEOC's Office of Legal Counsel, there staff attorneys who monitor that. Peter Gray is in the audience and has done that in the past and probably will be doing more of it. I may be doing some of it. We'll be tracking it and are certainly at the committee's disposal.

DR. McCABE: Thank you very much for your willing to do that, and Dr. Boughman, again, we wish you success during this session, but in the absence of that success, would you be willing to update us in June, update us in June either way, and then also help us with strategies for moving forward?

DR. BOUGHMAN: Absolutely.

DR. McCABE: Reed?

DR. TUCKSON: That summary was important, and I think that what I'm also hoping and I don't want to write off -- we can talk later about things to do between now and then. I don't want us to look like we're giving up, but I think if you could before the next meeting really give us as much specificity around what were the determinant issues and then, secondly, Huntington's point which I thought was also key, which is perhaps we could then as a part of our fact-finding and greater level of detail and credibility of information gathering, perhaps convene some of the folks who are the faces, so that we could understand the issues better, but paradoxically also give some voice, some visibility to that effort going forward,

perhaps which then can be sent more directly from here to some of the key decisionmakers.

DR. BOUGHMAN: Well, one of the things that I might suggest, I will certainly keep Sarah and the staff in the loop with regard to all of the data and the examples that we are able to collect by March 10th, and then she might be able to distribute some of that information to the committee members even during this session as we gather some of the data from around the country and the stories that we have, so that should you as private citizens and/or in talking to others around you utilize any of that information in making your comments.

DR. McCABE: Debra, and then Alan.

DR. LEONARD: I do think that we should write another letter, and can it be done by March 10th?

DR. McCABE: Yes. I figured we would take that up when we got to the issue among the 12 issues, but I had heard yesterday some suggestion about doing that and certainly was hearing that this morning as well. So I thought we would discuss the specifics at that point.

Alan?

DR. GUTTMACHER: It's no longer necessary for me to say anything.

DR. McCABE: I would point out that there are a number of references to genetic discrimination in the book that was passed out to you today.

Yes, Hunt?

DR. WILLARD: Notwithstanding what might be in the book, for ASHG to actually put on its website anonymized case statements. I mean, we all go around and talk about this --

DR. BOUGHMAN: Yes.

DR. WILLARD: -- to either our colleagues or the public and to be armed with six really strong examples of genetic discrimination, anonymized obviously, and be able to quote them with chapter and verse would be very useful and that would be a very valuable thing for, I think, ASHG to do.

DR. McCABE: Some of them are matters of public record, so they don't need to be anonymized.

DR. WILLARD: There are two examples that at least I know of that are always trotted out, but everyone has memorized those. It's always nice to have another half dozen.

DR. McCABE: There are others, because there are cases that were heard within the U.S. Uniform Services. There are other cases as well as the two that went before the EEOC.

Yes, Cindy?

MS. BERRY: Joann, in the course of your meetings, have the Republicans surfaced somebody who really cares about this issue to an extent that they would be willing to introduce the Senate version of the bill as a House companion and aggressively push it with the leadership? Because absent that, I mean, we may all be frustrated by comments that the House has its process and all that, but the fact of the matter is something as important as this issue is, and we all think it's of critical importance, the House is not going to bypass their committee process. Their committees want to have an impact on an issue like this. They don't really want to dismiss it and say okay, we'll just accept whatever the Senate did.

So we're faced with that reality and the way around it is to have a

Republican member join with the Democrat. Bipartisan is always the best, but a real aggressive Republican member who's willing to champion this and work within the leadership to push some version of S. 1053 through their process because I don't see us bypassing the House process.

So there is an alternative way which is to kind of ram it through the process as quickly as possible and constantly badgering the leadership in the House to just allow it to happen, and I was wondering -- it's sort of a longwinded question -- has somebody like that surfaced?

DR. BOUGHMAN: There is nobody that has truly stepped forward that is in a position of strength in the House that we can count on, and we are challenged because the committee leadership has changed. Representative Tauzin has stepped down. Representative Barton is now the chair of that committee and this is a brand-new issue for Representative Barton, although we've had multiple meetings with his staff and with the representative.

We did get Representative Zach Wamp from Tennessee who wrote a commentary in the Washington Times which has been oft-quoted now on the Hill, but there have been 200 Republicans that have signed on to 1910 or 180 or something. Many Republicans have signed on. They just have not stepped forward to take a leadership role.

MS. BERRY: The problem is it's sponsored by a Democrat. So the leadership, despite the fact that there are lots of Republicans supporting it, it's not viewed as a Republican bill. So that's why I suggest flipping it, having it the other way around, having a lead Republican and then being joined by Democrats and have it be pushed through that way, but it's easier said than done.

DR. BOUGHMAN: That's the key and in fact we are clearly aware of that strategy. One of our hopes even with Representative Zach Wamp because Senator Frist has come out so strongly in favor of this and took a leadership role on the Senate side. Being from Tennessee, we had hoped that that might in fact be helpful. It has not gone as far as we had hoped.

DR. McCABE: Thank you very much. Clearly, this is a topic that will come up later in the morning as we go through the remaining issues. We appreciate your updating us today and look forward to another update at our June meeting. Thank you very much.

DR. BOUGHMAN: Thank you, Mr. Chairman. I wonder if, since I didn't know that I needed to put my name on the list twice, might I just say on behalf of the American Society of Human Genetics that we commend the work of the committee on these 12 priorities. As you know, we are working very hard on these, not only on the genetic discrimination issue, but as you heard from me last time, on the education and training issue.

We have been continuing our work and would hope that this committee could do what they could to in fact encourage the Secretary to be supportive of training, especially issues as was pointed out yesterday that go across agencies. This is part of the larger plan of HHS and this is one of the opportunities that the Administration has to in fact have success in that area.

We, too, although ASHG is the umbrella organization, many of our members are active clinically and obviously the umbrella of access with coverage and reimbursement issues are extremely important to us. Many of the other issues that you're talking about are issues of ongoing discussion for members of ASHG and the leadership.

I won't take time now, except to say that we appreciate your hard work and resolve to move some of these things forward and the leadership and membership of ASHG stands ready to help you in any way that we would be able to during your deliberations.

Thank you.

DR. McCABE: Thank you very much.

That ends the public comment. We're now going to go back to the process we had begun yesterday, which is to work through the 12 issues. Just to remind everyone, we had gotten through five of the issues so far using the categories, the hurricane classification, as someone noted. We have one in Category 2, education and training. Category 2 is high priority but can be dealt with, and there was some discussion about this last evening after the meeting, fairly quickly, probably better fairly readily because it may not be a number of them are in that category, that they will all be dealt with quickly. Staff has only so many hours in a day and/or monitor. So there's one which is education and training.

There are two that are in Category 3, transcends all issues. This is access and public awareness. There have been some discussions already that discrimination might fall into that field, into that category. There's also sentiment for Category 2. And then two for Category 4, coverage and reimbursement and large population studies are in Category 4.

We are not using Category 1 at this time because that will be a default category that those who do not make the top priority list will fall into. Being relegated to Category 1, I would point out, however, does not mean forever condemned to disinterest by the committee. It just means that it doesn't meet our top priorities. Once we deal with those issues at the top of our priority list, then we will look and see if something else has come along that we should consider and if not move on to Category 1.

So with that just summary of what we had done yesterday, our next is pharmacogenomics, and that is Emily.

DR. WINN-DEEN: Thanks, Ed.

DR. McCABE: And also, we have seven to get through, and we had relegated an hour to sort of wrap this up. We've already spent a good bit of time on genetic discrimination this morning, I think appropriately so, but we want to have a good hearing for all of these. If we could aim to try and do them in 10 or at the most 15 minutes, that would be very good.

DR. WINN-DEEN: Thanks. I just want to take two minutes, one minute maybe, to recap the issue and then we'll have some open discussion. So the issue with pharmacogenomics is how to deal with the fact that there's genetic variation among individuals that may influence their ability to respond to drugs and also how genomics is used to develop new drug targets.

So I think in terms of issues before us as a committee, the three key things that I'd like to focus on are what is already being done in this area to move things into the practice of medicine, what are the barriers that remain, and then sort of what can we do about it.

I'd say from the point of view of research, there's a lot being done. We've heard information about the Human Genome Project and the SNP Consortium and the HAPMAP Project and putting research tools in place to find associations. We heard testimony yesterday about large population studies and how they might be an integral part of moving the research level forward.

I'd like to actually hear from Steve Gutman, if he would comment on the federal regulations, both pharmacogenomic data as well as the companion diagnostic guidance that's under development, and then any other testimony about research that's in progress, so that we can get some handle on whether this is something the committee needs to do something about or if everything is fairly well in hand.

DR. McCABE: Steve?

DR. GUTMAN: Sure. There's actually a lot going on within our work group and Dr. Lesko's work group looking at pharmacogenomics and looking at what kind of guidance we can put into place and what kind of outreach we can put into place.

So far, there are two important guidance documents that have been issued. They're both on the webpage, one on the CDRH webpage and one of the Center for Drugs webpage. The first is a document that describes FDA's proposed approach towards multiplex testing. That's not specifically directed at pharmacogenomics, but it has many carryover applications and it discusses a couple of important things. The analytical issues. It talks about clinical issues, and it alludes to the ability for the agency to consider the use of literature and what is already known, so that wheels don't have to be reinvented.

The Center for Drugs had a workshop in November in conjunction with posting of a document on pharmacogenomics data. I think it is reasonably well known, but if it's not, I will reinforce the issue that in fact drug companies do not have the option when there is well-established pharmacogenomics data that has relevance to the safety and efficacy of drugs. They are by law and by regulation mandated to submit that information.

What is beguiling or bedeviling about this particular area, of course, is that there's lots of information that's incompletely pedigreed or established and drug companies probably are reasonably confused about how to process and handle the data and the drug guidance is specifically designed to try and provide some insight for when data is considered sort of preliminary and when it's more germane to a submission and introduces a very novel idea, that when there is information that is preliminary, a thing that the drug community could do to assist FDA would be to craft voluntary data submissions to be in a protected way, cordoned off and looked at by the agency so that we could get some familiarity with data issues and review issues.

At the end of the November workshop, Dr. Woodcock made the promise that the agency would put on a fast track and as a high priority some kind of general guidance that would help people who would be either visionary enough, bold enough, or daring enough to consider crafting a diagnostic in conjunction with the therapeutic, and in some cases that is a really wise thing to do because the diagnostic isn't being only used for drug discovery, it may be the heart and soul of the use of the therapeutic, and from our perspective, at the very least, when the drug is being developed, there's a unique opportunity to have conjoint or parallel or coordinated studies that, contrary to popular belief, devices and drugs can in fact work together. We can co-review, we can co-schedule panel meetings, and we can even cross-reference labeling.

So we do have the capacity in a timely manner to do that and we actually would like to do that. We'd like to raise the sensitivity of both drugs and diagnostic companies about the advantage to them, the economic advantage, the scientific advantage of killing two submissions with one stone, and in fact our experience is that in some cases, that may be a window of opportunity that's not replicated and that if you fail to study the diagnostic during

the critical or pivotal drug studies, you've suddenly got a drug that's on the market. It's all dressed up and it has no place to go in terms of the diagnostic and we're ending up trying to piece together a mess to try and support the drug.

So I hesitate to say things are on the fast track for FDA, but in fact this document is on the fast track for FDA. I'd be disappointed if it's not out within a couple of months.

DR. McCABE: So is there anything that we could do, Steve?

DR. GUTMAN: Well, you could keep your eyes open to that document and comment, and in fact, although the other documents are now probably at the end of their comment period, if you suddenly haven't read them and would like to read them and provide us with insight, it's probably not too late to integrate good ideas into either document.

DR. WINN-DEEN: Steve, can you give us -- I know the multiplex testing public comment closed, I think, in November and the pharmacogenomic one in February. Can you give us sort of an update on when you expect the revised with comments updated?

DR. GUTMAN: Again, I always hesitate to predict, but I think they're both very high-priority items. So I would be surprised if, within the next couple of months, both aren't reissued.

DR. WINN-DEEN: Other issues from anyone on the committee?

(No response.)

DR. WINN-DEEN: Ed, do you want to comment?

DR. McCABE: So to me, it sounds like this is either a 2 for monitoring or a 4 to evaluate the priority and to vote.

Debra, did you have something that you wanted to comment on?

DR. LEONARD: No, that's fine.

DR. WINN-DEEN: Can I ask one other question? I'm very interested in -- and I know you're not the right branch of FDA to answer this question, but I'm going to pose it anyway -- in what the FDA views as the transition force behind actually putting things in labeling for drugs that are on the market. How is the FDA going to handle pharmacogenomics and genetics and integration of that into marketed drugs?

DR. GUTMAN: Carefully. It is a real challenge. I mean, it is a real challenge. I think the agency, however, is very much interested in doing that in a measured and integrated way, that we do recognize, that Dr. Lesko and his group recognize that there's evolving information that really can make for better medicine certainly in the future, perhaps right now, and so they are actively looking at ways to go back and figure out how to make labeling.

The drug laws are a little bit more restrictive. They're actually tougher for their labeling and that's tougher for the companies but also tougher for the FDA, but there's great interest in that. I don't know exactly how they'll do that, but I know that there's active discussion about trying to make labeling more insightful as new diagnostics enter the market.

DR. WINN-DEEN: So is this something that you think we could ask Dr. Lesko to come and give us a follow-up on?

DR. GUTMAN: I do. I do, and he's exactly the right person.

DR. McCABE: Alan, and then Debra.

DR. GUTTMACHER: I agree, Mr. Chairman, with your assessment that this is either a Number 2 or a Number 4. I would think of it more as a Number 4 simply

because it seems to us that pharmacogenomics in some ways will be the leading edge of clinical uptake of genomic medicine and because of the impact it will have on providers or patients, et cetera, I think it probably is something that would behoove the committee to remain involved with at a fairly high level.

DR. McCABE: Yes, and I agree. As I said yesterday, I think it's changing how we practice medicine from the fear of suits. Certainly at our institution, that's the case.

Debra?

DR. LEONARD: Two comments. One, a question. Are there research funding gaps? Because I know that there are polymorphisms that affect specific drug metabolisms out there. The clinicians don't know what to do in response to them. If you would detect certain polymorphisms that do affect specific drugs, there aren't recommendations out there for dosing changes or modifications.

So are there research gaps between what we even currently know about polymorphisms that affect drug effects and metabolism and the practice of clinical medicine, and is that something that we need to address or could address in this committee?

The second one is --

DR. McCABE: Can I just take that one first, so I don't get lost in the series of questions?

DR. LEONARD: Sure.

DR. McCABE: But I teach this and so I can tell you the answer to that is yes, there are gaps, and I think that's a very important point because it's one of the ways we can advise the Secretary, where there are gaps in the funding. Even for the one I cited yesterday with the aminoglycoside-induced hearing loss, we don't know what the thresholds are for that. They appear quite low, but here we know that there's a pharmacogenomic problem and we still don't know how it should really influence, other than avoiding the drug completely. It looks like for that one, that may be the appropriate thing to do. But I don't know that anybody has tested that, quite honestly.

DR. LEONARD: But there are lots of examples like that.

DR. McCABE: Right.

DR. LEONARD: Could there be an RFA or something with specific funding targeting this kind of translational research?

DR. McCABE: Well, that would also push it to a 4 then because it's going beyond the oversight issue which is what we've heard from Steve which looks like it's moving along on a fast track, but once you have the oversight, you still need the evidence base to effect the practice of medicine.

You had another point. I interrupted you.

DR. LEONARD: No, that's fine. The other thing, in my reading of this, I was trying to determine -- I know pharmacogenomics is kind of overarching, but I don't see how it's distinguished from all the other genetic information that will come out of the Human Genome Project and why we focus on that as opposed to all the other different disease genomics that will come out of understanding the Human Genome Project.

DR. WINN-DEEN: I think one of the reasons is just as Alan said, this is where a lot of people in the field see sort of an immediate uptake and a very broad application. So preceding the introduction of genetics into common complex disease, this is probably the first time that we'll get out of the nice of monogenic disease and into a very broad across all

disciplines kind of implementation potentially of genetics in medicine.

DR. LEONARD: But basically, if you take the broad approach of pharmacogenomics which includes drugs targeted at specific mutations that cause disease, then you're talking about all of genomic medicine. You're just talking about the drug design part of it, but the first part that will come out is the diagnostics because then you will be able to diagnose the specific polymorphisms and reasons for. So the diagnostics will have to actually come first, and until you have those polymorphisms known, you won't have the pharmacogenomics this drug targeting a specific mutation aspect of pharmacogenomics.

DR. WINN-DEEN: No, I completely agree. The first implementation is drugs out there today and understanding the influence of genetics on response rate and dosing. The second wave is the new drugs that are being introduced that have been developed with the knowledge of genomics behind them.

DR. LEONARD: But there's also the concern that the pharmacogenomic analysis of existing drugs is not something that drug companies want to do because it decreases their market.

DR. WINN-DEEN: Oh, absolutely. Drug companies don't want to do it.

DR. LEONARD: But do physicians want to do it?

DR. WINN-DEEN: Yes. Should we do it for the practice of medicine?

DR. McCABE: Chris, and then I'm going to move us toward a vote.

DR. HOOK: I was just going to make a comment to support moving it up to 4, in that again beyond monitoring, speaking with Dr. Veenstra yesterday, he was thinking that at about six months, they would have the information on the cost-benefit analysis of the impact of preventing adverse reactions and so on. I think that's something we ought to keep before the committee and bring out to the public once that's available.

DR. McCABE: Good. Thank you. So I'll take that as a motion, to make it a 4. Do I hear a second to the motion?

DR. WINN-DEEN: Second.

DR. McCABE: So second from Emily. Any further discussion of this? Anyone who wishes to argue that it should move to a different category?

(No response.)

DR. McCABE: Okay. In the absence of further discussion, all in favor, say aye.

(Chorus of ayes.)

DR. McCABE: Any opposed?

(No response.)

MR. MARGUS: Just for the record, I want to abstain.

DR. McCABE: So Brad Margus is abstaining from this vote. So that is a Category 4.

Next, I think we can probably move through fairly quickly because we had pretty extensive discussion yesterday and this morning on genetic discrimination. Genetic discrimination and genetic exceptionalism are tied for 7 and 8 position. We'll just take them alphabetically.

So discrimination first. What I heard was some specific discussion about getting a letter, so moving it to a 2, and there was also some discussion which I think I led yesterday that it also may be somewhat pervasive. I wouldn't want that to detract from the

urgency of dealing with it now, however. So if we were to choose a category, I guess I would recommend Category 2, and we've been monitoring and continue to monitor. Hopefully, we won't have to monitor it too much longer, but in the absence of that, we can monitor it actively and not passively.

Do I hear any discussion? It seemed pretty clear from the discussion this morning and the body language that people wanted us to move forward with a letter on this, so it would be a 2 and a high priority on 2, but I'm happy to entertain further discussion.

(No response.)

DR. McCABE: Do I hear a motion then?

DR. WILLARD: So moved.

DR. McCABE: So Hunt, and a second, Chris seconding it to move it to a Category 2. All in favor, say aye.

(Chorus of ayes.)

DR. McCABE: Any opposed?

(No response.)

DR. McCABE: Abstain?

(No response.)

DR. McCABE: Okay.

DR. WINN-DEEN: So Ed, are we going to discuss the specifics of writing the letter now or are we going to save it for later?

DR. McCABE: Well, technically, we still need to vote on these, and Chris came up with a voting scheme. We had not been able to figure it out because I wasn't sure how we were going to keep the ones in the different categories and if somebody mixed it up, how we'd be sure they hadn't mixed it up, but we will rank Class 2 issues as A, B, C, D, et cetera, and then those will be converted to numbers. Staff can do that readily, but that way we'll be sure if somebody votes the wrong thing in the wrong category. So we can use the sheets that we had and then Category 4 will be by the numbers.

So we can do that later, and I think we should take that vote before we have the discussion, but then I would think we can discuss how we would deal with the top priority in both Category 2 and Category 4.

Next is genetic exceptionalism, and I lost my crib notes here. Hunt. I was going to say that ought to be Hunt's. If it's not his, but it is yours, Hunt.

DR. WILLARD: This is an issue which was moderately ranked by the members and ranked towards the bottom by the ex officios. The issue here, and we heard a little comment on it yesterday, is the extent to which genetic and genomic information is inherently unique and should receive special consideration. We actually heard a comment yesterday that whether or not it should receive special consideration, it is receiving special consideration.

I think it's useful to frame the issue into two separate categories. The issue brief alludes to this but doesn't actually explicitly separate them into two issues. The first is looking at the question of genetic exceptionalism for the information itself. So is genetic and genomic information inherently different? There are many who argue it is, a few who argue it isn't, but the argument in favor, of course, is that the information because it's a unique identifier, because it's present from the time of conception, is very different from virtually all, if not all, other types of information.

The second category is not to consider the information per se but the uses of the information, either as technology or as a knowledge base, and whether considerations of the uses of that information should be considered differently, and there, I think there's probably a larger number of parallels where other new technologies or other new types of information which of course have been dealt with for decades and decades in different contexts, whether this truly is different or whether it's just the newest form of new technology and new information, and in that sense, it does cut across a whole bunch of other issues that are on this list in terms of direct-to-consumer access, oversight, patents, public awareness, professional education.

We keep coming back to issues. We're now addressing all of those in the context of genetic information, but is it really the same story we might have applied to thinking about new ultrasound modalities or imaging modalities or different diagnostic tests, et cetera, et cetera? So I find it very useful to treat those very different and we might come up with a very different answer overall.

To phrase the question and then I'll open it up for comments. To me, the question is, is there value in this committee addressing this to the extent that one gets to a document, essentially a background document, that would lay out these issues and would that be of value, either to the Secretary or to some of the ex officio organizations who are wrestling with the issue of do we need to treat this separately, especially, or can we simply relax a little bit, take a deep breath and say, oh, this is just the same way we dealt with something else 3 years ago and let's not get all keyed up with it being "genetic information" or "genomic information."

So I would phrase the question as is it worth this committee's time in addressing it, simply to phrase the issues and to make recommendations on whether it should or shouldn't be or the extent to which it is or isn't very different from previous paths we might have been on?

So having phrased the question, framed the question, I'll open it up for comments. Yes?

DR. CAROME: Mike Carome from OHRP. It's our view in interacting with institutional review boards that review research, that they do view research involving genetic testing or banking samples for future unspecified genetic testing research to be unique, perhaps have risks that exceed minimal in relationship to other tests that only involve blood drawing or taking a swab of the mucosa, that therefore there may need to be additional protections for privacy and confidentiality than other similar type research, and so it's our view that there is exceptionalism at the level of the IRB in reviewing these activities and perhaps they might benefit from guidance on how to handle that, if that's true, what are the reasonable levels of protections that should be in place, and other similar issues.

DR. WILLARD: So your argument is it isn't well in hand and you could benefit from some comment from us?

DR. CAROME: Yes. We certainly get requests at least from IRBs, chairs, members, administrators. What are the appropriate protections? Does this type of research demand additional confidentiality protections and other types of research? Lots of questions about banking or establishing repositories and how should those be handled, how should the protections be put in place, how should control of those samples be maintained. So for us, it is an important issue.

DR. WILLARD: Thank you.
Other comments? Yes, Agnes?
MS. MASNY: I think it's an important issue that we address, especially after hearing Dr. Boughman's presentation, that because I think that it's not clear the definitions of both why genetics is exceptional and the potential uses, and as we heard that the members of the House think that the EEOC will cover some of the discrimination issues related to genetics, and I think that if we could spell this out a bit more, it may even be important in the document that we put together or a letter that we put together to the Secretary regarding why is this information so important. I see it as that genetic information is unique. It is special and that I think that we need to spell out why and that it may be able to be addressed, especially in the letter regarding discrimination.
DR. McCABE: Other comments?
MS. CARR: Can I ask, Mike, if the committee, the Advisory Committee to the Secretary on Human Research Protections would have any plans in the future, do you know, to address the research aspects of how IRBs are handling this and/or would you see this committee being a more appropriate venue for those kinds of discussions?
DR. CAROME: Right now, as far as I could tell, it's not on the radar or the priorities of the Advisory Committee on Human Research Protections, and my view would be that this committee has better expertise in that arena and might be a better source of advice to the Department on those topics.
DR. WILLARD: Maybe I can address the question to a few of the ex officios since at least the majority of you ranked it at the bottom of your list from which I take it that, for example, in the FDA or the FTC, that you feel one of two things, and I guess I'd like to figure out which it is.
Either it's totally in hand, you're very comfortable with believing that there is genetic exceptionalism and you're marching well down that path with that in mind, or you've decided that there isn't genetic exceptionalism and therefore you're dealing with this with genome information just the same way you did with other examples that have come across your desks.
So the low ranking to me means you're confident in one of the two of those answers.
DR. GUTMAN: Well, you have to realize there's been a change in ranker here. The agency probably in its regulatory approach and in its response to the recommendations of SACGT is casting a slightly broader net and actually is focusing on the issue of risk in a way that probably transcends genetic exceptionalism. That would not suggest that there aren't very unique things about genetics. It would be disingenuous to say that, but it would suggest that many of the unique things about genetics may be things that are outside of the focused scientific review that we bring to the table.
MR. DAYNARD: The FTC has one advertising standard that applies to all media, all marketers, any kind of claim across the board. It doesn't vary which therefore is very easy to defend when someone doesn't like what we do. So exceptionalism doesn't help or hurt in terms of the FTC when it reviews advertising.
On the other hand, I think I recognize that it's unique and for that reason, some of the arguments as to why we should at some point in the future take on a case could be very important for the FTC to do, but that's once we get past the threshold of does it violate the

FTC Act because it's deceptive.

DR. WILLARD: Thank you.

Debra?

DR. LEONARD: To me, this seems like a kind of philosophical question, and if SACGHS did come to some conclusion about whether genetic information is exceptional or not, and I think there are arguments on both sides, I don't see how that would be that useful because outside of this committee, people would still argue about whether it's exceptional or not and take their own viewpoints, and I don't think making a decision about whether genetic information is exceptional or not would inform the discussions of this committee because when it is exceptional, we'll treat it that way, and when we figure it's not, we won't.

So I'm not sure what the purpose of this discussion is, what having this discussion and reaching some conclusion would achieve.

DR. WILLARD: Brad?

MR. MARGUS: I agree with Debra. I kind of felt in a way it was Category 3 and that certainly any other subject we cover on the committee, we should question whether we're guilty of genetic exceptionalism and it isn't particularly relevant to just genetics.

But otherwise, if we want to make it a 2 or 4, Hunt, what would you envision that the product would be that we would add in our letter to the Secretary to have all his troops making sure they're watching out for that? Are we going to take some kind of action that increases awareness of this? I have the same little problem that I don't know how you end up with a concrete action plan.

DR. WILLARD: Cindy?

MS. BERRY: I actually would argue that it's one of those issues that transcends the other issues, and when we examine whether it's coverage and reimbursement or education and training or whatever, that we just have in mind to what extent are genetics unique and let's hone in on the things that are particular to the field when we are coming up with our proposed actions.

So don't reinvent the wheel and come up with a whole new form for something that we don't really need to do because it would be really the same thing we would do in other medical contexts, but focus in on the unique aspects. So I would sort of vote for putting it in that category where we should just consider it, not have the special separate action item or plan of attack for this category but simply consider it with each issue that we look at and to make sure that our actions are focused appropriately and targeted to the unique aspects of genetics.

DR. McCABE: I would just go back to OHRP who was looking for guidance. So if we did go with it as a Category 3, then we would also have to look at where there might be opportunities to assist the agencies and look to those opportunities perhaps outside this list of issues.

DR. WILLARD: Well, or within. I mean, if large population studies emerges as an issue that we want to tackle, then clearly advice to OHRP in that context would fit very well. I mean, I'm perfectly comfortable as to Number 3, just adding this to this sort of hall of mirrors that will reflect all of our deliberations in terms of are we appropriately considering it exceptional or not.

Reed?

DR. TUCKSON: I would just come down where you just ended, Hunt, on

that. I think that, as I've thought about it again, there are areas within this field, obviously otherwise we wouldn't have a committee, if there weren't some issues of particular and special importance, but if we could put it in the overall hall of mirrors and be able to at some point, though, have in our record that says let us understand that this field is moving to be integrated into the regular practice of medicine and where that is occurring, we should recognize that. We shouldn't add unnecessary burdens and obstacles and hurdles here that add administrative and other costs to health care.

I mean, it's part of a continuum, but where there are specific issues as we have described and identified, where there are specific issues that need to be dealt with, then we should deal with those, and I just think it's almost a statement of philosophy or background, a guiding principle.

DR. McCABE: And I think that kind of statement would help OHRP, too, would be my guess, at least as a guiding principle with then perhaps some more consultation.

DR. FELIX-AARON: In addition to having this statement that declares the guiding principle, would it be also helpful to the committee to have a discussion about what is unique, what aspects are unique because of the innovation, because of where the field is, and what is inherently unique?

Because as I listened to the discussion, it seems to me that part of the argument for exceptionalism is because of where the field is and how quickly it's moving and that as we learn more about the field, I mean, what is noted as exceptional 10 years from now would not be exceptional, and so some sort of informed discussion that sort of tries to delineate what we think. Then again, getting to the philosophical because again it is a philosophical stance, but some guidance as to what time will take care of and what issues time may not take care of.

DR. McCABE: And I would think that even if it should move to a Category 3, that doesn't preclude us from discussing it in the future. Certainly, we discuss genetic discrimination with some regularity.

I'm hearing consensus develop. So do I have a motion?

MR. MARGUS: Yes.

DR. McCABE: Okay. Brad, with a second by Debra that it go to a Category 3. Any further discussion of this?

(No response.)

DR. McCABE: All in favor of the motion, say aye.

(Chorus of ayes.)

DR. McCABE: Any opposed?

(No response.)

DR. McCABE: Abstain?

(No response.)

DR. McCABE: Now we have oversight and that is Debra.

DR. LEONARD: Just as background, oversight is talking about oversight of genetic tests, particularly of interest, SACGT work, the laboratory developed tests that did not necessarily go through the FDA review process and clearance, and this is something SACGT focused a lot of attention on, and I think it had an impact on things that were implemented to make changes to provide oversight to genetic tests.

So genetic tests are a part of the diagnostic tests in the broader sense and are

overseen by FDA in the premarket, the CLIA program for certification of laboratories to perform clinical tests, and there are a number of other agencies that are reviewed in the brief that you provided.

One of the things that a professional organization has done, the College of American Pathologists has added specific test validation questions to its checklist. This has now been implemented. They're part of the existing molecular pathology checklist which is where most molecular genetic testing laboratories would be reviewed, if they're reviewed by the College of American Pathologists.

So the question is, how does this committee view the status of the oversight of genetic testing and genetic testing laboratories, and is this something that you think needs more attention by the committee, by the current committee?

DR. McCABE: I'm just going to go on record as a member of the committee, that I think I said this before, the SACGT had a lot of activity on this area. I think a lot of what we had set in motion is moving forward, and we have been monitoring it at this time.

I would caution us. I think there are a lot of other things to do and to go back and reengage with this issue in a major way, I think, would distract us from some other very important topics.

DR. LEONARD: Emily?

DR. WINN-DEEN: Yes, I think I'd like to agree with Ed on that. I think the concerns that were raised, rightly or wrongly, provided a pretty good 3-year public discussion through SACGT and a lot of input and sort of coming to consensus on what is the right thing to do in the area of oversight and most of those programs are now moving along.

I personally would vote to put this as a Category 2 where we obviously want to make sure that things continue to move forward and are properly implemented, but not something that we need to put a lot more committee energy behind at this time.

DR. LEONARD: Joan?

DR. REEDE: I just would like to hear from the ex officios since this was ranked as Number 2 in terms of the particular issues that they think still need to be addressed.

DR. LEONARD: Steve, I think that's addressed to you probably.

DR. GUTMAN: Well, from our perspective, this is work in progress. So there is ongoing deliberations. Those ongoing deliberations are frankly quite focused on nuances of the ASR rule. They actually are quite interesting, perhaps quite profound, and they're unrealized. They're likely to continue, whatever the committee's recommendations are. We are interested in this area and they're likely to probably be a little bit slower than I would have predicted, in part just because the assessment takes time and in part because if there's anything that I think I might have overestimated and I should have just paid attention to how smart SACGT was, and the fact that SACGT had so much difficulty with the restratification wasn't an accident. It was because the restratification is so hard.

So for FDA and for professional groups, we've followed the notion that we should try and be informed and sort of interactive with people in the roundtable. The restratification is actually understanding what we can do in the existing regs and statute is challenging, but then trying to figure out how to mesh that with a risk profile that's reasonable and non-chilling is much harder than I would have thought.

DR. LEONARD: Hunt, and then Reed.

DR. WILLARD: I'm hearing rather than a Number 2, I'm viewing this as a Number 4 and let the chips fall where they may. It may not rank very high because we feel that it's perfectly under control and being dealt with, but I guess I don't see it as a Number 2 in the sense that there's something that we can do quickly or readily, but it's a Number 4 and if it ends up being a Number 1 at the end of the day, then so be it.

DR. LEONARD: But the 2 category also has a monitoring component. So it's not necessarily an action but monitoring as well. So maybe Sarah could put the categories up there.

DR. McCABE: And it was originally or monitoring and we made it and/or monitoring.

DR. LEONARD: Right. So there are now two options. One is to put it in Number 2 and one in 4.

DR. WILLARD: My fear is, is that, nothing is going to be in Number 1 at the end of the day here and you're going to be monitoring everything and in that sense, that's going to potentially cut into our ability to do anything effectively in the Number 4 category. That's one man's concern.

DR. LEONARD: Or you'll have -- well.

Reed?

DR. TUCKSON: Yes. I really do sort of feel strongly about this one. I appreciate Ed's experience which I lived through the last committee, but with great respect to all of the agency heads and representatives that we've had here, I have left each of our testimony sessions with the clear lack of appreciation for coordination across the government agencies.

I'm, quite frankly, not impressed that there is anybody in government in charge of this agenda and who looks at this every day coordinating. I think what you see is really talented people in each of the agencies who come here and are working their tails off, but you don't get a sense of a coordinated consistent plan anywhere above them. This is not an indictment of anybody, but it's an observation.

I am particularly concerned, given that the very excellent leadership that we have in Health and Human Services by Secretary Thompson, is about to go through a transition very shortly to somebody else, and there is an inevitable learning curve that takes time with a new group of people coming forward.

So I think what we have to experience and appreciate and prepare for is a continuing of the lack of coordination across the agency, and so I think that we have a responsibility to the Secretary's Office, both to this one and the one coming, to be attentive to this issue of oversight and, quite frankly, support for our colleagues around the table who can't always make their own case within the organization, given the kinds of structures and rules within a bureaucracy.

So I think that that's a unique opportunity that we have. Whether or not we make it Number 1, no, but I think as long as we're very clear on this and/or monitoring and Hunt's point about not letting this get lost in the shuffle, I'll be fine with it in Number 2, but if not us, who?

DR. LEONARD: Other comments?

(No response.)

DR. McCABE: So what I'm hearing from the last two speakers is that it

sounds more like a 4.

DR. LEONARD: Could I ask a question of Judith? What is happening with the CLIA program? I don't know who's the appropriate person to address the question, but of moving forward, adding genetic-specific components to the CLIA program?

MS. YOST: Currently, there is a draft proposed rule that has been done with CDC and CMS working together collaboratively, and we are negotiating the last pieces of areas that still need to be discussed. When that is complete, we still have impact statements and preambles to do, because you really can't write those until you know what the content of the regulation is going to be.

The basis of the proposed rule, of course, is the result of the Notice of Intent that was published by CDC several years ago and the comments that were received, and so we are following up on that. Once we have completed negotiation on the actual language in the regulation, we plan to proceed expeditiously with the remaining pieces, get it on the CMS regulatory schedule, and then, in areas where there still may be differences of views, to solicit specific comments in those areas for the proposed rule.

Just as a point of information, all CLIA regulations do need to be published through CMS. We are the regulatory agency. Once we get it on the schedule, then, of course, it's in the control of people beyond us, but it is our plan to have it there within the very near future.

DR. McCABE: And might CDC also comment on this, Linda?

DR. BRADLEY: Yes. This is kind of preliminary, but I did want to let you know that we are beginning to develop and fund a model approach with the goal of CDC providing coordination and support to develop a process for sustained evidence-based review of genetic tests.

Obviously, this is a big undertaking. We're hoping to engage stakeholders to find out what kinds of information people really want and what kinds of information will be useful to them, where those thresholds are for determining usefulness, to put into place some sort of a system for building on the ACE Project and other international experience with health technology assessment, doing a certain number of systematic reviews and maybe even looking at the need for a fast track mechanism to get a response out quickly once something new happens that might have an impact on practice.

Obviously, part of that is disseminating information in ways that are useful, and looking at some postmarket data collection projects to see if we can look at utilization and performance and practice. We're really just at the beginning of putting this together, so I'm sure we'll be talking to you about it more, but just to let you know that we are working on this.

DR. LEONARD: Judith?

MS. YOST: I just wanted to provide some follow-up to what I had said, in that one of the most difficult issues in this regulation is actually defining what is a genetic test. Do we start with glucose and work our way around or do we focus on something that assesses DNA or mutations? So we're working through that issue and that is one piece.

The other thing, I just want to reiterate what I have said in the past, is that CMS and CDC are very willing to work with private and professional organizations on how that oversight would take place for genetic testing to ensure that it's handled the most effective way possible.

Lastly, of course, there are a lot of behind the scenes that we would address,

too. Operational-logistical types of things that would need to occur in order for this to actually have a genetic testing specialty, everything from revising the way that Medicare identifies tests to the CLIA application and so forth down the line. Everything we do is based on the specialty in which the test is located. So we are working with that behind the scenes as well as the more visible aspect of the regulation.

DR. LEONARD: Thank you.

Linda?

DR. BRADLEY: One additional comment that I failed to mention is that one of the key goals in this project is to integrate with the systems that are already in place, primarily the U.S. Preventive Services Task Force, and other agencies that have projects in these areas, not to create new infrastructure necessarily, but to integrate this into what already exists.

DR. McCABE: So do I hear a motion for categorization of the oversight issue?

DR. LEONARD: We heard to put it in 2 or to put it in 4.

DR. McCABE: Yes. I heard the argument shifting toward 4, was what I had heard.

DR. LEONARD: Although I think 4 in my mind is those that require in-depth study by SACGHS. I think in-depth study has already been done by SACGT, and there are a lot of actions that are now trickling down since the government also does not move very quickly with all the processes that have to be gone through, and so I don't see this as something that warrants in-depth study by this committee but more a monitoring function. So I move to put it in Category 2.

DR. McCABE: Can I have a second to that motion? Second, Barbara. There were others who favored Category 4. Do we have some discussion?

DR. TUCKSON: I would just say that in all these things, the "legislative history" is important to capture, and I think that the wa that Debra has described this and given that the committee, I think, -- I've heard no one to say that the oversight coordination issues are not anything other than a high priority for us.

DR. LEONARD: And 2 is high priority.

DR. TUCKSON: I think I feel comfortable that there is a sense of the committee that we will be attentive to this and this will be reflected in how we do our agendas and in our behavior going forward, and with that, at least as one of the people that were on the make this important caucus, I would feel comfortable with this.

DR. LEONARD: Emily?

MR. DANNENFELSER: Further discussion?

DR. LEONARD: Emily, and then Hunt.

DR. WINN-DEEN: I guess I would rather see it as a Category 2 where it stays high priority with monitoring than a Category 4 where it ends being the lowest priority Category 4 and as such might get actually less attention than if we leave it as a Category 2.

DR. LEONARD: Hunt?

DR. WILLARD: I guess I'm comfortable with the rephrasing of it by Reed and Emily with my concern that we're not removing anything from the table and therefore effectively we're still going to wind up with 10 high-priority items which I don't think is workable, but that's my only concern.

DR. LEONARD: I think we have to see what happens after they're all categorized and we go through the vote.

DR. McCABE: So there's a motion on the floor to make oversight a Category 2. That motion has been seconded and discussed. Any further discussion of it?

(No response.)

DR. McCABE: If not, all in favor, say aye.

(Chorus of ayes.)

DR. McCABE: All opposed?

(No response.)

DR. McCABE: Abstain?

(No response.)

DR. McCABE: And just for the record, I was telling Sarah I'm not voting on these. I will vote in the event of a tie, just so that it's recorded that way, which we haven't gotten close to so far.

Next is DTC/DAT. Cindy? I apologize, Cindy, that I usurped her discussion for discrimination before.

MS. BERRY: I'll make up for it now.

(Laughter.)

MS. BERRY: No, I think this actually should be fairly straightforward in light of our discussion on exceptionalism. What I was hoping to do is to focus on the unique aspects of direct-to-consumer advertising as it pertains to genetic technologies because DTC obviously is out there in the drug arena. That horse is out of the barn and I don't think we're going to have any ability to stuff him back in there or even should try, but because there are instances where consumers have no gatekeeper, so to speak, no physician.

In the area of drugs, if I feel like I need the purple pill, whatever that is, I go to my doctor and I say I need the purple pill and then he'll say, well, no, you're not a candidate or yes, you are, and he'll determine that and write a prescription, but for certain genetic technologies, there is nobody like that. There's no genetics professional running interference. So I would say the direct access to genetic technologies is probably the unique area here that we might want to focus our attention on.

There obviously is a link to public awareness which we discussed earlier in looking at the entities that are already examining this issue and trying to take some action. It's clear that there are jurisdictional authorities with FDA, FTC, CLIAC. The National Human Genome Research Institute has got a meeting, I think, in our materials. NCHPEG is looking at this.

So the question I pose to the group is are there gaps in the activities that are being undertaken by federal agencies and private entities? Is this a need that needs to be directly addressed by this committee or do we think that the efforts are already sufficient and add to that the fact that the states do have a role as well.

So I want to hand it over to Chris.

DR. HOOK: This has been an issue that has concerned me after surfing the Internet and seeing the number of highly-concerning types of claims that are being offered to people in terms of the predictive value and also as a means of hawking herbs and other things through a genetic mechanism, and I was very disturbed after we discussed this at the last meeting that it really hadn't gotten on the radar screen of the agencies that are empowered to

intervene in these areas, and I don't know that we have to undertake a huge study of this, but I think it warrants a high priority at least with a quick action.

If it's necessary to make a formal statement, that this should be something high on the radar screen of the FTC and other agencies so that they can be encouraged to intervene in this area, then maybe that's something we could do as a 2 with a quick action, but it is a high priority in my mind.

MS. BERRY: Debra, and then Joan.

DR. LEONARD: I think, like the genetic discrimination, the DTC/DAT issue is who has been harmed. Has there been harm done? I don't know that there's documentation that anyone has been harmed. I think providing information, I fall more on the side of giving consumers the option and having them seek out their own information and that makes them question and ask for more information and go to medical professionals to get help or further information.

So I'm not sure that anyone is being harmed by the direct-to-consumer marketing of herbals and they do it for makeup. So where do we draw the line? Is it things that you put in your mouth or genetics is known now to be kind of the future of everything, and so there's a lot of genetic type of marketing or genetic tainted or directed marketing going on for a lot of things.

DR. HOOK: In that we already have a public which has not been well educated as we've already talked about and confused over these issues, the more that these sorts of issues enter in and add to the confusion and essentially denigrate the utility and the actual good uses of genetic information, I think it's going to end up being a roadblock to achieving some of the other priorities we've talked about or indicated are important in fulfilling or realizing the HGP dream for the appropriate utilization of this material.

So I see it as it may be difficult to hazard, but as we know how things and entrepreneurs can proliferate faster than regulation and other things may be able to counteract or appropriate educational systems can counteract, I do see it as harming our goals.

MS. BERRY: Joan, and then I have Reed, Martin, and then would love to hear from Matthew and Steven.

DR. REEDE: I think, like Hunt, my concern is that we're going to end up with nothing in Class 1, and in some ways, I think that's fine because I don't think the message that we should have is that there's nothing here, something here is not of a high enough priority. I'm not sure that that's the message we would want to send, and so I would put forward when we actually start to look at Category 2, part of that is quick action items that we're supposed to act on and the other part is monitoring. They're very different types of things and we've lumped them all together and what we may want to do at the end of this is separate them out into which ones are the quick action and which ones are the ones that are really just monitoring because it's difficult for me to have very different types of activities all lumped into one category.

But Number 1, I'm not sure the message we want to send to anyone is this is not a high enough priority for us to attend to.

MS. BERRY: Reed?

DR. TUCKSON: I think that I sort of see this as a Number 3. This is really so fundamental to so many of the issues that are before us. I've expressed this before. I'll keep it shorter. I am terribly worried on the access side for this new technology, to how the overarching context of the waste of health care assets in this country.

I don't care what we do. At the end of the day, nobody can afford all of the new things that are coming forward in today's health care system. Another 2.46 million uninsured last year versus this year. There are some fundamental incompatibilities, and so if we're going to talk about access to care, we have to be very concerned about the way in which people are driven to the use of health care resources. So direct-to-consumer is essential in that.

We have to care about the prioritization of which things in health care work and which things don't work and what things are priorities. So the prioritization of health care issues are important. Public information and education is on our list and clearly people will need support at being able to make sense out of not only genetics generally, but then in the area of how do you make sense out of all these claims and counterclaims? So that's our public education effort.

Professional training and education, as we just heard a moment ago, is essential here. How many of our clinicians are prepared, quite frankly, to counsel around the purple pill, the blue pill, the red pill, much less a new genomic test? They aren't prepared for any of these things and that's why we have so much waste.

So this is clear to our professional education, and then, finally, we get from Linda a moment ago at CDC a conversation about their work around the evidence basis of tests and which things work and cost effective. So again that's part of it.

So in a fairly detailed way in my mind, this is extremely important, but it's important because it transcends all of the issues, and I would sort of see this then as a Number 3, and while you may not have to attack it head on, if we aren't doing something in each of those areas that I've just ran through, guarantee you then we're going to be off target, and if we do things in each of those areas, we will have, I think, addressed the issue or at least the infrastructure for this DTC issue.

MS. BERRY: Martin?

MR. DANNENFELSER: I think if we're going to say that this is an exceptional issue, then I think that we need to be concerned about how it's marketed to the public. I don't think we can put it in the same category as cosmetics or something like that. I think we need to be concerned that the public is not getting bad information and I think the points that were just made are very good, that people need to know. Doctors, nurses, all of the people who would be involved in this area need to know what's good and what's bad and then be able to inform the public.

MS. BERRY: Matt?

MR. DAYNARD: Ed, yesterday you were talking about resurrecting the SACGT brochure and I think that's a great idea. This area isn't in the Commission's radar screen simply because dietary supplements is a $6 billion industry. It's a hot topic and is on our radar screen. Ephedra, unsafe herbals, people dying. This isn't the only criteria that the FTC has, but it may need a push. I'm not afraid to admit that in this area. So the brochure might be a good idea.

In that brochure, you could tell consumers and doctors to complain to the Federal Trade Commission if they see misleading advertising. For example, I have a program in the refractive surgery area where local docs make wildly outrageous claims for the efficacy of laser surgery. You can get rid of your reading glasses in a day. But I can't sue local docs. The Federal Trade Commission can't run roughshod over local docs. I mean, our charge is that we have to take action in the public interest which means as many consumers as possible.

So I do have a voluntary program where doctors send me advertising and I send a little letter to the doctor saying, well, I'm aware of this advertising, and unless you have competent and reliable scientific evidence that thus and such is true, you may want to reconsider and you may want to give me a call, and I get about 20 docs a year to voluntarily change their advertising without involving the Federal Trade Commission itself.

I could do something similar in this area, but the Commission might need a little push. Do the brochure, send a letter to the chairman, tell doctors and consumers to complain to the Federal Trade Commission, tell them why they need to, tell them what to look for, and then if there's a good case that I want to consider, I'll come to you and I'll ask you what the harm is. Is it because people are forgoing proven medical treatment, because the test shows one way or another that they are or are not predisposed to some disease?

I think this is an important issue, and I think eventually we're going to take some action. In the interim, we could help do a brochure. This has been done before. We did it in the area of LASIK surgery. We called it "Basic LASIK." People should go into this surgery with their eyes wide open.

(Laughter.)

MR. DAYNARD: And we hadn't brought a case. This was very unusual for the FTC to do. Typically, we bring a bunch of cases and then we have consumer education on top of it, but it's not always necessary. So the overriding point is the FTC in any area of advertising has to get the most bang for the buck. We're a small agency. We can't possibly take care of all the fraud out there by ourselves. So we coordinate with the FDA on a daily basis, and I'm sure we'll do the same in this area. We coordinate with state attorneys general. We coordinate with private associations to whom I give speeches all the time because prevention is the best medicine really, and I suppose I'll be doing the same here.

I'm going to be speaking at the Genome Institute meeting in a couple of weeks. So there are things you can do. State your position, do the brochure, tell consumers and doctors to complain, and the FTC will be there.

MS. BERRY: Steve, you didn't volunteer, but I was wondering if you had anything you wanted to add.

DR. GUTMAN: Well, I actually spoke to this at the last meeting and one of the problems from my agency's perspective is that we don't have really good regulatory tools for addressing it. So we actually are reliant on FTC and FTC has resources in which they have to make very careful decisions.

So I think Debra's comment is interesting because it depends, I guess, on how you construe harm, whether false information and worry and expense, and I don't know that there are dead bodies all around, but I think that this is an area of frankly not just in genetics but certainly this is just like an Arabian bazaar. It affects drugs of abuse. It affects herbals, just wild.

So it's replete with opportunity, even small things would help here, but the agency has weak regulatory tools. So from our perspective, it would require regulatory or legal changes, I think, before we can be a major player.

DR. FELIX-AARON: We have talked about a number of tools to address this issue. I mean, the legal, regulatory. What we haven't spent much time talking about is the education tools, decision support tools to help consumers make informed choice, and, I mean, an option for the committee to consider is where are the opportunities to develop and

disseminate tools for consumers to make informed decisions as well as for providers.

I think that it's an area that the committee could decide that it wanted to tackle. I was particularly impressed with the FTC's tool where they sort of had this website that you went through. I mean, I think those types of tools are very important. They're very effective, and in the absence of really sharp regulatory and other tools, I think education and educating consumers is an important opportunity.

MS. BERRY: Paul, and then Hunt.

MR. MILLER: It strikes me, to sort of build upon Reed's earlier comments about government and about leadership, that this might be a perfect sort of example to sort of try to think outside of the box of how do you address this particular problem, and I don't know if the issue is so much one of regulation and sort of suing people but really of educating the consumers so that they are aware that this sort of lurks out there, and it strikes me that the FTC brings to the table tremendous consumer protection, expertise, and framework, and this committee or HHS in general, in combination with NIH, brings the science together.

And so to the extent to rather maybe than doing a brochure really sitting down and saying this might be a one-time priority project where you get the chair of the FTC, Secretary of HHS, to do some sort of press advisory, sit down with USA Today or something, with a bunch of information and say you know what, this genome stuff is really exciting, but there are shysters out there lurking, and I want you to know about it and more than any sort of brochure, a couple of well-placed articles or press briefings would sort of put the issue on the table, alert people, maybe even generate some interest in a conference by which you work with the state attorney generals association to do a little briefing about what's out there.

But that kind of sort of putting it on the table, letting the government agencies that have the expertise speak and identify the issue, and let others sort of take the ball, and I think that's to me about as much as we can do right now on the issue. But to really think creatively about how you can combine expertises of government agencies to work together and create something a little new and different but useful.

MS. BERRY: I'm getting the hook, so quickly from Hunt and Debra, and then we'll wrap up.

DR. WILLARD: I confess that this is one of these issues where I just don't see why this is different than diet pills, than the public's lack of ability to understand fat metabolism, than the public's ability to understand whether information from body scans is useful or isn't useful.

So I'm just as frustrated as all kinds of people that the public doesn't have the knowledge base to deal with a whole range of issues, one of which is genetics and genomics, but I have a difficulty elevating this in my own mind to a major issue when there's all these other aspects of truth in advertising and very clever people who are actual shysters, know exactly where to position their statements that allow them to hide and be covered behind at least a few general terms. So this to me is the exceptionalism issue, and I just have trouble elevating this one.

DR. LEONARD: I would think that, like Hunt had argued before, this is a Category 4 or Class 4 and we should rank it among the other priorities and see where it falls out.

DR. McCABE: As Reed was leaving to go back to his blue-ribbon panel, he said he was hoping it would be a 3 and I will state that, but having heard the discussion here,

I'll take that as a motion, Debra, to make it a Category 4. Do I hear a second to the motion? Yes, Kim has a second to the motion.

Further discussion? Anybody wish to speak to it being in another category?

(No response.)

DR. McCABE: All in favor, say aye.

(Chorus of ayes.)

DR. McCABE: Any opposed?

(No response.)

DR. McCABE: Abstain?

(No response.)

DR. McCABE: Okay.

MR. DAYNARD: Ed, could I just make a statement? If you do want the FTC to get this on its radar screen as soon as possible, I do think some sort of other communication between the committee and the FTC would be very helpful in terms of stating that there is this overriding issue out there you're concerned about, which is the Category 2 sort of part and not a year from now part in Number 4. Thanks.

DR. McCABE: Thank you.

We can talk about each of these after we do the vote. We need to have the break after the discussion of all 12, so that we can do the votes, not that I'm holding your break hostage to the process.

Next is patents and access and that is Debra.

DR. LEONARD: So patents was ranked low yesterday, both by the members and the ex officios, and I hope that is not because you don't see the patent issue as a very high priority issue, but we've already acknowledged that all 12 of the issues are high priority.

So the issue with patents is that patents are being enforced and licensed in such a way that it's inhibiting the use of genetic information, particularly in diagnostics. So you end up having a sole provider of a medical service by a patent holder which I don't think is in the best interests of the public health.

I think that it's ranked low because of Francis Collins' comment yesterday, that there's a National Academy of Science study being done over the next 18 months to look at the impact of patents on research and clinical practice and that there will be recommendations that come out of this analysis.

So I think that in looking at the four questions, we would be duplicating the efforts of this NAS study in the area of patents. So I don't know where that means we classify this, but I'm trying to get to our break. I would like to see it as a 4, with the understanding that we would hold it and it obviously would not be a high priority for probably when you vote, with the idea that we will sort of follow what happens with the NAS study, particularly when they are finishing their study and making recommendations and review what those recommendations are and what this committee could do to help with implementation of changes or whatever comes out of that analysis.

Discussion?

DR. REEDE: I see it more as a 2, because looking at our categories, 4 meant that SACGHS would do an in-depth study, and it sounds like the National Academy is doing an in-depth study right now, so we would be duplicative, and I'm sure what we would be

able to do within our meetings would not in any way compare to what they would do over an 18-month study. So I think monitoring the progress might make more sense than us putting it on our agenda for an in-depth right now.

DR. LEONARD: Emily?

DR. WINN-DEEN: I guess I feel compelled to point out that I don't think the issue of patents and access is any different for genetics than for other biomarkers or diagnostic platform technologies that are applied in other areas of laboratory medicine, and so in this area, I don't think genetics is an exceptional category in any way, other than it's the newest thing and so it's more likely that there's patent filings on innovative markers as well as platform approaches.

But I would say if you think back to ACGT, there were huge issues around patents. There were huge issues around patents for monoclonal antibodies and whether they would be broadly licensed for immunoassay or not. So this is something that's been in existence through the course of the development of new technologies for clinical medicine and from that point of view, I don't think it's exceptional and maybe doesn't need to be separately taken up by this committee.

DR. LEONARD: Except that by controlling a gene sequence, you basically control that disease, and I don't think that's the case with other biomarkers, if you will. There are other ways to work around that, but if you control a gene sequence that is related to a disease and you enforce in ways that are restrictive, then you limit the research, the clinical observations, the access. You limit a lot of aspects of what can be done in understanding that disease. So in that sense, I think it is different than other situations.

Other comments? Discussion? And Joan, I appreciate your comment and agree that it's a Category 2, most likely.

DR. McCABE: So do we have a motion? Joan. Category 2. Second by Chris. Further discussion?

(No response.)

DR. McCABE: All in favor, say aye.

(Chorus of ayes.)

DR. McCABE: Any opposed?

(No response.)

DR. McCABE: Any abstain?

(No response.)

DR. McCABE: Okay. So patents and access is a Category 2, and then, Emily, you wrap up as chair of this task force to have the last issue.

DR. WINN-DEEN: So I get the vision statement thing. So normally, I'm not a big believer in touchy-feely kind of things. I'm a much more analytical kind of person, but I think it does help shape a group's purpose to try and have some kind of statement of vision and what is the overarching principle that we're trying to address with this committee's work. So I think that's why it got on the agenda.

In terms of actual implementation, I mean, obviously from the day-to-day working world, things like coverage and reimbursement are real meaty issues, but I thought it was interesting to note that the ex officios rated it Number 4, presumably because there's some feeling that to have some overarching statement might help inform sort of the mission of other agencies as well as this committee.

So I'll just throw that open to any of the ex officios that wanted to comment about why they did rate it high. I'm very happy to hear from anyone on our committee about why they rated it at the bottom. It's not something that I would say we should spend oodles and oodles of time on, but it might be useful to just have sort of a common vision of where we want to go as a group.

Anybody? Okay. Someone from the ex officios rated this highly, and I'd like to hear from someone who rated it highly.

MR. DAYNARD: It's just that I've never seen a report from an important committee like this that didn't have a vision statement. It sort of is like the executive summary of what you want to do or what you've been doing and where you're going and sort of focuses everyone's attention on what you want it to be focused on. That's why I rated it highly.

DR. WINN-DEEN: Ed?

DR. McCABE: And maybe this is a misunderstanding, but I'll explain why I rated it low and that is, I feel that we were given the vision statement in our charge from the Secretary and that to recast that would be merely to move words around but not to really -- I mean, we really can't change our charge. That's why I thought it was redundant with what we had already done.

DR. WINN-DEEN: Hunt?

DR. WILLARD: I would agree with Ed, except that we have just spent a day and a half essentially recrafting or at least reordering that charter, and it could be that at the end of today, there is value in coming out with a one-pager that says okay, here are the issues that we have decided to prioritize and that would stand as our vision statement. So it doesn't require in-depth effort, it doesn't require consistent monitoring, but there may be some value in having a statement that describes what we decided after yesterday and today.

DR. McCABE: Sarah and I were having a sidebar here, because I could see this moving to a Category 2, and I wasn't sure that it was going to be very quick on the part of staff to do this, but Sarah, if it was more of a summary of our deliberations and sort of more of a progress report almost of what we've accomplished in the meetings that we've had, that, Sarah says, could be done in real time, in some reasonable period of time, as long as it's one page.

DR. WINN-DEEN: Any other discussion? Okay. Well, Brad, if you'd like to make a motion, I'll listen to it.

MR. MARGUS: I move to make it a 2.

DR. McCABE: So Brad made the motion. Debra has seconded this. Any further discussion?

(No response.)

DR. McCABE: Not hearing shrieks from behind me from Sarah that this isn't possible, all in favor of the motion, say aye.

(Chorus of ayes.)

DR. McCABE: Opposed, nay.

(No response.)

DR. McCABE: Any abstain?

(No response.)

DR. McCABE: Thank you very much.

Now, before you take your break, I would remind you that you have a green sheet. This is for the members and the ex officios.

DR. REEDE: Can we divide the 2s?
DR. WILLARD: Let's do that after.
DR. McCABE: Let's do the 2s, and we'll sort through, but what we have for 2s, you ranked them by A, B, C, D, E. Just to go through, the 2s that we have are education and training, genetic discrimination, the oversight, and then the patents and access and vision statement. So you need to rank those A, B, C, D, E, et cetera.
For those that you will number in the same column on the same sheet, those will be then as coverage and reimbursement, large population studies, pharmacogenomics, and direct-to-consumer direct access testing.
So if you could now do those. A, B, C is 2. A is equivalent of 1.
MS. MASNY: Just to clarify?
DR. McCABE: Yes?
MS. MASNY: We actually are going to put the class that they're in and then rank it?
DR. McCABE: No, if you just use the letter. They're already in a class. So if you just use the letter and the list and some won't have anything. Sarah was just saying should we subclassify 2 into monitoring versus. So we'll do that later would be my recommendation.
We'll resume at 10:30.
(Recess.)
DR. McCABE: The voting is done. The virtual envelope is about to be opened. We're doing Class 2 first. So as you can see, genetic discrimination came out top on the members' list, tied for Number 1-2 on the ex officios' list. Education and training workforce came out Number 2, again tied 1-2 on ex officios. Members and ex officios had oversight as Number 3. The only place where there's a real difference is patents, access, and vision statement are in that order on the members' list and the reverse order on the ex officios' list. So I think it's impressive that genetic discrimination yet comes out at the very top as it has consistently through this committee and a prior committee.
Why don't we go ahead? We don't want to keep people guessing. We'll go to Number 4, then we'll come back to Number 2 and decide what we're going to do with it. So the next is more for information. We'll then come back and decide what we're going to do with Category 2.
So here, there was a little less agreement. The coverage and reimbursement was Number 1 or Number 2. Number 1 on the members' list, Number 2 on the ex officios' list. Large populations was Number 2 on members, Number 3 on ex officios. Pharmacogenomics, Number 3 on members, Number 1 on ex officios, and DTC/DAT was Number 4 on both lists.
So having seen the lists, let's go back to look at Category 2 and see what we could do. So let's talk about what we can do quickly as well as readily. So there is some urgency, as we heard today, to put together a letter on genetic discrimination, and what I have heard from the discussion, but I want some further discussion of this to give guidance to Sarah and her staff, is that this would be a letter to Secretary Thompson encouraging the Secretary to put the administration's support behind S.1053 and that because this is such a major concern of this committee and our perception from the public outreach from the prior committee, SACGT, that this is a major concern of the American people, that the most expeditious way is to move S.1053 from the desk, whatever the appropriate terminology is, and have that move through the

House.

Do I hear any further discussion of this? Is that appropriate? Because what we have heard is -- and there was some discussion at the break -- should another bill independent of 1053 go through the House, then there will be significant difference. It will go into a conference committee and will be hung up substantially.

Given the concern of the people, the unanimous nature of passage of S.1053, we should move forward, try to have that move forward in the House.

Hunt?

DR. WILLARD: Two issues related. It was my understanding that the administration had already signaled its desire to sign S.1053 if it got through the House. So I'm not sure urging the administration's support is anything they haven't already done, but that's just for clarification.

The second question is whether we have any authority or advisability to write to anyone other than Secretary Thompson or given the nature of our charter, that's the only route we can go through.

DR. McCABE: Yes, that's really the only route we can go through. If we are invited, then we can be available to others, if requested, and those requests are done through all the appropriate etiquette or rules, but really, we, as committee members, that's our reporting structure.

DR. WILLARD: And to my first point, maybe Francis can update.

DR. COLLINS: So yes, there was a Statement of Administration Policy, an SAP, issued by the White House at the time of the passage of S.1053 in the Senate indicating that the White House supported the bill and the president would sign it in the form in which it had just been passed.

But the failure to take action in the House is not something the administration would have no interest or ability to intervene with. In fact, it is often the case that, especially when you have the same party controlling the administration and the House and the Senate, that the administration expressing a strong desire to see a piece of legislation move forward can have a seriously positive impact on what happens.

So I do think it's highly appropriate for this committee to urge the Secretary to use every bit of the weight of his office to try to urge the leadership of the House of Representatives to take action on this bill.

DR. McCABE: Yes, I think it's a different signal, if we could get their attention and have them move as opposed to saying we're willing to sign, really putting some pressure on the process.

Barbara?

MS. HARRISON: I was thinking about what Reed was saying earlier and maybe if it would be possible to focus the letter a little more toward whatever the concern is that the House has that they're not getting this bill through and that kind of feedback is something that can be received in the next week, so that by the time the letter was formed, it could be a little more focused to say if we want to make the argument that in this case, genetic exceptionalism is key and that this really is different and there is a need for this type of legislation, if maybe that's the hold up, or just maybe to somehow direct the letter so that maybe it'll have more effect, and past letters have been effective but maybe to be effective in a different way.

DR. McCABE: Yes, Debra?

DR. LEONARD: My concern with making the letter a recommendation to specific or trying to inform is I'm not sure we understand that and I'm not sure that anyone does, and so I think just whatever is needed to move it is what we're asking the Secretary to do. I don't know that being more specific than that is going to help.

DR. McCABE: Yes, I think that this will be one tool that will be available to those who are advocates for this. I think we've heard what the American Society of Human Genetics is proposing to do. That will involve some more grassroots activities, but I think when you put them together that they'll be somewhat complementary.

I would think, also, that what I will interpret from this committee and the prior committee is that we're in favor of genetic non-discrimination legislation and we feel this is an urgent need. The most expeditious route is with movement of S.1053 now through the House, but I think also we have to be realists and we're doing that because this is the most expeditious route.

Our goal is to get genetic non-discrimination legislation to the American people because that's what we've heard. So we should not become sole advocates for this route.

Yes, Joan?

DR. REEDE: The other part I'd also heard, in addition to having a quick response and a letter going out, was continued monitoring and the potential for having some presentations or testimony at our next meeting and I just wanted to raise that again.

DR. McCABE: Thank you. I think that will be important, and as I thought about it, that will be important even after the passage of this legislation because it will be important to then monitor the impact of that legislation and whether it really does make a difference. So yes, continuing to monitor it would be appropriate.

Anyone else have any thoughts on points to make in this letter?

(No response.)

DR. McCABE: So that one will be moved forward at least in terms of this work product, which will be a letter to Secretary Thompson. We will continue to monitor it. It will not move off of our plate simply because we've written the letter. It hasn't to date. I don't anticipate that it would, but just to make it clear for the record that we will continue to follow this.

If we look at priorities then, education, training, and workforce. Look at who was responsible for that. So Hunt, you were responsible for that. I'll let you lead the discussion in terms of something that we could do, recognizing it's in the queue behind the letter. It's probably reasonable to expect Sarah and her staff to do two of these things, plus begin to work on one or two of the items from Category 4.

So what could we do in the interval between now and the next meeting?

DR. WILLARD: I certainly think we could ask the ex officios and other interested parties to let us know what action we could take to help them in their efforts. I mean, I think part of the reason we put this in Category 2 was we acknowledged there were significant efforts ongoing, led by other organizations, academic or professional, and so the issue, other than us simply monitoring that, is to ask them what can we do to add weight to that and specifically in terms of HHS.

Otherwise, to me, it's a monitoring issue just to know what's going on out there. We've already heard presentations from two meetings ago, I guess, the very first meeting

on workforce issues. At some point in time, maybe it's suitable for an update. My guess is that it's probably too early for an update right now, but here's a case from my perspective where working with the ex officios, we could actually find out what we could do, none of which would take too terribly much time and effort on our part, but nonetheless we could push our weight around such as it be.

Joan, and then Emily.

DR. REEDE: I think the other part was mentioned was that the SACGT had a working group on education, and I don't know if it had preliminary report or other information. I think it would be useful for us to be able to review that.

DR. WILLARD: Francis?

DR. COLLINS: I didn't want to go out of position here. I thought you had already got Emily on your list.

DR. McCABE: Emily.

DR. WINN-DEEN: So I guess the other thing that I think we heard was a request for genetic counselors to be elevated to allied health profession status, so that they can --

DR. WILLARD: Is that a coverage and reimbursement issue?

DR. WINN-DEEN: Maybe that's coverage and reimbursement issue.

DR. FEETHAM: That issue was dealt with at the last meeting and it was clarified that the funding is available for the education and there are the application process and so that part of it is done. That's separate from the reimbursement issue, but it's important to know that that was clarified in writing at the last meeting.

DR. WILLARD: Francis?

DR. COLLINS: So I did communicate with Joe McInerny, who's the executive director of NCHPEG, the National Coalition for Health Professional Education in Genetics, since this came up yesterday, to see what his sense would be of the gaps that exist in a very challenging agenda here for education of health professionals about genetics.

He agreed with the suggestion that was raised yesterday about licensure and certification as an area where relatively little progress has been made, recognizing, however, that this is a very tough problem because it's primarily managed at the state level and it's not clear what SACGHS might be able to do about this either, but it certainly is an area where relatively little has been done and probably NCHPEG is not in a very good position to have an influence, and, of course, when it really comes to trying to implement changes in health professional qualifications, licensure and certification is often the way to really make something happen. So that would be an area of potential investigation.

He also indicated that NCHPEG has not been as successful as they hoped in convincing those who are responsible for medical school and nursing school curricula development to do a more forthcoming and forward-looking job of incorporating new concepts of genetics and genomics into their curriculum, and a statement from SACGHS to, for instance, the AAMC indicating the importance of this from the perspective of this committee could actually be useful.

Finally, he confirmed something that Joan brought up yesterday, the importance of focusing on diversity of the workforce when it comes to genetics professionals or health care professionals with familiarity with genetics, and while NCHPEG has identified that as a major priority and has a working group devoted to it, I think he would welcome the chance

to interact with SACGHS about possible strategies for achieving this. That's not very specific. I think that would require a follow-up conversation that would delve more deeply into what that might look like.

But those were the three areas, just conveying to you from Joe's perspective and from my perspective, because I'm the chairman of the board for NCHPEG, what might be possible collaborative/complementary undertakings that could contribute to this Class 2 issue here.

DR. WILLARD: Suzanne?

DR. FEETHAM: I concur with Francis of keeping the pressure on and the visibility, and as we mentioned yesterday possibly bringing in the key groups, like AAMC and AACN, who are the ones who really have the influence to nudge curricula changes. I think it makes sense. It's another way of having influence.

A letter was mentioned yesterday to reinforce the interest of this by the committee to the Secretary, I think has merit. Again, it is seen as a priority. We're just completing a report to Dr. Duke, the head of HRSA at this point in time, analyzing all of the genetic activities, not just education and training, across all of the agency, but again our being able to include in that report to her of the focus, of the interest of this group will just reinforce the significance of that. So that has a ripple-down effect that has merit to keep it on the screen.

DR. WILLARD: Thank you.

Ed?

DR. McCABE: And I just want to comment that this apparently is a topic that's extremely interesting beyond this committee because Dr. Boughman was approached to have the material she presented to us published and so that suggests that this is of considerable interest.

So with those comments then, we will work on putting together materials for the next meeting, but spreading the net a little bit more broadly, looking at the issues that have been discussed here, including diversity, engaging some of the other groups, like AAMC, perhaps ACGME was talked about as well, because that's where we could really begin to have an influence at least on medical education and look beyond that.

So we can begin to work on that for the next meeting, if that's acceptable with everyone. Okay?

DR. LEONARD: Who works on nursing education curriculum?

DR. FEETHAM: That would be AACN, and again you're talking about the 2.7 million nurses. So that group, I think, is --

DR. LEONARD: But I think if we're going to have AAMC, we need AACN, also.

DR. McCABE: Well, we'll look at the groups and try and cast that net broadly, but I hear you.

DR. WILLARD: And from a procedural standpoint, I mean, since this is a Number 2 and not a Number 4, how do we move forward? We've just listed a half dozen groups that we want to hear from which suddenly to me begins to smell like a Number 4 because we're now using up a day of a meeting rather than dealing with it quickly.

DR. McCABE: Well, it probably won't be a day of the meeting. If people felt we had the information to move forward at this point, I would think that then we would use that to craft a letter to the Secretary. Because I understand it's a 2, this isn't an in-depth study,

but, I mean, if we want to just say that it's important to have education and to look at these factors in terms of workforce, we could say that.

My feeling was I'd like to be a little bit better informed of the issues, but we could set aside time to outline the elements of the letter at the next meeting, so that a product of the next meeting would be that letter to the Secretary.

DR. WILLARD: I mean, I wonder if we can't invite submission from those groups of simply background data and information by staff so that we actually had in front of us a lot of the information rather than sort of getting it all in a 24-hour period. I mean, if the goal was to aim for writing a letter after the June meeting, one could almost put together a task force, an inter-meeting task force of three or four to collect that information from the six or seven relevant groups, find out what's out there and use that as a way of then identifying are there gaps where there isn't adequate attention.

DR. McCABE: Six or seven is a good number. We have to be careful that we not exceed nine because then it has to go through clearances in the government process. It becomes a survey rather than just gathering data. So six to seven is a very good number that you chose.

Emily?

DR. WINN-DEEN: The only advantage I can see of actually having those people come here is to hear it back to them. If we just ask for their input, we get sort of one-way communication. If they come here and have to testify and answer questions, they get a message back beyond what a letter to the Secretary might convey back to them and so that's just something to balance in terms of program time versus background reading time.

DR. McCABE: Debra?

DR. LEONARD: My question was what effect does our writing a letter to the Secretary have in influencing AAMC and AACN, and can we write letters directly to those organizations as opposed to the Secretary?

DR. McCABE: My guess is we'd have to look into that, but I would think that a letter to the Secretary that would discuss some of these important aspects for medical education, but we can look into that between now and then. I think we can do both. In terms of the previous comments, I think we could request written documents prior to the meetings, so people could be prepared, but then we could have very brief presentations, very brief presentations, and lots of time for discussion with them. So I think that would be reasonable to do.

Sarah, do you want to comment?

MS. CARR: Well, I was thinking of another idea, which is rather than addressing letters specifically to the heads of those organizations, you could communicate to all of them in a general way through some sort of resolution, one- or two-page sense of the committee about the importance of their efforts, because you have a bully pulpit, you don't just speak to the Secretary. That's your first task and responsibility, but I think that's one product or tool you could use as well.

DR. McCABE: Debra?

DR. LEONARD: Could we do what Hunt suggested and have several people actually look at the data and maybe draft a resolution or something that could come back as something that this committee would then review at the June meeting?

DR. McCABE: So we will be accepting volunteers for that group. Hunt,

are you willing to have the lead on this?

DR. WILLARD: Let the record show I was assigned to be the lead.

(Laughter.)

DR. McCABE: Is there anybody else who would --

DR. WILLARD: I'm happy to contribute to this process.

DR. McCABE: Anyone else? Joan, Kim, Agnes, and Barbara. Thank you. So you all will work on that in the interval so that we can have a draft resolution which again will speed things up and certainly can be influenced by what we receive and what we hear.

Francis, Sarah's saying are there any other task issues regarding licensure, those sorts of things? Are there any other tasks that we should assign ourselves?

DR. COLLINS: It's not easy for me to answer that question. I think if this group is collecting information, one of the critical sources would be to go directly to Joe and get an enumeration of what has already been attempted in licensure and certification, where the roadblocks were, and then perhaps at the next meeting to be able to assess whether there's a role, in addition to this resolution which I liked that concept a lot, but is there an additional role that could be carried out?

Obviously, as you say, ACGME would be an important part of this as well.

DR. McCABE: Thank you, and also AAMC with their Council of Deans as another leverage point.

Okay. So we've dealt with those two and are moving on.

Yes, Suzanne?

DR. FEETHAM: Just as a reminder, I mean, one of the activities as you get the report from NCHPEG was what was done in looking at the year 3 exams in medicine and doing an analysis of the questions and which of those were genetics, and there was some good insight that was learned from that.

We have often said that to get in the curricula, you get it on the licensure, but there are also, I think, is merit in what we're talking about in reaching AACN, AAMC, because I think they can influence getting it on the exams, also. So I think it's a two-way process.

DR. McCABE: Thank you.

Yes, Joan?

DR. REEDE: Hunt's just brought to my attention to make sure that, and part of my reason for volunteering for this group that will put forth this resolution, is to make sure that, in addition to looking at issues, such as licensure certification, et cetera, that we look at issues of diversity across the workforce and that be incorporated in any resolution.

DR. McCABE: Yes. I think we would all agree with that.

Now moving on, my sense from the discussion was that oversight is a monitoring. That was a 2 for monitoring. Do we think it's important and it needs to be monitored? Does anybody have an action item? Yes, Debra?

DR. LEONARD: Can I go back to the education?

DR. McCABE: Sure.

DR. LEONARD: Can you add also to that that we're going to invite people to the June meeting for discussion? I mean, that's part of this process, also. Thank you.

DR. McCABE: Emily?

DR. WINN-DEEN: So at the appropriate time, and I don't know if June will

be appropriate time because we have to sort of wait and see how FDA bureaucracy ends up, but I would like to hear an update on the various guidance documents that FDA is developing to provide sort of a regulatory framework for incorporation of genetics into medicine sort of in a global way and likewise at the appropriate time when the CLIA regs are getting ready to go out for public comment and if we have something that Judy or someone from the CLIAC subcommittee would like to present, but we can't say we'll definitely do that at the June meeting because we don't know if the things will be ready, but if they are, I'd like to hear updates.

DR. McCABE: So to some extent, we'll depend on our agency ex officios to help us know when the right time for that is. I think we need to be cautious because my guess is June is filling up as we're sitting here. But if there's something you could give us updates on either of those oversight activities.

Patents and access. My impression, also, was that that was important and therefore needs to be monitored. Anyone have an action item that they want to raise on that? Hunt?

DR. WILLARD: It's just the long-term one of when the NAS study is done, that someone should come and present the results of that and discuss it with us, but that's at least 18 months off, if I understood it.

DR. McCABE: Debra?

DR. LEONARD: We had also discussed having liaisons. Was it to the NAS?

DR. COLLINS: That was for the large population study. I think the NAS in general is not that friendly to the idea of liaisons.

(Laughter.)

DR. McCABE: That's really considered independent, and I think they want to be independent of the government, but that was the large populations and that was welcomed to have liaison.

So anything else then on patents and licensure?

(No response.)

DR. McCABE: Okay. So we will monitor that. Again, we will depend to some extent on our agency representatives. If we go too long without hearing, we will ask, but if there's something happening that we should know about, please let us know there as well.

Then Sarah had an idea on the vision statement. So this was her volunteering. A number of people, including myself, have said that with all the work that went into the issue statements, that those should be published, and Agnes mentioned that, also, and I've heard other people say that as well, that this was really important, that we ought to get these published. I think you're on the record, Agnes, for having said that.

So the issue briefs should go beyond just the minutes of this meeting, I would think, and Sarah was thinking we could incorporate Hunt's suggestion of sort of summarizing. It would be good to put some context around the issue briefs, now having heard them, so that we could summarize the process that we've been through up through this meeting as an introduction to the issue briefs and that would serve then as a documentation for the Secretary of what we had accomplished and where we thought the emphasis should be, also.

Any discussion of that? Sarah, is it reasonable to think that maybe we could have a draft of that for the next meeting?

MS. CARR: We can certainly aim for that.

DR. McCABE: Okay.
MS. CARR: I think it might be doable, depending on what else you want.
DR. McCABE: Yes, depending on what else we put on your plate. Emily?
DR. WINN-DEEN: So I think the drafting should be done with the publication vehicle in mind. So I think we should put some thought into what is the best publication vehicle, and then is it published on the website, is it published in JAMA, is it published in Science magazine, is it published in U.S. News and World Report? So what kind of publication vehicle are we thinking about when we say they should be published?
I think that drives the format of the statements as well as sort of the education and reading level. So who are we aiming at actually reading these and utilizing them?
DR. McCABE: Debra?
DR. LEONARD: Well, given the book that we were just given, maybe the New England Journal would be an appropriate first approach since they've already done this series and may want to know, moving toward the future, what the issues are.
DR. McCABE: Yes, I think they already have just done the series, and I'll tell you who I was thinking of. When we were thinking of just the issue briefs standing alone, I was thinking of Genetics in Medicine, but when you put the commentary on top of it which makes it a policy piece more so than just the issue briefs, I think we could pitch it to JAMA. They like policy. Kathy Deangelous, I think, would get this, who is the editor-in-chief. So I would pitch it to JAMA with a backup being GIM.
DR. LEONARD: I think it has to go to a general medicine, not a genetic-specific journal.
DR. McCABE: Then we need to have backups if JAMA says no. So that would be general and that's why I was thinking Genetics in Medicine as a backup, not as a primary, but if there are other general ones for backups.
DR. WINN-DEEN: So something like Nature Medicine? I mean, I know that's not a U.S. journal, so it might be an issue.
DR. McCABE: I don't know that that would be the issue. The issue would be the policy interest in it.
Joan?
DR. REEDE: I agree with looking at the respected scientific literature as a place to put this information, this policy information, but I think there's the other part of informing the public and the majority of the public is not reading the New England Journal or JAMA, and so I think it may need two vehicles, a vehicle that will reach the policy and scientific community, but another type of vehicle that the public can understand and will have better access to.
DR. McCABE: Well, I think there, we would rely on the combined activities of the PR people for the Journal. There might be a way to do both, if we were able to get a high enough visibility vehicle for this.
DR. REEDE: I agree that there may be ways to do both, but I think we have to keep in mind as we're putting it forward that there's a part of educating the public about this at the same time that we're trying to educate the other community.
DR. McCABE: So is that a reasonable goal then, that we will move toward trying to put these together with an introductory piece? Hunt?

DR. WILLARD: I just wanted to support Debra's comment that I think Genetics in Medicine would be an inappropriate vehicle because it's a narrow audience. It's preaching to the choir, and we already heard today the choir's getting smaller. So I'm not sure that's the right audience at all.

DR. McCABE: So what would be a backup?

DR. WILLARD: So notwithstanding the need to find a backup, I think that would take a little bit of thought on all of our parts, but I would keep it out of the genetics literature in the first instance.

DR. McCABE: Well, if everyone could be thinking of that. I'll tell you my standard and it's in the book that Linda and I have written on how to succeed in academics. Whenever I submit a paper, I have a list of three journals to which I'm going to submit it, one which I think is a longshot, JAMA obviously is that, one which I think is about 50/50, and one which I think is a slam dunk. It's a good psychological tool to deal with rejection. So we need to be thinking about that.

(Laughter.)

DR. McCABE: Kay?

DR. FELIX-AARON: Health Affairs is another consideration for a broad policy audience.

DR. McCABE: Good. So JAMA, Health Affairs, and anybody have any others that we could look into?

(No response.)

DR. McCABE: Well, we've got two. Sarah needs some clarification of something.

MS. CARR: We've put up there "describe the task." I just want to be clear that you want first the report that's put together to be submitted to the Secretary, is that right, and then on top of that seek publication in a journal?

DR. McCABE: I think that is appropriate for our responsibilities. That will require some clearances then through the Secretary's Office which I think should we not do that, Sarah and I would have our wrists slapped. It's the nature that we have to have those clearances.

Okay. So we've dealt with Class 2, and I think we have some reasonable approach to each of these. I think it will be a reach, quite honestly, to have this ready for publication at the next time, but hopefully we can have it close to ready for the Secretary.

DR. LEONARD: Ed, can I make a suggestion?

DR. McCABE: Sure.

DR. LEONARD: If the staff needs help with the report, they could use the same work group.

DR. McCABE: Good. Thank you. That will be very good to help. Thank you for volunteering, Emily.

DR. WINN-DEEN: Thank you. No problem.

DR. LEONARD: I did volunteer the entire work group, not just Emily.

DR. McCABE: No, obviously, we're going to need some help with this. Sarah?

MS. CARR: Before we leave Class 2 issues, and I'm sorry to ask for repetition of this because I think you've said it, but I just want to be clear that under education,

training, and workforce, the only thing that you've assigned yourselves to do at this point is the drafting of a resolution, and I go back to the three things that Francis mentioned and then Suzanne Feetham also spoke.

So I just want to be sure that we shouldn't be adding to the list. In the diversity, the focus on diversity within education, I think, I just don't want us to lose because I think we should put it up there if there are things that down the road a bit.

DR. McCABE: What were your three points, Francis? Because diversity was one of them.

DR. COLLINS: It was one of them. So licensure and certification, Point Number 1. Curriculum development in health professional training, medical schools, nursing schools and so on, and diversity training.

DR. McCABE: Okay. Anyone else have key points? Hunt?

DR. WILLARD: But the explicit job for, I guess, staff is not preparing the resolution, it's collecting the data to allow us to then prepare the resolution. So that means chasing after the six to seven different organizations to find out what they're doing and get their reports. Then we can think about the resolution.

DR. McCABE: Maybe I was just thinking in my own track, but I was thinking we could actually pursue those in parallel, to pursue a draft of the resolution while we're collecting the data which then could modify the resolution, but at least beginning to draft the elements of the resolution. If we think those are three key elements, I think we could go from there and then we could be informed with the argument being that it's easier to edit than to compose.

DR. WILLARD: No, that's fine, but no where up there does it say contacting those groups and getting reports and data from them prior to the June meeting.

DR. McCABE: Okay. We will work on that, too. Other points? Debra?

DR. LEONARD: And the work group that's drafting the resolution with staff will take into account those three points.

DR. McCABE: Plus helping to identify the six or seven organizations. Joan, would you chair that group? Would you be willing to chair that group? Thank you.

So as soon as we're done adding to that, recognizing I violated one of the things I said I would not do on this committee which is establish a work group. So I would prefer to call it a task force because its work will be done at the next meeting, having seen these take a life of their own. So I much prefer task force as to work group.

DR. WINN-DEEN: Yes. I mean, I think from the point of view of the vision statement, that's, I think, sort of the end of what the agenda task force would see as their final work product. So I think that's just an appropriate, whatever, three-month extension to our team effort.

DR. McCABE: Thank you.

Now we're on to Class 4. So coverage and reimbursement. That issue is Number 1 on the members' list and Number 2 on the ex officio list. I think we will follow the members' vote but be informed by the ex officio vote. The fact that that is Number 1 and Number 2 on the two lists, I think, says it's important to both groups.

Just a general thing before we get into the details. We had said when we started out that we would narrow this down to one to three items. We ended up with four. We have two significant tasks before us at the next meeting. No, the one will be done. The letter

on supporting antidiscrimination legislation will be done. So we have two tasks from Category 2 that we will need to work on at the next meeting.

I would argue then that these are four things that we need to engage over the next year or so and that probably it is realistic to engage one of them, but for the discussion today before lunch and after lunch have a plan for how we will deal with that at the next meeting, and then the other thing I'd like to do now -- so to me, the obvious one for that discussion is coverage and reimbursement since it's Number 1 on the members, Number 2 on the ex officios.

What I'd like to do briefly now is to discuss the other three items and see if the list per the members is acceptable to everyone and then to begin to think because I think we're going to have to put -- if we are going to have to think about what we're going to do and these are going to be put off till the fall, is there anything that people feel need to be done before that?

So discussion? So let's hold coverage and reimbursement for now. We'll get back to that one. Emily?

DR. WINN-DEEN: So I think we heard Francis say yesterday that there's a group at NHGRI that's looking into this whole formulation of large population studies and how that should be handled. I'd like to hear maybe, Francis, do you think it's appropriate for you to come and report to us? Do you want to engage us in some kind of informed discussion and advice to that group? What do you think would be the most helpful to moving that forward?

DR. COLLINS: So again, this comes at a time where this is very much a process, an evolution. The group has not actually been fully formed yet in terms of who the members are going to be. This will be largely constituted of external experts who we will ask to look at the various possible study designs and over the course of the next six months or so try to give us advice about what exactly would be scientifically and the most compelling way to proceed as well as addressing the myriad of ELSI issues that are raised by the possibility of carrying out a study of this magnitude where data access is intended to be fairly open and available.

We would welcome whatever this committee would like to do as far as a liaison to that enterprise. We will be working quite intensively on this in the next six months but in a way that I think would potentially be benefitted by a liaison relationship with the committee, and I'd certainly be glad at the next meeting and any meeting thereafter to give a full report on how this is progressing.

Again, this is still very much up in the air in terms of exactly what timelines and what kind of products are going to come out of this next six months worth of deliberation.

DR. WINN-DEEN: What about funding support or some kind of statement to get that kind of level of support going as well?

DR. COLLINS: I think that would come better when one has a clearer definition of what you're asking for funding for. Right now, it's still a bit on the general side here, that we'd like to see prospective large-scale population-based cohort study that would collect gene and environment information on common diseases, but exactly what that would look like, I think the first question after somebody says we need support for this is how much is it going to cost and that, of course, depends very much on what the exact details of the study design are, and we're really not there yet.

So let me say I completely embrace and welcome this committee's strong

interest in this because I think this is a critical part of the future agenda, if we're really going to take advantage of what we're learning about the genome and apply it effectively to human health, and I would like very much at the appropriate moment, if the committee felt comfortable doing so, to hear a strong vote of endorsement of the need for such a study, but I think the time might not be quite yet for that, given that it will raise more questions than it answers and it will be better to have a more precise definition of what we're talking about before asking you all to sort of speak in favor of it.

DR. McCABE: And do you think the fall is a reasonable time in terms of your timeline, that that would be an appropriate time to bring it back?

DR. COLLINS: I think it would be.

DR. McCABE: Hunt?

DR. WILLARD: Francis, is your group and/or would it be helpful for this committee to formally evaluate some of the efforts going on in other countries? In other words, I could imagine inviting two or three people from DeCODE, from BioBank, from some of the Asian efforts, and just hear how they're doing and how they view the uniqueness of their particular populations, so we could reflect off of that and figure out what we might do?

DR. COLLINS: We will very much be doing that. In fact, the meeting we had in December which was sort of the first step in this, we had representation from the leadership of the U.K. BioBank. We had Cary Stef there from DeCODE. We had somebody from Estonia.

So I think we're very much aware of the importance and trying to tap into that experience and certainly this work group that we contemplate proceeding with for the next six months will have strong connections to the U.K. BioBank which, by the way, they're very excited about having a chance to be part of that process. I think they're feeling a little embattled and they're kind of pleased to hear that there might be some endorsement of the importance of this from another country.

So I think we have that base pretty well covered. Again, having a liaison with this group would be valuable as well.

DR. McCABE: So it looks like the timeline for the October meeting to bring this back for more in-depth discussion at that time. We can work on what exactly that would be. Yes, we'll work with Francis and identify the liaisons, but I think that right now, I want to get down the timeline that we could plan to maybe spend a half a day. Certainly, we don't want to duplicate what you're doing at that time, but if you just want to record that as what we will do, but do you think that we could have a half a day and bring in appropriate folks, but inform this committee but not duplicate exactly what you've done?

DR. COLLINS: I think that would work well.

DR. McCABE: Okay. Good. So we'll work with you on that.

Debra?

DR. LEONARD: Could you also, when you come to do that half day, bring to us information about ways that we could help you or reinforce or those sorts of things, not just what you've done?

DR. COLLINS: Absolutely, and I really appreciate your phrasing it in those terms, because I think we're going to need a lot of help to get something of this magnitude off the ground.

DR. McCABE: But I think we would also want to be informed about what

other activities may be ongoing in the federal agencies, because we heard that the VA is pursuing something. So we would want to hear broadly what is going on in the federal agencies.

DR. COLLINS: Yes, and again, our work group aims to try to collect information and make judgments based on that of all of the large-scale enterprises that might potentially be the foundation for such a study, and we've had conversations already with the VA about this. So that will be very much part of our efforts as well.

DR. McCABE: And you're cataloging to the extent possible what's going on in the private sector?

DR. COLLINS: Yes, and one of our goals in this next six months is to fully survey that and to get a better sense of the interest in the private sector, of being a fully formed partner in such an enterprise, both in terms of access to the data and in terms of supporting the enterprise.

DR. McCABE: One of the things that might be good, Francis, would be is you identify individuals who are less enthusiastic about this. We might want to hear from them as well.

DR. COLLINS: Certainly.

DR. McCABE: Thank you. Is everybody comfortable that we have a plan then for large population?

Pharmacogenomics. It's Number 3 on the members' list, Number 1 on the ex officios' list. So what are thoughts about how we should approach pharmacogenomics? Debra?

DR. LEONARD: Maybe since it's Number 1 on the ex officios' list, they can tell us what they would like done?

DR. McCABE: Thank you. So those of you who are advocates for this being higher, we recognize it's important, but what could we do with respect to pharmacogenomics? I would assume that people were enthusiastic about it and had a reason for the enthusiasm.

DR. GUTMAN: I actually didn't vote because I didn't have a ballot, but the deal here is that from my perspective, the agency -- I hesitate to use the word "well," but certainly has things in hand. So there's a lot of initiatives going on, and I'm actually not sure that there's any exigency to having this committee weigh in, unless at some point you perceive something was going in the wrong direction.

In addition to the documents, we have a request. So whether it's at the next meeting or the meeting after, we can certainly update this group on where our thinking is in the general area.

We are reconstituting the Pharmacogenomics Roundtable. The Roundtable looks to me as though it will be a joint initiative with sponsorship by BIO, PhRMA, and the TDM Renaissance Group of AACC. If this committee would like to send a representative to that reconstituted roundtable, you certainly would be welcome to do that.

The meeting is quite exploratory in that it's not clear that there actually is a need for a pharmacogenomics roundtable, but that's a work item that perhaps someone here could be a liaison to.

DR. McCABE: Yes, Hunt?

DR. WILLARD: One item that I don't know the full details of this, but that

we might pay attention to here, there is a white paper that I saw a draft of that I thought was being sent to either NIH Director's Office which came both out of academic institutions and companies, pharmaceutical companies, to form a series of national centers for drug discovery or something of that sort that would have been an integrated activity in the general area of pharmacogenomics, how to develop large clinical trials that would be necessary in order to proceed on this.

I know Millennium was involved in this. I know the Harvard Associated Hospitals were part of this and that was supposed to have gone to Zerhouni's office, and I don't know if it ever did or didn't. I'm looking at Francis for some blink of recognition.

DR. COLLINS: Yes, it did,and I don't know the outcome of the meeting with Zerhouni to discuss that proposal, and obviously it comes at a time where the NIH roadmap has been unveiled and which has some of those same intentions as far as focus on translation into clinical benefit, and I'm sure that's part of the considerations of how that would fit, but I'm not further informed about what the follow-up might be.

DR. WILLARD: But from the standpoint of our charge to identify potential gaps, that means there's at least one fairly extensive group that's thought a lot about this and has identified a potential mechanism that might be useful for us to hear about.

DR. McCABE: Emily?

DR. WINN-DEEN: The other thing I'd be interested in hearing about, which I think Debra brought up in her earlier discussion on the topic this morning, is what mechanisms are available to actually translate genotype and drug interactions into appropriate dosing regimens, so that the practicing physician can actually take specific action, and so I would be interested in hearing about any specific programs not aimed so much at just finding things and also from the FDA point of view.

I know Larry Lesko has talked a lot about that, that they don't seem to be getting that kind of submission with drug submissions. So it might say this drug is metabolized by enzyme X, but it doesn't tell you what to do about that. Should you address those? Should you do anything? So how can we actually start to move this into medicine?

DR. LEONARD: So could there be an RFA or something for submissions specifically addressing how you would dose in response to having certain polymorphisms?

DR. McCABE: I would suggest that our recommendations would be a bit more general. I mean, it would be identification.

DR. LEONARD: But is that something that could be done?

DR. McCABE: First, we would need to identify the problem which I think we have identified here and that is that it isn't impacting dosing. We don't really understand that at this time.

Francis?

DR. COLLINS: So I refrain from speaking because I didn't hear the discussion this morning and again NIH ranked this high but not at the top, but I think the pressing question really is how do we get from where we are right now to a circumstance that we all hope to see come true where the use of polymorphism data is a valuable adjunct to choice of the right drug for the right patient, and what are the roadblocks in getting there? There are several one can think of. Lack of data has just been mentioned as a major one. How do you know what the right thing to do is?

The whole logistical question of how do you actually set up a circumstance

where a physician who's preparing to write a prescription can get the genotype information in time to actually make a judgment because lots of prescriptions are written at a time where you don't really want to wait two weeks in order for the dosing to start. So how do you get that part of the equation solved in a fashion which we're quite a distance away from and not to be neglected, the whole question of informed consent and is a pharmacogenomic test really different than a genetic susceptibility test which has been argued about in many fora, but I don't think it's ever really been resolved, recognizing that a lot of things that you use for pharmacogenomic tests may also carry with them information about potential risks of disease, say CEPT, polymorphisms, in-heart disease, which both play a role in what your likelihood is of getting coronary artery disease and what your likelihood is of responding to a statin.

So that issue, I think, also is sort of lying out there with a bit of discordance in view and maybe that's something that could be addressed, but it seems like it's sort of this menu of obstacles between where we are and where we want to go, and is there something that this committee could do to try to knock down some of those barriers by identifying areas that need additional research, by addressing regulatory barriers that are getting in the way or whatever.

DR. McCABE: Debra?

DR. LEONARD: Two points. One is diagnostic tests using molecular methods can be done with rapid turnaround time, despite beliefs out there. So we do those for APL. We do a T1517 in a day, so that they can be treated. So there are ways to get those rapid turnarounds, to write a prescription.

DR. COLLINS: But they're not widely disseminated those ways. So that, if you were trying to do this sort of on a national basis, how would you organize the laboratory services to make that possible?

DR. LEONARD: Right, but I think that that can be overcome, and ACMG has written recommendations for other genetic tests, like Factor V Leiden and prothrombin, that they don't recommend having informed consent. So there are genetic tests out there that are considered low enough risk and useful enough and widely used enough that you wouldn't have to go through the informed consent process.

I think when you're linking the proper use of a drug to avoid an adverse outcome to a genetic test, then that is something that would not be so high risk that you might be able to avoid going through the informed consent process.

DR. McCABE: We're just discussing the timing of lunch. Excuse me.

Linda, and then Brad.

DR. BRADLEY: Just a comment on process. As I sit here and listen to this, pharmacogenomics is also interesting because it's sort of a case study for everything else we've been talking about for the last two days, in that it includes population studies, introduction of genetic testing and oversight, coverage and reimbursement, access, education, discrimination. All of those things will be worked through over the course of the next however many years, and so it's almost an intriguing way to take these different challenges and barriers one by one and think about what the committee can do to address them as they come up.

DR. McCABE: Thank you.

Brad?

MR. MARGUS: So I agree completely. There are going to be areas I think where we might want to think about pharmacogenomics and the FDA may not be focusing on

it. So clearly pharmaceutical companies who want to come out with tests and drugs will be working with the FDA, but to Debra's question about getting those associations that you can inform treatment today with existing drugs.

One of the things, if you did put an RFA out, that would be a real challenge. I think it's just DNA samples, and while you can wait to set up a massive BioBank, there are actually trials being run everyday where I think we could encourage or someone could encourage collection of DNA sooner.

There are other examples where I think the pharmacogenomics is tremendous but not much may happen and that is, for example, in drugs about to go off patent or generics. Again, no one's going to touch that typically in the pharmaceutical industry, and yet clearly CMS, for example, might actually be interested in knowing if there's an expensive drug out there where 40 percent of the people who take the drug don't really respond. If there were a genetic test to screen those people out, you'd see the cost-benefit analysis would be easy.

So I think there are broader issues around pharmacogenomics, besides just the very important issues of providing a safe harbor to pharmas and biotechs so that they're not afraid to start reporting some data and giving the agency a lot to look at. I think there are broader ones that some have already mentioned about informed consent and all that.

So I still am in the camp that it's worthy of us to review it and maybe to hear from people from these different areas, not just pharmas and biotechs and the FDA, but some of these other clinicians who can benefit.

DR. McCABE: And the timing might be right. Dr. Veenstra said that within six months, he might have better data on ADRs, and I think we're talking about that it would be in the queue for October, depending on what else is for October. We'll decide in June whether we can do it in October or whether it moves to the meeting after October, but it will be in the queue and we can start roughing out exactly what it is that we want to include at that time.

Is that okay then, if we have that as a plan? We have some of this discussion to remind us of what we want to pursue at the time. And then, we have DTC/DAT which was fourth on both of the lists. Thoughts on DTC/DAT? Yes, Hunt?

DR. WILLARD: Just to wake people up, I would take it being Number 4 as a sign that it should be classed as a Class 1 hurricane and be left there.

DR. LEONARD: I second.

DR. McCABE: Recognizing that it will get moved up then, that we're not saying it's unimportant, we're saying it's not important enough for us to consider it within the time horizon we're looking at for planning of these meetings Is that a fair assumption? Clearly, we've heard from discussions here that people are very concerned about this, but that it will move on and be in the queue behind pharmacogenomics.

Hunt, do you want to vote on that? Hunt has been urging us to use Category 1.

Paul?

MR. MILLER: I was just going to ask, does that mean that given Matthew's comment about sort of the little prodding that might be helpful -- I'll interpret what you said. He didn't say this, but a little prodding from this committee to FTC to sort of focus on this issue a little bit more in the form of a letter, in the form of sort of a little prodding, that that sort of falls off and that that doesn't occur?

DR. McCABE: Hunt?
MR. MILLER: That's a question.
DR. WILLARD: No, I think that's perfectly appropriate and takes relatively little effort on our part, and it does underscore the fact that we are assigning this to a high priority, just not the highest priority, and simply urge the FTC to step up its vigilance to the extent it can in tracking this information and informing us if and when it gets to the boiling point where you might think it's worth renewed attention from us.
DR. McCABE: Sarah would like clarification.
MS. CARR: Are you requesting the committee send a letter to FTC?
MR. DAYNARD: No.
DR. McCABE: No, no. We can't do that.
(Laughter.)
MS. CARR: Well, no. The reason I'm asking is that the charter, our charter indicates that we advise the Secretary of Health and on request other ex officio agencies. So if you were requesting the perspectives of this committee about the importance of that issue, we could, I think, rightly write directly to FTC. Otherwise, I think we would ask our Secretary to contact FTC.
MR. DAYNARD: Yes. Well, we engage in advocacy program ourselves because we have expertise in antitrust and consumer issues, but we don't do it sua sponte. We have to get an official from an agency, state AG, or a congressman or a Senator or whomever or Secretary Thompson. Someone in office like that has to do the requesting. So I don't think I can do the requesting, and I doubt frankly whether I'm going to get Chairman Muris to do the requesting either because he has no clue what's going on.
(Laughter.)
MR. DAYNARD: So let's do whatever. I'm talking about here in genetics.
(Laughter.)
MR. DAYNARD: I support my chairman wholeheartedly. He's wonderful.
MR. MILLER: The record will reflect that you support your chairman.
(Laughter.)
MR. DAYNARD: Yes. But all he knows about this area is the letter from Secretary Thompson which he promptly gave it over to my division and said, "Well, I'm no Matt. Okay. So here you go." But that's all. So you do whatever you can do, and I also assume there are other individuals in the committee have offered their assistance and we may even meet at the staff level and that may be all that's necessary to get things started.
DR. McCABE: Debra, Emily, and then Francis.
DR. LEONARD: That's okay.
DR. McCABE: Emily?
DR. WINN-DEEN: The other thing I heard that might be helpful is this sort of information gathering role and maybe Sarah can be the central repository, but as any of us find these kind of interesting websites or that we think might be an issue that we start to sort of data gather and put together at least some kind of compendium of questionable sites, that then potentially in the future we can take some action on or get some idea of how many are like totally wild or unfounded claims are out there.
MR. DAYNARD: Right, or any individual in the room can do that and send them to me, and I'd also like to know, if it's possible, just how big an industry we're talking

about right now in terms of home brew tests being advertised to consumers or whatever other category you might have information about.

DR. McCABE: So why don't we then have Matthew be the repository for those? You can copy Sarah on them, but they would be of immediate interest to FTC. So they don't end up being catalogued until we get around to this and move it from a Category 1 to a Category 4.

Francis?

DR. COLLINS: As an alternative in terms in terms of trying to express the committee's view to FTC, to having the Secretary take that on because that might take some time. Earlier, we heard this alternative of a resolution.

Would a resolution from SACGHS indicating their concern about the proliferation of direct marketing of genetic tests to consumers of questionable scientific validity, would that be useful to FTC in terms of making decisions about where to invest your resources?

MR. DAYNARD: Absolutely.

DR. McCABE: Okay. If we were to do that, then that probably leaves it in Category 4, and I think realistically we're talking about getting to it in October, putting a group together. Perhaps we could do it in June, though June is looking pretty full to me right now.

MR. DAYNARD: Our June is pretty full, too. So, I mean, when you can do it, that's great.

DR. COLLINS: I guess I was thinking of a pretty simple three-sentence resolution, but maybe you're imagining something more complex.

DR. McCABE: Well, if it's something very simple, then we can put together a task force to do that, and we can have help from our ex officios who seem to already have this written on the paper in front of them.

Is that acceptable, Hunt? Because then that leads it as a Category 4, if we're going to take --

DR. WILLARD: Then I lose interest in what category it is because it's going to be dealt with so quickly and effectively, we'll be done.

DR. McCABE: Well, no, but I think it will then in terms of further in-depth, it will fall behind pharmacogenomics, but we can do something quick to help FTC.

Okay. So do I have some volunteers for this task force to deal with DTC/DAT? Who's left? Brad? Agnes?

DR. WINN-DEEN: Chris was really interested.

DR. McCABE: That's right. Chris told me if something happened with this, he would. So Brad, Agnes and Chris, and we'll call on ex officios as necessary. So we can try and do something brief but then follow up after pharmacogenomics.

So with that, we have a plan for all four of these Class 4s.

The lunch is for the members and ex officios who are out in the hallway. I would suggest that this is a convenient time to take a break. We will resume in about 15 minutes. It will be a working lunch, and our goal then will be to look at coverage and reimbursement and outline our tasks between now and the next meeting so that we can pursue that.

Thank you. We've gotten a bit done in terms of setting of priorities. I'm really quite pleased with what we've accomplished so far.

(Recess.)

AFTERNOON SESSION (12:40 p.m.)

DR. McCABE: We're getting very close to quorum issues. We've got eight people. Our quorum is seven. So we're locking the doors.

(Laughter.)

DR. McCABE: You'll have to talk to Sarah or one of her staff if you wish to leave.

I think we're going to wrap this up quickly before we get into that problem. Cindy has come up with sort of an outline of what we could do to address our Number 1 in Category 4 which was coverage and reimbursement.

So Cindy, since this is your schema, do you want to orient us to it, please?

MS. BERRY: It was just an effort to figure out how we might produce a work product that's actually very useful to the Secretary and we just sketched this out really quickly. So there are lots of gaps and deficiencies, but the general concept is that we would produce a report to the Secretary on this issue. I took the liberty of coming up with an objective. People may disagree with it, but the general objective is to improve access to genetic technologies by ensuring coverage and appropriate reimbursement in all health care settings.

So then, there would be two parts, two general parts to the report. The first tackling coverage, the other tackling reimbursement, and in the coverage section, we want to know what's the current state of play? What's the status right now of coverage for genetic technologies in private health plans and in federal programs, for example, and then outline what are the barriers to coverage? To the extent that these technologies, tests, and services are not covered, what are the primary barriers that we've identified?

Then thirdly, what are the options for addressing each barrier? Options could include legislative options which may or may not mean actual legislation being introduced and signed into law, but it could involve just involving members of Congress and highlighting the issue, using the congressional bully pulpit, regulatory efforts, again could involve an actual regulatory process or something less than that. It could involve the agencies in some sort of press event highlighting the issue, public relations campaigns, something like that, and then a whole series of private efforts that we might be able to come up with.

And then, moving to the second phase of the report or the second part of it dealing with reimbursement, what are the existing reimbursement mechanisms? We've heard some of that yesterday. Analyzing both federal programs and private health plans. How are they different? Then how do we effect a change? I think the general message that we got was that the reimbursement is inadequate and in some cases non-existent. How do we change that? That, I think, is going to require a lot of effort, too, because what we heard yesterday was that in some cases, it may actually require legislative change.

So I have the same categories, legislative, regulatory, and private efforts, and then the last part there is just for our group to think about where we need more information. We got a head start on some of the information that we would need to compile a report like this, to put one together, but there are gaps.

I know that Hunt talked about it might be useful to hear from some of the major health systems, like Mayo Clinic and some others, and there are a variety of groups, organizations, agencies, private companies that we might need to hear from. Health care

providers and whatnot. That's just sort of the general sketch.

DR. McCABE: I'll tell you why this has some appeal to me. First of all, it's laid out very nicely before us, but it also is not an in-depth white paper kind of thing. I mean, we need to gather some information, but I don't think this is one of those documents that's going to take us two years to gather the information.

I think it's reasonable to gather the information over the course between now and the next meeting in June. Whether we can complete it by then, I think, would be open to question, but I think we could certainly have a draft. We could know where we needed to fill some gaps in the document and probably have it completed by the October meeting.

I think that it asks the question at the end, what additional information do we need? So it's not saying that we have to have everything right now, but it's allowing the door to remain open, recognizing that we're not going to have everything in this document. So I think it has some appeal because it's something that I think we could finish in a reasonable time frame, like over the next six months or so.

Is that what you were thinking, also, Cindy, when you proposed this?

Yes, Debra?

DR. LEONARD: This is great. I like the approach. I think we need to add something of an introduction under objectives so that there's some description of what is unique to genetic testing, like genetic counseling, the informed consent process, the uniqueness of the molecular-based CPT coding system, although we did hear yesterday that the entire laboratory fee schedule is out of date and inadequate. So the types of things that make this unique, genetics not being acknowledged as a specialty area, those kinds of things.

DR. McCABE: Other thoughts? Let's let Sarah catch up.

DR. LEONARD: Can I add one other thing?

DR. McCABE: Debra?

DR. LEONARD: Since Joan left, I almost feel like I have to be her representative, which is that I think we have to deal with issues of the uninsured, underinsured. I don't think anything that's done with existing insurance or regulatory agencies or legislative is going to address those who don't have coverage already which kind of moves us in the direction of should we be recommending something like universal health care coverage.

DR. McCABE: I think that could move us from what I had thought was achievable, Debra.

(Laughter.)

DR. McCABE: It's a lofty goal, but I don't know if we can do that by the fall. But thank you for reminding us of that. Yes, Sarah has added that under the introduction.

Yes, Agnes, and then Barbara.

MS. MASNY: But coming back to the issue about universal health coverage, I didn't know if, for the record, since we did receive that challenge from Sharon Terry yesterday, asking us did we really want to make a clear statement about what some of the underlying barriers and problems are and that just in the introduction, if we could say given that we do not have universal health coverage, that working within the existing system, we'll try to identify other ways that we could address reimbursement and coverage.

DR. McCABE: We can look at how we can say that there.

Barbara?

MS. HARRISON: I also think you used your skill well and got our thoughts

organized here. I wanted to make sure -- I'm sure it doesn't -- exclude more immediate action, that we were advised on or asked to do during the course of the meeting these past couple of days, one of which was, I guess, to have two possible communications to CMS, one involving encouragement about the development of CPT codes for genetic counseling and evaluation, and also for genetic counselors to be recognized as allied health professionals, and those were just two action items that were kind of put out there. I just wanted to see if there was interest in doing that amongst the committee and where that would fit in our schemata here.

DR. McCABE: So, Judith, in terms of CPT codes, that's probably not the right person from CMS to address that, but that really is an AMA problem as opposed to a CMS problem, unfortunately, but it's certainly something that we could address.

DR. LEONARD: But the CPT coding issue is being addressed somewhat b the alphanumeric modifier system that's been proposed and may be part of the October publication of the CPT book. So that may be something that we could keep in mind as we are looking at this.

DR. McCABE: So we could check back in October to see how that was, and then the other thing is recognition of genetic counselors as -- I'm not sure what the proper term is. Recognized allied health professionals? Do you know the appropriate terminology there, Judith?

MS. YOST: I'm sorry?

DR. McCABE: That's a HRSA issue, Suzanne?

DR. FEETHAM: Again, I mean, that's a whole different framework. They are recognized within the vernacular of HRSA as allied health professionals. That's not an issue within our agency. It's a different issue when you're talking about reimbursement and that's a lot of other disciplines that would have the same concern about that.

DR. McCABE: Right, and my understanding is that a lot of that is a state issue, state by state issue. Judith, do you know? Do you know how that works? Barbara?

MS. HARRISON: I don't know if Dawn Allain would like to speak on this at all or give us any guidance.

DR. FEETHAM: I would just like to be sure when we're talking of the language that we see that in your objective, you've got genetic technology/services. I think for us to move forward with this -- and again you've identified the uninsured, underinsured, which is certainly a population we focus on at HRSA from a training perspective in all disciplines, but also certainly in our Bureau of Primary Health Care for care and keeping the language with the services, I think, will serve the entire population well because it's a broader cut than just the technology and would encourage you to keep that as part of the program, and again some of the work we're doing within HRSA in the Bureau of Primary Health Care may help inform what you're talking about.

DR. McCABE: Suzanne?

DR. FEETHAM: Cindy had, in the objective, genetic technologies and services. I'm just saying as we move down, it just keeps saying GT which some people could read and say that's genetic testing or just the genetic technologies, and I'm just urging us to keep it with services because that's a different level of discussion and it would fit in with the research that Judith Cooksey is doing, et cetera.

DR. McCABE: Okay. So wherever it says GT, it should say GT/GS?

DR. FEETHAM: But I'm just saying sometimes that kind of thing gets lost,

and I think it's a very different message in how you go about this, by keeping it services, particularly when you're looking at the entire population of the country which includes the underserved populations.

DR. McCABE: This is Dawn Allain, who is President of NSGC.

MS. ALLAIN: Suzanne is actually right as far as HRSA. We are recognized as allied health providers under the auspices of HRSA. But for CPT code and billable entities, it's part of the Medicare, I believe it's called the Plan B rules or Medicare B rules, and that's actually statute and genetic counselors are not listed. Physician assistants are, psychiatrists are, but you have to actually be listed in the statute, and so because of that, CMS cannot recognize us as allied health providers and so this is one of the major blocks for genetic counselors to be considered as billable providers.

DR. McCABE: So I would suggest that one of the things we need to do is look at the statutory language there and examine that as a part of this process.

MS. ALLAIN: Thank you.

DR. McCABE: Thank you.

Further thoughts on amplification of this outline? Yes, Martin?

MR. DANNENFELSER: Should we say anything to the effect of it being medically-related genetic technology? I mean, most of it is going to be, but if there are going to be cases where you can find out all kinds of information about genetics that may not have a medical implication.

DR. McCABE: I would think that at this point in time, it would be best to focus this and especially having been through this process with the prior committee where we began to look at things beyond medical. It does broaden the scope tremendously and make it a little bit difficult to get our arms around it. So I think that's a very important comment.

Yes, Emily?

DR. WINN-DEEN: So I'd just like to come back to this whole issue of getting appropriate CPT codes and all that kind of stuff. Respectfully of AMP and CAP's position, I've heard from other groups, specifically AdvaMed, that do not feel that that proposal is viable or workable, and so I think there's still some debate about whether even the -- I don't know enough about it to say who's right or who's wrong or how that works out, but just that there's still some debate about whether even the proposal that is currently up for discussion is workable. Would it be recommended? So I just, I think, would like to explore that whole issue in a little bit more depth and get more information. We heard sort of one data point from AMP this time, but could we hear a little bit more broad?

DR. McCABE: Can you just define that acronym for us? AdvaMed?

DR. WINN-DEEN: It's an advocacy group for medical health care companies. A-D-V-A-M-E-D.

DR. McCABE: So we would want to explore beyond AMP's position.

DR. LEONARD: Just for the record, the College of American Pathologists headed up that work group. AMP was just a member along with AACC and a lot of other organizations.

DR. McCABE: Okay. Other points we need to consider? Because we will start to rough this out so that we can have some data. Remember, the proposal is that this was Number 1 in Category 4. So this will be of the Category 4 issues, this will be the one that is the focus of the June meeting.

Do you need more guidance, Sarah? Okay.

DR. WINN-DEEN: Sarah, could you give us a little sort of outline of maybe your vision for how we would split up the June meeting for sort of input talks versus discussion based on sort of where we are so far?

MS. CARR: Actually, I think I would need a minute to kind of go back and see what else we put on in June. But if you have ideas and --

DR. WINN-DEEN: No, no, I'm just concerned because we did put a bunch of Category 2 things in June and now we want to actually work on this in June, and so, I mean, you can do this.

MS. CARR: Maybe we can have another task force to help us plan the June meeting and sort through some of it because I think we did add quite a bit for June.

DR. LEONARD: Well, we have two resolutions and a report, but the question is can those be given to the full committee two weeks before or some period of time before, so we have the time to read and review, so that the discussions may be a little briefer during the meeting?

DR. McCABE: I think certainly that model certainly helped us with this meeting, having the issue briefs beforehand, and then people weren't assimilating the information and then working on it and rank ordering it all at the same time. People had had time to think about it. So to the extent possible, we will get it to people ahead of time. That, quite honestly, is not only dependent on Sarah and her staff but also on us, because frequently it has to do with us getting things back to Sarah.

MS. CARR: And do we want to hear from the six or seven organizations? The two resolutions are on DTC and education. Do we also want to invite and have a panel of those associations to come? That's half a day of presentations, I'd say.

DR. LEONARD: The presentations were supposed to be very brief and targeted.

DR. McCABE: Yes.

DR. LEONARD: If any.

DR. McCABE: Initially, I had thought the presentations would be a half a day, but as we talked about it, we can probably get it down to three/eighths of half of a day or something, so that we would have time to fit a resolution.

DR. LEONARD: Well, also, if these organizations --

DR. McCABE: We can get it under a half a day, so we can do a resolution and that within a half a day. The key thing is, I think what we said is we would have paperwork out so people could review and we would have the organizations addressing us and answering questions and very, very, very brief presentations, one or two PowerPoint per presentation, if we were going to allow them to do that at all. So it's mainly going to be discussion and moving on.

MS. CARR: So they should not be invited to make a presentation on their activities, simply come to answer questions?

DR. McCABE: Their presentations would have been received by us beforehand.

MS. CARR: The information. Okay.

DR. LEONARD: Exactly, because you're going to be asking for six or seven organizations to give information. So that information can be provided, and I would see

that the meeting should be more of a discussion of what they plan on doing to address the issues.

DR. McCABE: So we'll have no PowerPoints, then, is what I'm hearing, and just have discussion.

MS. CARR: And there was also some discussion about having presentations from people who've been discriminated against in some way, and so it would be helpful to have some sense of how much time to devote to that and effort to identify people and so forth.

DR. WINN-DEEN: Maybe ASHG or this outreach effort that they're doing to gather some cases. I'm not sure if we actually have to have people come and testify, unless we feel that that additional public forum is useful, but it certainly would be, I think, very helpful to all of us on the committee to have those case studies pulled together as something that we could draw from and particularly since a lot of the issues may have to do with this whole insurance and insurability kind of issues as it affects coverage and reimbursement as well. Our people not seeking coverage and reimbursement because of fear of discrimination or action being taken.

DR. McCABE: Paul?

MR. MILLER: I would just say, in addition to ASHG, but also the Genetic Alliance might have access to those kinds of stories and maybe sort of request papers or written documents or some sort of written testimony to be submitted might be really useful and helpful.

DR. McCABE: So Sarah has asked for a group to put this together. Putting together these meetings is a real art because the amount of work that is crammed in here and the amount of work that goes ahead. Is there anyone who would want to be involved on that task force with Sarah? So Debra, Kim, Barbara. I'm always involved in that, so I'm happy to be a part of it. So we've got a group of four individuals then, and I would say that we should use our judgment whether we have just stories or individuals there. I think sometimes the individuals can be quite compelling.

Yes, Debra?

DR. LEONARD: There are two kinds of stories that come to mind. One is the genetic discrimination in which they've had testing and because of the results, they've had repercussions. The other is related to coverage and reimbursement. What are the hardships put on patients when they don't have coverage or payment through their policies and have to pay out-of-pocket for services that they need because of their genetic predispositions?

DR. McCABE: And the other group that may be less willing to come forward is those in terms of discrimination issues, those who have not been willing to be tested under their true names, and I can tell you as a geneticist that's a significant group, but they will be much less willing to come forward.

Emily?

DR. WINN-DEEN: So Ed, maybe to that point, the way to track that is not through the patients but through some practicing medical geneticists who might just sort of in their practice, other people who decide to have it, what's the breakdown between those who are tested under their own name versus under a pseudonym and just gather data in that way rather than do anything that would --

DR. McCABE: Yes. It's going to be hard that way also, quite honestly, because a lot of these patients then just go off and do it because they do not want it even

recorded in their medical record that they are doing this. So it really is something that's happening, and I think it's very hard to get a numerical quantitation of this, but I can tell you it is significant.

Yes, Debra?

DR. LEONARD: Is this something that the genetic counselors could address and provide data to the committee on since you actually interact with the patients and counsel them and see the results of whether they get the test or don't get it?

MS. ALLAIN: NSGC is actually currently working with the Coalition for Genetic Fairness and ASHG to collect this data. I mean, our hope is that we're going to have some of this data before March 10th. So I think when Joann was talking about coming back with a report, that kind of data would be included in that report that would come back to this committee in June, if you wanted it then.

DR. McCABE: Good. So that would be very helpful. Anything else? Sarah, do you have everything you need? Other points that people want to make? Any of the ex officios want to make any additional points about this?

If not, I want to congratulate the committee on getting a lot of work done. You've set the course for the next year very effectively, and I think we'll have some action items that we can get out and certainly we'll have the one on non-discrimination. We've gotten direction from you about the structure of that letter. That letter will be going out with dispatch, so that it can impact on this session, and the others, we will bring back to you at the next meeting as we discussed.

Thank you very much and everyone travel safely.

(Whereupon, at 1:07 p.m., the meeting was adjourned.)